

# FEDERAL TRADE COMMISSION DECISIONS

FINDINGS, OPINIONS, AND ORDERS  
JANUARY 1, 2012, TO JUNE 30, 2012

PUBLISHED BY THE COMMISSION

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**MEMBERS OF THE FEDERAL TRADE COMMISSION  
DURING THE PERIOD  
JANUARY 1, 2012 TO JUNE 30, 2012**

JON LEIBOWITZ, *Chairman*  
Took oath of office September 3, 2004.

J. THOMAS ROSCH, *Commissioner*  
Took oath of office January 5, 2006.

EDITH RAMIREZ, *Commissioner*  
Took oath of office April 5, 2010.

JULIE BRILL, *Commissioner*  
Took oath of office April 6, 2010.

MAUREEN K. OHLHAUSEN, *Commissioner*  
Took oath of office April 4, 2012

DONALD S. CLARK, *Secretary*  
Appointed August 28, 1988.

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# FEDERAL TRADE COMMISSION DECISIONS

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FINDINGS, OPINIONS, AND ORDERS  
JANUARY 1, 2012, TO JUNE 30, 2012

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IN THE MATTER OF

## HEALTHCARE TECHNOLOGY HOLDINGS, INC.

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4340; File No. 111 0097*  
*Complaint, October 28, 2011 – Decision, January 9, 2012*

This consent order addresses the \$340 million acquisition by Healthcare Technology Holdings, Inc. of SDI Health LLC (“SDI”) from SDI Health Holdings LLC. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by lessening competition in the U.S. markets for promotional audits and medical audits. The consent order requires Healthcare Technology, among other things, to divest SDI’s promotional audits and medical audits business.

### *Participants*

For the *Commission*: Jordan S. Andrew, Erin L. Craig, Karen Espaldon, Lynda Lao, Gregory P. Luib, Stephen A. Mohr, Christine Palumbo, Mark Silvia, and Priya Viswanath.

For the *Respondent*: Leah Brannon and David I. Gelfand, Cleary Gottlieb Steen & Hamilton LLP.

### COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Healthcare Technology Holdings, Inc. (“Healthcare Technology”), a corporation subject to the

## Complaint

jurisdiction of the Commission, has entered into an agreement to acquire, through its wholly owned subsidiary IMS Health Incorporated (“IMS”), all of the membership interests in SDI Health LLC (“SDI”) from SDI Health Holdings LLC (“SDI Holdings”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

**I. RESPONDENT**

1. Respondent Healthcare Technology is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 83 Wooster Heights Road, Danbury, CT 06810. Respondent Healthcare Technology, through its wholly owned subsidiary, IMS, is engaged in the research, development, production, and sale of healthcare data and analytics.

2. Respondent Healthcare Technology is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

**II. THE ACQUIRED COMPANY**

3. SDI Holdings is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 1 SDI Drive, Plymouth Meeting, PA 19462. SDI Holdings, through its wholly owned subsidiary, SDI, is engaged in the research, development, production, and sale of healthcare data and analytics.

4. SDI Holdings is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of

### Complaint

the Clayton Act, as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

### **III. THE PROPOSED ACQUISITION**

5. Pursuant to a Membership Interest Purchase Agreement (“Acquisition Agreement”) dated January 13, 2011, Healthcare Technology, through its wholly owned subsidiary, IMS, proposes to acquire all of the membership interests in SDI from SDI Holdings (the “Acquisition”).

### **IV. THE RELEVANT MARKETS**

6. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the production and sale of:

- a. promotional audits; and
- b. medical audits.

7. For the purposes of this complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

### **V. THE STRUCTURE OF THE MARKETS**

8. Promotional audits provide estimates of pharmaceutical promotional activities for individual branded drugs in areas such as physician detailing, product sampling, and advertising. Pharmaceutical manufacturers and other customers use promotional audits to assess their promotional share of voice, or their share of spending in various promotional categories, which in turn helps such customers to determine their promotional budgets. The \$16 million market for promotional audits is highly concentrated; only IMS, SDI, and Cegedim S.A. offer promotional audits in the United States. IMS has a 30 percent share of this market, SDI has a 68 percent market share, and Cegedim has a 2 percent market share.

9. Medical audits provide estimates of disease-specific diagnoses made and therapies prescribed by physicians.

## Complaint

Customers use medical audits to assess, among other things, the size of therapeutic areas, which products are used to treat particular diseases, and prescribing and treatment trends. The \$9 million market for medical audits is highly concentrated, with IMS accounting for 53 percent and SDI accounting for the remaining 47 percent of the market.

**VI. ENTRY CONDITIONS**

10. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because of the significant time and expense required to recruit panels of physicians to provide the data underlying the estimates included in promotional and medical audits. In addition, entry is not likely because the sales opportunities available for any potential new entrant are likely too small to justify the cost of entering the markets.

**VII. EFFECTS OF THE ACQUISITION**

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating actual, direct, and substantial competition between IMS and SDI in the markets for promotional audits and medical audits and producing a virtual monopoly in these two markets, thereby: (1) increasing the likelihood that IMS would unilaterally exercise market power in these markets; and (2) increasing the likelihood that consumers would be forced to pay higher prices for these products.

**VIII. VIOLATIONS CHARGED**

12. The Acquisition Agreement described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

## Order to Hold Separate

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this twenty-eighth day of October, 2011, issues its Complaint against said Respondent.

By the Commission.

**ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Healthcare Technology Holdings, Inc. (“Respondent Healthcare Technology”) through its wholly owned subsidiary, IMS Health Incorporated (“IMS”), of SDI Health LLC, and Respondent having been furnished thereafter with a copy of a draft of the Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent

## Order to Hold Separate

Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets:

1. Respondent Healthcare Technology is a corporation organized, existing, and doing business under and by virtue of the laws of the state of Delaware, with its office and principal place of business located at 83 Wooster Heights Road, Danbury, CT 06810.
2. The Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Hold Separate and Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Healthcare Technology” means Healthcare Technology Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Healthcare Technology Holdings, Inc. (including SDI Health LLC, after the Acquisition Date), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “SDI” means SDI Health LLC, a limited liability corporation organized, existing, and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 1 SDI Drive, Plymouth Meeting, PA 19462.

## Order to Hold Separate

- C. “Commission” means the Federal Trade Commission.
- D. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final Decision and Order by the Commission; and
  2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- E. “Effective Date” means the date on which the divestitures and assignments pursuant to Paragraph II or VII of the Decision and Order are consummated.
- F. “Held Separate Business” means the SDI Audit Business, SDI SFSS, SDI OSA, SDI Report Generator (including all development and maintenance thereof), and the Held Separate Business Employees.
- Provided, however,* Respondent Healthcare Technology may use SDI Report Generator as allowed under the license described in Paragraph II.A. of the Order.
- G. “Held Separate Business Employees” means the Designated Audit Employees and any full-time, part-time, or contract employee of SDI who devoted more than 50% of his or her time to the SDI Audit Business, SDI SFSS, SDI OSA, or SDI Report Generator.
- H. “Hold Separate” means this Order to Hold Separate and Maintain Assets.
- I. “Hold Separate Period” means the time period during which the Hold Separate is in effect, which shall begin on the Acquisition Date and terminate pursuant to Paragraph VII hereof.

## Order to Hold Separate

- J. “Monitor” means any monitor appointed pursuant to Paragraph III of this Hold Separate or Paragraph VI of the Decision and Order.
- K. “Orders” means the Decision and Order and this Hold Separate.

**II.****IT IS FURTHER ORDERED** that:

- A. During the Hold Separate Period, Respondent shall hold the Held Separate Business separate, apart, and independent as required by this Hold Separate and shall vest the Held Separate Business with all rights, powers, and authority necessary to conduct its business. Respondent shall not exercise direction or control over, or influence directly or indirectly, the Held Separate Business or any of its operations, or the Monitor, except to the extent that Respondent must exercise direction and control over the Held Separate Business as is necessary to assure compliance with this Hold Separate, the Decision and Order, and all applicable laws.
- B. Until the Effective Date, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the SDI Audit Business, to minimize any risk of loss of competitive potential for the SDI Audit Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the SDI Audit Business except for ordinary wear and tear. Respondent shall not sell, transfer, encumber, or otherwise impair the SDI Audit Business (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the SDI Audit Business.
- C. The Held Separate Business shall be staffed with sufficient employees to maintain the viability and competitiveness of the Held Separate Business. To the

## Order to Hold Separate

extent that such employees leave or have left the Held Separate Business prior to the Effective Date, the Manager, with the approval of the Monitor, may replace departing or departed employees with persons who have similar experience and expertise or determine not to replace such departing or departed employees.

1. In connection with support services or products not included within the Held Separate Business, Respondent shall continue to provide, or offer to provide, the same support services to the Held Separate Business as customarily have been or are being provided to such businesses by SDI as of the date of the Acquisition. Respondent's personnel providing such services or products must retain and maintain all Confidential Business Information of or pertaining to the Held Separate Business on a confidential basis, and, except as is permitted by this Hold Separate, such persons shall be prohibited from disclosing, providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any person whose employment involves any of Respondent's businesses, other than the Held Separate Business. Such personnel shall also execute confidentiality agreements prohibiting the disclosure of any Confidential Business Information of the Held Separate Business.
- D. Respondent shall offer to the Held Separate Business any services and products that Respondent provides, in the ordinary course of its business, to their other businesses directly or through third party contracts, or that it has provided in the ordinary course of its business directly or through third party contracts to the Held Separate Business at any time since before the Acquisition Date. The Held Separate Business may, at the option of the Manager and with the approval of the Monitor, obtain such services and products from Respondent. Subject to the foregoing, the services and products that Respondent shall offer the Held Separate

## Order to Hold Separate

Business shall include, but shall not be limited to, the following:

1. human resources and administrative services, including but not limited to payroll processing, labor relations support, pension administration, and procurement and administration of employee benefits, including health benefits;
  - a. federal and state regulatory compliance and policy development services;
  - b. environmental health and safety services, which are used to develop corporate policies and insure compliance with federal and state regulations and corporate policies;
  - c. financial accounting services;
  - d. preparation of tax returns;
  - e. audit services;
  - f. information technology support services;
  - g. processing of accounts payable and accounts receivable;
  - h. technical support;
  - i. procurement of supplies;
  - j. maintenance and repair of facilities;
  - k. procurement of goods and services utilized in the ordinary course of business by the Held Separate Business; and
  - l. legal services.
2. The Held Separate Business shall have, at the option of the Manager and with the approval of the Monitor, the ability to acquire services and

## Order to Hold Separate

products from third parties unaffiliated with Respondent.

**III.****IT IS FURTHER ORDERED** that:

- A. Respondent shall hold the Held Separate Business separate, apart, and independent of Healthcare Technology on the following terms and conditions:
1. Stuart A. Samuels shall serve as the Monitor, pursuant to the agreement executed by the Monitor and Respondent and attached as Exhibit C to the Decision and Order (“Monitor Agreement”).
    - a. Respondent shall, no later than one (1) day after the Acquisition Date, pursuant to the Monitor Agreement, transfer to and confer upon the Monitor all rights, powers, and authority necessary to permit the Monitor to perform his duties and responsibilities pursuant to this Hold Separate, in a manner consistent with the purposes of the Decision and Order and in consultation with Commission staff, and shall include in the Monitor Agreement all provisions necessary to effectuate this requirement.
    - b. The Monitor Agreement shall require that the Monitor shall act in a fiduciary capacity for the benefit of the Commission.
    - c. The Monitor shall have the responsibility for monitoring the organization of the Held Separate Business; supervising the management of the Held Separate Business by the Manager; maintaining the independence of the Held Separate Business; and monitoring Respondent’s compliance with its obligations pursuant to the Orders, including maintaining the viability, marketability, and

## Order to Hold Separate

competitiveness of the SDI Audit Business pending divestiture.

- d. Subject to all applicable laws and regulations, the Monitor shall have full and complete access to all personnel, books, records, documents and facilities of the Held Separate Business, and to any other relevant information as the Monitor may reasonably request including, but not limited to, all documents and records kept by Respondent in the ordinary course of business that relate to the Held Separate Business. Respondent shall develop such financial or other information as the Monitor may reasonably request and shall cooperate with the Monitor. Respondent shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with this Hold Separate or the Decision and Order or otherwise to perform his duties and responsibilities consistent with the terms of this Hold Separate.
- e. The Monitor shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
- f. The Commission may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with performance of the Monitor's duties.

## Order to Hold Separate

- g. Respondent may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- h. Thirty (30) days after the Acquisition Date, and every thirty (30) days thereafter until the Hold Separate terminates, the Monitor shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate. Included within that report shall be the Monitor's assessment of the extent to which the SDI Audit Business is meeting (or exceeding) its projected goals as reflected in operating plans, budgets, projections, or any other regularly prepared financial statements.
- i. If the Monitor ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Commission may appoint a substitute Monitor consistent with the terms of this Hold Separate, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of the substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any substitute Monitor, Respondent shall be deemed to have consented to the selection of the proposed substitute Monitor. Respondent and the substitute Monitor shall execute a Monitor Agreement, subject to the approval of the Commission, consistent with this paragraph.
- j. The Monitor shall serve until the day after the Effective Date; *provided, however*, that the Commission may extend or modify this period

## Order to Hold Separate

as may be necessary or appropriate to accomplish the purposes of the Orders.

2. No later than one (1) day after the Acquisition Date, Respondent shall enter into a management agreement with, and shall transfer all rights, powers, and authority necessary to manage and maintain the Held Separate Business, to Kelly M. Sborlini (“Manager”).
  - a. In the event that the aforementioned individual declines an offer to act as a Manager, or accepts the position of Manager and subsequently ceases to act as a Manager, then Respondent shall select a substitute Manager, subject to the approval of the Commission, and transfer to the substitute Manager all rights, powers, and authorities necessary to permit the substitute Manager to perform his/her duties and responsibilities, pursuant to this Hold Separate. The Manager named under this Paragraph may be the same person named as Monitor in Paragraph III.A.1.
  - b. The Manager shall report directly and exclusively to the Monitor and shall manage the Held Separate Business independently of the management of Respondent. The Manager shall not be involved, in any way, in the operations of the other businesses of Respondent during the term of this Hold Separate.
  - c. The management agreement between Respondent and the Manager shall provide that:
    - i. Respondent shall provide the individual who agrees to serve as Manager with reasonable financial incentives to undertake this position. Such incentives shall include a continuation of all employee benefits,

## Order to Hold Separate

including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to assure the continuation and prevent any diminution of the Held Separate Business's viability, marketability, and competitiveness until the Effective Date has occurred, and as may otherwise be necessary to achieve the purposes of this Hold Separate; and

- ii. Respondent shall, at the option of the Manager, offer to continue the Manager's employment for a period of no less than one (1) year following the Manager's acceptable completion of service as a Manager at terms no less favorable than those pursuant to which the Manager was employed prior to the Acquisition; *provided, however*, this requirement shall not apply if the Manager was removed from service for cause.
  
- d. The Manager shall make no material changes in the ongoing operations of the Held Separate Business except with the approval of the Monitor, in consultation with the Commission staff.
  
- e. The Manager shall have the authority, with the approval of the Monitor, to remove Held Separate Business employees and replace them with others of similar experience or skills. If any Person ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Manager, in consultation with the Monitor, may request Respondent to, and Respondent shall, appoint a substitute Person, which Person the Manager shall have the right to approve.

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- f. In addition to Held Separate Business employees, the Manager may, with the approval of the Monitor, employ such Persons as are reasonably necessary to assist the Manager in managing the Held Separate Business.
  - g. The Monitor shall be permitted, in consultation with the Commission staff, to remove the Manager for cause. Within fifteen (15) days after such removal of the Manager, Respondent shall appoint a replacement Manager, subject to the approval of the Commission, on the same terms and conditions as provided in this paragraph.
3. The Monitor and the Manager shall serve, without bond or other security, at the cost and expense of Respondent, on reasonable and customary terms commensurate with the person's experience and responsibilities.
  4. Respondent shall indemnify the Monitor and Manager and hold each harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's or the Manager's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor or the Manager.
  5. Respondent shall cause the Monitor, the Manager, the Held Separate Business Employees, and each of Respondent's employees having access to Confidential Business Information of or pertaining to the Held Separate Business to submit to the Commission a signed statement that the individual

## Order to Hold Separate

will maintain the confidentiality required by the terms and conditions of this Hold Separate. These individuals must retain and maintain all Confidential Business Information of or pertaining to the Held Separate Business on a confidential basis and, except as is permitted by this Hold Separate, such Persons shall be prohibited from disclosing, providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any other Person whose employment involves any of Respondent's businesses or activities other than the Held Separate Business.

6. Except for the Manager, Held Separate Business Employees, and support services employees involved in providing services to the Held Separate Business pursuant to this Hold Separate, and except to the extent provided in this Hold Separate, Respondent shall not permit any other of its employees, officers, directors, agents, or representatives to be involved in the operations of the Held Separate Business.
7. Respondent's employees (excluding the Held Separate Business employees and employees involved in providing support services to the Held Separate Business pursuant to Paragraph II.C.6) shall not receive, or have access to, or use or continue to use any Confidential Business Information of the Held Separate Business not in the public domain except:
  - a. as required by law; and
  - b. to the extent that necessary information is exchanged:
    - i. in the course of consummating the Acquisition;

## Order to Hold Separate

- ii. in negotiating agreements to divest assets pursuant to the Consent Agreement and engaging in related due diligence;
- iii. in complying with this Hold Separate or the Consent Agreement;
- iv. in overseeing compliance with policies and standards concerning the safety, health, and environmental aspects of the operations of the Held Separate Business and the integrity of the financial controls of the Held Separate Business;
- v. in defending legal claims, investigations, or enforcement actions threatened or brought against or related to the Held Separate Business; or
- vi. in obtaining legal advice.

Nor shall the Manager or any Held Separate Business Employees receive or have access to, or use or continue to use, any Confidential Business Information not in the public domain relating to Respondent or its businesses, except such information as is necessary to maintain and operate the Held Separate Business. Respondent may receive aggregate financial and operational information relating to the Held Separate Business only to the extent necessary to allow Respondent to comply with the requirements and obligations of the laws of the United States and other countries, to prepare consolidated financial reports, tax returns, reports required by securities laws, and personnel reports, and to comply with this Hold Separate. Any such information that is obtained pursuant to this subparagraph shall be used only for the purposes set forth in this subparagraph.

8. Respondent and the Held Separate Business shall jointly implement, and at all times during the Hold Separate Period maintain in operation, a system, as

## Order to Hold Separate

approved by the Monitor, of access and data controls to prevent unauthorized access to or dissemination of Confidential Business Information of the Held Separate Business, including, but not limited to, the opportunity by the Monitor, on terms and conditions agreed to with Respondent, to audit Respondent's networks and systems to verify compliance with this Hold Separate.

9. No later than five (5) days after the Acquisition Date, Respondent shall establish written procedures, subject to the approval of the Monitor, covering the management, maintenance, and independence of the Held Separate Business consistent with the provisions of this Hold Separate.
  10. No later than five (5) days after the date this Hold Separate becomes final, Respondent shall circulate to employees of the Held Separate Business, and to Persons who develop, produce, market, or sell IMS Medical Audit Products or IMS Promotional Audit Products, a notice of this Hold Separate and the Consent Agreement.
- B. The purpose of this Hold Separate Order is to maintain the full economic viability, marketability, and competitiveness of the SDI Audit Business through the divestiture, transfer, and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the SDI Audit Business and to prevent the destruction, removal, wasting, deterioration, or impairment of any assets of the SDI Audit Business except for ordinary wear and tear.

**IV.**

**IT IS FURTHER ORDERED** that not later than thirty (30) days after the Respondent signs the Agreement Containing Consent Order, and every thirty (30) days thereafter until Respondent Healthcare Technology has fully complied with its

## Order to Hold Separate

obligations to divest, assign, grant, license, transfer, deliver, or otherwise convey the SDI Audit Business as required by Paragraph II or Paragraph VII of the Decision and Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Hold Separate Order and the related Decision and Order;

*Provided, however,* that, after the Decision and Order in this matter becomes final, the reports due under this Hold Separate Order may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph IX of the Decision and Order.

**V.**

**IT IS FURTHER ORDERED** that Respondent Healthcare Technology shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger, or consolidation of Respondent; or
- C. any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

**VI.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Hold Separate Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondent Healthcare Technology made to its principal United States offices or headquarters' address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

## Order to Hold Separate

- A. access, during business office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with the Orders, which copying services shall be provided by Respondent at the request of an authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

**VII.**

**IT IS FURTHER ORDERED** that this Hold Separate Order shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
  - 1. The later of:
    - a. The day after the divestiture of the SDI Audit Business, as required by and described in the Decision and Order, has been completed and the Monitor, in consultation with Commission staff and the Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers, and other transitions related to such divestiture are complete, or the Commission otherwise directs that this Hold Separate is terminated; or
    - b. Three (3) days after the related Decision and Order becomes final.

By the Commission.

## Decision and Order

**DECISION AND ORDER**  
**[Redacted Public Version]**

The Federal Trade Commission ("Commission"), having initiated an investigation of the proposed acquisition by Healthcare Technology Holdings, Inc. ("Respondent Healthcare Technology") through its wholly owned subsidiary, IMS Health Incorporated ("IMS"), of SDI Health LLC and Respondent Healthcare Technology having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Healthcare Technology with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent Healthcare Technology, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent Healthcare Technology of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent Healthcare Technology that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent Healthcare Technology has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

## Decision and Order

1. Respondent Healthcare Technology is a corporation organized, existing and doing business under and by virtue of the laws of Delaware with its office and principal place of business located at 83 Wooster Heights Road, Danbury, CT 06810.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “Healthcare Technology” means Healthcare Technology Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Healthcare Technology Holdings, Inc. (including SDI Health LLC, after the Acquisition Date), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “SDI Holdings” means SDI Health Holdings LLC, a limited liability corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 1 SDI Drive, Plymouth Meeting, PA 19462.
- C. “SDI” means SDI Health LLC, a limited liability company organized, existing, and doing business under and by virtue of the laws of Delaware, with its office and principal place of business located at 1 SDI Drive, Plymouth Meeting, PA 19462.
- D. “Commission” means the Federal Trade Commission.

## Decision and Order

- E. “Acquirer” means the Person approved by the Commission to acquire the SDI Audit Business pursuant to Paragraph II.A or Paragraph VIII of this Order.
- F. “Acquirer Audit Employee” means any person employed by the Acquirer who has devoted any of his or her time to SDI Medical Audit Products or SDI Promotional Audit Products after the Effective Date.
- G. “Acquisition” means Respondent Healthcare Technology’s acquisition of SDI Holding’s membership interests in SDI.
- H. “Acquisition Date” means the date on which the Acquisition is consummated.
- I. “Confidential Business Information” means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person’s business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, technologies, processes, or other trade secrets.
- J. “Copyrights” means rights to all original works of authorship of any kind Related To the SDI Audit Business, and any registrations and applications for registrations thereof, including, but not limited to, the following: all such rights with respect to all promotional, marketing and advertising materials, educational and training materials for the sales force, and sales forecasting models; copyrights in all process development data and reports Relating To the SDI Medical Audit Products or the SDI Promotional Audit Products, including copyrights in all raw data, statistical programs developed (or modified in a manner material to the use or function thereof (other than through user preferences)) to analyze research data, market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer

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information; all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, manufacturing records, manufacturing processes, and supplier lists.

- K. “Designated Employee” means:
1. any employee or person filling the job descriptions listed in Confidential Exhibit A to this Order; and
  2. any other person who has been identified by the Acquirer and the Monitor, and determined by Commission staff to have devoted more than 50% of his/her time to SDI Medical Audit Products or SDI Promotional Audit Products in the twelve (12) months preceding the Acquisition Date.
- Provided, however,* that the employees named in Confidential Exhibit A-1 to this Order are not Designated Employees.
- L. “Divestiture Agreement” means any agreement that receives the prior approval of the Commission between Respondent Healthcare Technology (or a Divestiture Trustee appointed pursuant to Paragraph VII of this Order) and an Acquirer to purchase the SDI Audit Business, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission.
- M. “Effective Date” means the date on which the divestitures and assignments pursuant to Paragraph II or Paragraph VII of this Order are consummated.
- N. “Hold Separate” means the Order to Hold Separate and Maintain Assets, with Paragraphs I.F and I.G now superseded by the following:
1. Paragraph I.F.: “Held Separate Business” means the SDI Audit Business, SDI OSA, SDI Report Generator (including all development and maintenance thereof), and the Held Separate Business Employees.

## Decision and Order

*Provided, however,* Respondent Healthcare Technology may use SDI Report Generator as allowed under the license described in Paragraph II.A. of the Order

2. Paragraph I.G: “Held Separate Business Employees” means the Designated Employees and any full-time, part-time, or contract employee of SDI who devoted more than 50% of his or her time to the SDI Audit Business, SDI OSA, or SDI Report Generator.
- O. “IMS Medical Audit Products” means products developed and sold by Respondent Healthcare Technology that contain estimates of disease-specific diagnoses made, and therapies prescribed by, physicians in the United States, including, but not limited to, the product known and sold as National Disease and Therapeutic Index.
- P. “IMS Promotional Audit Products” means products developed and sold by Respondent Healthcare Technology that contain estimates of pharmaceutical promotional activities in the United States, including but not limited to products known and sold as Integrated Promotional Services and IMS Promo 360, and any and all components thereto.
- Q. “Kantar License” means the February 26, 2010, license agreement between Competitive Media Report, LLC (d/b/a Kantar Media Intelligence) and SDI.
- R. “Medical Audits” means products developed, produced, and sold that contain estimates of disease-specific diagnoses made, and therapies prescribed by, physicians in the United States, other than IMS Medical Audit Products and SDI Medical Audit Products.
- S. “Patents” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention

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registrations, in each case existing as of the Acquisition Date, and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, Related To any product of or owned by Respondent Healthcare Technology as of the Acquisition Date.

- T. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, division, or department, or other business or legal entity.
- U. “Promotional Audits” means products developed, produced, and sold that contain estimates of pharmaceutical promotional activities in the United States, other than IMS Promotional Audit Products and SDI Promotional Audit Products.
- V. “Recently Signed Customer” means any third party that entered into a new contract for the purchase of any IMS Medical Audit Product or IMS Promotional Audit Product from IMS any time during the period beginning ninety (90) days before the Acquisition Date and ending the day after the Effective Date.
- Provided, however,* any third party that renews a contract for an IMS Medical Audit Product or IMS Promotional Audit Product that was in existence prior to 90 days before the Acquisition Date is not a Recently Signed Customer.
- W. “Relating To” or “Related To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- X. “SDI Audit Business” means all assets Relating To the SDI Medical Audit Products and the SDI Promotional Audit Products, including but not limited to:

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1. all information owned by, or in the possession or control of, SDI, that is not in the public domain and that is Related To the research, development, marketing, commercialization, cost, supply, sales, sales support, or use of the SDI Medical Audit Products or the SDI Promotional Audit Products, including, but not limited to, all past and present lists of physician survey participants (including name, address, and relevant contact information), customer lists, current and historical customer purchases and data, historical data, complaints, vendor lists (including the name, address, and relevant contact person for each past and present vendor for a period of the past three (3) years) and any other information possessed by SDI in any location Relating To the SDI Medical Audit Products or the SDI Promotional Audit Products.
2. all of the following Related To: (1) each SDI Medical Audit Product owned by SDI or for which SDI has the right to sub-license to third parties as of the Acquisition Date, (2) each SDI Promotional Audit Product owned by SDI or for which SDI has the right to sub-license to third parties as of the Acquisition Date and (3) the SDI Report Generator:
  - a. Copyrights;
  - b. Patents;
  - c. Software;
  - d. Trademarks;
  - e. Trade Dress;
  - f. trade secrets, know-how, utility models, design rights, techniques, data, inventions, practices, quality control methods in process, protocols, methods and other confidential or proprietary technical, business, research, development and other information, and all rights in any

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jurisdiction to limit the use or disclosure thereof;

- g. rights to obtain and file for Patents and Copyrights and registrations thereof;
  - h. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing;
  - i. the exclusive right to all intellectual property used in the research, development, and sale of SDI Medical Audit Products, SDI Promotional Audit Products, and the SDI Report Generator, including, but not limited to, Software, computer programs, Patents, licenses (including licenses to third-party software if transferable and sub-licenses to software modified by SDI), know-how, risk analysis, certificates of analysis, goodwill, technology, trade secrets (including, but not limited to, recipes and formulae), technical information (including, but not limited to, final product specifications), marketing information, protocols (including, but not limited to, operational manuals), quality control information, Trademarks, trade names, service marks, logos, and the modifications or improvements to such intellectual property; and
3. all of SDI's rights, title, and interest in all physical assets Relating To the development, manufacture, sale, and distribution of the SDI Medical Audit Products and the SDI Promotional Audit Products including, without limitation, the following:
- a. all equipment, supplies, computer hardware, and other tangible personal property Relating To the production, development, and sale of SDI Medical Audit Products and SDI Promotional Audit Products.

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*Provided, however,* that SDI Audit Business does not include any real property, plant facilities, or buildings.

*Provided, further, however,* that SDI Audit Business does not include any products that are developed, produced, or sold by SDI as, or assets or employees used exclusively for, SDI SFSS, SDI OSA, or SDI Vector One.

- Y. “SDI Audit Customer Contracts” means the customer contracts for the purchase and sale of SDI Medical Audit Products and SDI Promotional Audit Products, including but not limited to, the contracts identified in Exhibit B. SDI Audit Customer Contracts includes contracts between SDI and a customer that are not exclusively for SDI Medical Audit Products or SDI Promotional Audit Products, but include other SDI products, to the extent that such contracts pertain to the purchase and sale of SDI Medical Audit Products or the purchase and sale of SDI Promotional Audit Products.
- Z. “SDI DC Middleware” means the source code and the object code of those software components and data modules that host or support the execution and required data movements for the SDI DC Software and all corresponding documentation.
- AA. “SDI DC Software” means the software program used to collect, enter, and maintain all data Relating To the SDI Medical Audit Products and the SDI Promotional Audit Products, including the SDI DC Middleware and the SDI DC User Interface.
- BB. “SDI DC User Interface” means the source code and object code of the user interface programs for the SDI DC Software and all corresponding documentation.
- CC. “SDI Medical Audit Products” means the products developed, produced, and sold by SDI that contain estimates of disease-specific diagnoses made and therapies prescribed by physicians. SDI Medical Audit Products include but are not limited to the audit

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products known as Physician Drug and Diagnosis Audit (PDDA) and Physician Drug and Diagnosis Audit (including Pain Panel).

- DD. “SDI OSA” means the audit product developed, produced, and sold by SDI under the name Oncology Selling Audit.
- EE. “SDI PR Middleware” means the source code and the object code of those software components and data modules that host or support the execution and required data movements for the SDI Partner Rewards System, and all corresponding documentation.
- FF. “SDI PR User Interface” means the source code and the object code of the user interface programs for the SDI Partner Rewards System and all corresponding documentation.
- GG. “SDI Partner Rewards System” means the software program used by SDI to manage the physician panels Relating To the SDI Medical Audit Products and the SDI Promotional Audit Products, including the SDI PR Middleware and the SDI PR User Interface.
- HH. “SDI Promotional Audit Products” means the products developed, produced, and sold by SDI that contain estimates of pharmaceutical promotional activities, including all historical data associated with those products. SDI Promotional Audit Products include but are not limited to the audit products known as: Personal Selling Audit (PSA); Hospital Selling Audit (HPSA); Nurse Practitioner/Physician Assistant Promotion Audit (NPPA); Physician Meeting and Event Audit (PMEA); Direct to Consumer Advertising Audit (DTCA); Professional Journal Advertising Audit (PJA); Sample Distribution Audit (SDA); ePromotion Audit (ePromo); and Managed Care Promotional Audit (MCPA).
- II. “SDI Report Generator” means the software program used in conjunction with the SDI Medical Audit

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Products and the SDI Promotional Audit Products for the preparation and display of audit data and known as Report Generator Delivery (RG) Tool, including the RG Middleware and RG User Interface, and all corresponding documentation.

- JJ. “SDI RG Middleware” means the source code and the object code of those software components and data modules that host or support the execution and required data movements for the SDI Report Generator and all corresponding documentation.
- KK. “SDI RG User Interface” means the source code and the object code of the user interface programs for the SDI Report Generator and all corresponding documentation.
- LL. “SDI SFSS” means the audit product developed, produced, and sold by SDI under the name Sales Force Structures and Strategies.
- MM. “SDI Vector One” means the suite of products developed, produced, and sold by SDI under the Vector One name that rely on longitudinal anonymized patient level prescription data and other data sources to provide information on prescriptions, procedures, prescribers, payers, pharmacies, and other aspects of healthcare, including all historical data associated with those products. SDI Vector One includes the products known as Vector One: National (VONA), Vector One: Payer (VOPA), Vector One: Payer Dynamics (VOPD), Vector One: InSite Comprehensive Experience (VOICE), Vector One: Consumer Analytics (VOCA), Vector One: Market Pharmacy (VOMP), Vector One: Prescriber Extract (VOPEX), and Vector One: Prescriber (Provider Targeting) (VOPT).
- NN. “Software” means computer programs Related To the production and use of SDI Medical Audit Products or SDI Promotional Audit Products, including all software implementations of algorithms, models, and methodologies whether in source code or object code

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form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, Related To any of the foregoing and the content and information contained on any website; *Provided, however,* that Software does not include software that can readily be purchased or licensed from sources other than Respondent Healthcare Technology and which has not been modified in a manner material to the use or function thereof (other than through user preference settings).

- OO. “Trade Dress” means the current trade dress of a particular product or Person including, without limitation, product packaging, logos, and the lettering of the product trade name, brand name, or corporate name.

*Provided, however,* that Trade Dress does not include the name SDI or any manifestations thereof, except that (1) Respondent Healthcare Technology will not market a Medical Audit Product or Promotional Audit Product using the name SDI; and (2) Acquirer may reference that the SDI Medical Audits Products and SDI Promotional Audits Products were previously sold by SDI Health LLC.

- PP. “Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the SDI Medical Audit Products or the SDI Promotional Audit Products.

*Provided, however,* that Trademark does not include the name SDI, except that (1) Respondent Healthcare Technology will not market a Medical Audit Product or Promotional Audit Product using the name SDI; and (2) Acquirer may reference that the SDI Medical Audit

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Products and SDI Promotional Audit Products were previously sold by SDI Health LLC.

**II.****IT IS FURTHER ORDERED** that:

- A. Respondent shall divest the SDI Audit Business and assign the SDI Audit Customer Contracts absolutely and in good faith, as an on-going business, no later than 90 days from the Acquisition Date, to an Acquirer that receives the prior approval of the Commission and in a manner (including execution of a Divestiture Agreement with the Acquirer) that receives the prior approval of the Commission.

*Provided, however,* that if any of the SDI Audit Customer Contracts are not assignable or the contracting Person refuses to accept the Acquirer, Respondent Healthcare Technology shall use reasonable best efforts to facilitate the Acquirer's acquisition of a similar contract with similar terms from the customer.

*Provided, however,* that Respondent Healthcare Technology may retain a two-year, non-exclusive, fully paid-up and royalty-free license, solely to support SDI OSA and SDI Vector One, including the right to sub-license the SDI Report Generator to existing and new SDI OSA and SDI Vector One customers, to provide customer support to sublicensees, and to update the software as needed to support SDI OSA and SDI Vector One.

*Provided, further, however,* that Respondent Healthcare Technology may, at the end of the initial two-year license term, seek a two-year, non-exclusive license on terms negotiated with the Acquirer. Such license shall be limited solely to the provision of customer and technical support to the Respondent's sublicensees existing at the expiration of the initial two-year license term as needed to support solely SDI OSA and SDI Vector One.

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- B. At the Acquirer's option, Respondent Healthcare Technology shall assign to the Acquirer all intellectual property Relating To the SDI Medical Audit Products and the SDI Promotional Audit Products licensed to SDI and used with the SDI Audit Business, to the extent the licensor will agree to the transfer, including the Kantar License, absolutely and in good faith and at no minimum price.
- C. The Divestiture Agreement shall include, at the Acquirer's option, one or more transition services agreements for the provision of services to be provided by Respondent Healthcare Technology to the Acquirer. Such agreements shall be subject to the prior approval of the Commission and become a part of the Divestiture Agreement.
1. Such agreements may include, among other things:
    - a. an agreement for sales training and support;
    - b. an agreement for technical assistance. Such technical assistance agreement may include, among other things, training in the maintenance and troubleshooting of the SDI Report Generator software, including its source code; and
    - c. an agreement for information technology services, including but not limited to, data migration services.
  2. Respondent Healthcare Technology shall not terminate any transition services agreement before the end of the term approved by the Commission without:
    - a. the written agreement of the Acquirer and thirty (30) days prior notice to the Commission; or,
    - b. in the case of a proposed unilateral termination by Respondent Healthcare Technology due to

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an alleged breach of an agreement by the Acquirer, sixty (60) days notice of such termination.

*Provided, however,* such sixty (60) days notice shall be given only after the parties have:

- i. attempted to settle the dispute between themselves, and
  - ii. engaged in arbitration and received an arbitrator's decision, or
  - iii. received a final court decision after all appeals.
- D. Any Divestiture Agreement that has been approved by the Commission between Respondent Healthcare Technology (or a Divestiture Trustee) and a Commission-approved Acquirer shall be deemed incorporated into this Order, and failure by Respondents to comply with any term of such Divestiture Agreement shall constitute a failure to comply with this Order.
- E. The purposes of this Paragraph II of the Order are: (1) to ensure the continuation of the SDI Audit Business as a going concern in the same manner in which it conducted business as of the date the Consent Agreement is signed, and (2) to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

**III.**

**IT IS FURTHER ORDERED** that:

- A. Respondent Healthcare Technology shall, within five (5) days after the Effective Date, notify each Recently Signed Customer of its right to terminate its current contract for the purchase of IMS Medical Audit Products or IMS Promotional Audit Products. Such

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notification shall be in the form of the notification attached as Exhibit D to this Order.

- B. Respondent Healthcare Technology shall terminate the relevant contract within thirty (30) days of receiving a Recently Signed Customer's request to terminate. The Recently Signed Customer's right to terminate shall continue for six (6) months from the date the Recently Signed Customer receives notice pursuant to Paragraph III.A. Termination of the relevant contract shall be without penalty or charge, and shall be effective immediately upon request of the Recently Signed Customer.

**IV.****IT IS FURTHER ORDERED** that:

- A. Respondent Healthcare Technology shall allow the Acquirer an opportunity to recruit and employ any Designated Employee(s) under the following terms and conditions:
1. No later than seven (7) days after execution of a Divestiture Agreement, Respondent Healthcare Technology shall facilitate employment interviews between each Designated Employee and the Acquirer, including providing the names and contact information for such employees and allowing such employees reasonable opportunity to interview with the Acquirer, and shall not discourage such employee from participating in such interviews;
  2. Respondent Healthcare Technology shall not interfere in employment negotiations between each Designated Employee and the Acquirer;
  3. With respect to each Designated Employee who receives an offer of employment from the Acquirer, Respondent shall:
    - a. not prevent, prohibit, or restrict, or threaten to prevent, prohibit, or restrict the Designated

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Employee from being employed by the Acquirer, and shall not offer any incentive to the Designated Employee to decline employment with the Acquirer;

- b. cooperate with the Acquirer in effecting transfer of the Designated Employee to the employ of the Acquirer, if the Designated Employee accepts an offer of employment from the Acquirer;
  - c. eliminate any contractual provisions or other restrictions entered into or imposed by Respondent Healthcare Technology that would otherwise prevent the Designated Employee from being employed by the Acquirer;
  - d. eliminate any confidentiality restrictions that would prevent the Designated Employee who accepts employment with the Acquirer from using or transferring to the Acquirer any information Relating To the operation of the SDI Audit Business; and
  - e. unless alternative arrangements are agreed upon with the Acquirer, retain the obligation to pay for the benefit of any Designated Employee who accepts employment with the Acquirer, all accrued bonuses, vested pensions, and other accrued benefits.
- B. Respondent Healthcare Technology shall not, for a period of two (2) years following the Effective Date, directly or indirectly, solicit, induce, or attempt to solicit or induce any Designated Employee who is employed by the Acquirer, any Acquirer Medical Audit Employee, or any Acquirer Promotional Audit Employee to terminate his or her employment relationship with the Acquirer;

*Provided, however,* Respondent Healthcare Technology may place general advertisements for employees including, but not limited to, in

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newspapers, trade publications, websites, or other media not targeted specifically at the Acquirer's employees;

*Provided, further, however,* Respondent Healthcare Technology may hire Designated Employees or Acquirer Audit Employees who apply for employment with Respondent Healthcare Technology as long as such employees were not solicited by Respondent Healthcare Technology in violation of this Paragraph.

- C. For a period of two (2) years from the Acquisition Date (hereinafter "Restricted Period"), Respondent Healthcare Technology shall not solicit, induce, or attempt to induce any Person to transfer to Respondent Healthcare Technology any business Relating to the SDI Audit Customer Contracts assigned, transferred, or acquired pursuant to Paragraph II of this Order.

*Provided, however,* that nothing in this paragraph shall prevent Respondent Healthcare Technology from responding to an unsolicited invitation to bid on a contract from any Person during the Restricted Period.

**V.****IT IS FURTHER ORDERED** that:

- A. Except in the course of performing its obligations under the Divestiture Agreement, or as expressly allowed pursuant to this Order:
1. Respondent Healthcare Technology shall not provide, disclose or otherwise make available any Confidential Business Information Relating To the SDI Audit Business to any Person;
  2. Respondent Healthcare Technology shall not use any Confidential Business Information Relating To the SDI Audit Business for any reason or purpose. Among other things, Respondent Healthcare Technology shall not use such Confidential Business Information:

## Decision and Order

- a. to assist or inform Respondent Healthcare Technology employees who develop, solicit for sale, sell, or service Respondent Healthcare Technology products that compete with the products divested pursuant to this Order. For example, Respondent Healthcare Technology employees who had positions Related To the sale of SDI Medical Audit Products shall not be allowed to use any Confidential Business Information they may have about customers or the SDI Medical Audit Products to assist Respondent Healthcare Technology in the sale of the IMS Medical Audit Products;
  - b. to interfere with any suppliers, distributors, resellers, or customers of the Persons who acquired the SDI Audit Business;
  - c. to interfere with any contracts divested or assigned pursuant to this Order; or
  - d. to interfere in any other way with the Acquirer of the SDI Audit Business pursuant to this Order.
3. From the time of the Acquisition until the Effective Date:
    - a. Respondent Healthcare Technology shall not provide, disclose or otherwise make available any Confidential Business Information Relating to SDI OSA or SDI Report Generator to any Person; and
    - b. Respondent Healthcare Technology shall not use any Confidential Business Information Relating To SDI OSA or SDI Report Generator for any reason or purpose. Among other things, Respondent Healthcare Technology shall not use such Confidential Business Information:

## Decision and Order

- i. to assist or inform Respondent Healthcare Technology employees who develop, solicit for sale, sell, or service Respondent Healthcare Technology products that compete with the products divested pursuant to this Order.
  - ii. to interfere with any suppliers, distributors, resellers, or customers of the Persons who acquired the SDI Audit Business;
  - iii. to interfere with any contracts divested or assigned pursuant to this Order; or
  - iv. to interfere in any other way with the Acquirer of the SDI Audit Business pursuant to this Order.
- B. The requirements of this Paragraph V do not apply to Confidential Business Information that Respondent Healthcare Technology demonstrates:
1. was or becomes generally available to the public other than as a result of a disclosure by Respondent Healthcare Technology, or
  2. was available, or becomes available, to Respondent Healthcare Technology on a non-confidential basis, but only if, to the knowledge of Respondent Healthcare Technology, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information.

**VI.****IT IS FURTHER ORDERED** that:

- A. Stuart A. Samuels shall serve as the Monitor pursuant to the agreement executed by the Monitor and Respondent Healthcare Technology and attached as Exhibit C (“Monitor Agreement”) and Confidential Exhibit C-1 (“Monitor Compensation”). The Monitor

## Decision and Order

is appointed to assure that Respondent Healthcare Technology expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order and the Hold Separate.

- B. The Monitor Agreement shall require that, no later than one (1) day after the Acquisition Date, Respondent Healthcare Technology transfers to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities, pursuant to this Order and the Hold Separate, and consistent with the purposes of this Order.
- C. No later than one (1) day after the Acquisition Date, Respondent Healthcare Technology shall, pursuant to the Monitor Agreement, transfer to the Monitor all rights, powers, and authorities necessary to permit the Monitor to perform his duties and responsibilities, pursuant to this Order and the Hold Separate, and consistent with the purposes of this Order.
- D. Respondent Healthcare Technology shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - 1. The Monitor shall have the power and authority to monitor Respondent Healthcare Technology's compliance with the terms of the Order and the Hold Separate, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission including, but not limited to:
    - a. Assuring that Respondent Healthcare Technology expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order and the Hold Separate; and

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- b. Monitoring any agreements between Respondent Healthcare Technology and the Acquirer.
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Healthcare Technology's personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, Related To Respondent Healthcare Technology's compliance with its obligations under the Order. Respondent Healthcare Technology shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Healthcare Technology's compliance with the Order.
4. The Monitor shall serve, without bond or other security, at the expense of Respondent Healthcare Technology on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Healthcare Technology, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.
5. Respondent Healthcare Technology shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and

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other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, malfeasance, willful or wanton acts, or bad faith by the Monitor.

6. The Monitor Agreement shall provide that within one (1) month from the date the Monitor is appointed pursuant to this paragraph, and every thirty (30) days thereafter, the Monitor shall report in writing to the Commission concerning performance by Respondent Healthcare Technology of its obligations under the Order.
  7. Respondent Healthcare Technology may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *Provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor:
1. The Commission shall select the substitute Monitor, subject to the consent of Respondent Healthcare Technology, which consent shall not be unreasonably withheld. If Respondent Healthcare Technology has not opposed, in writing, including the reasons for opposing, the selection of a

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proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Healthcare Technology of the identity of any proposed Monitor, Respondent Healthcare Technology shall be deemed to have consented to the selection of the proposed Monitor.

2. Not later than ten (10) days after appointment of the substitute Monitor, Respondent Healthcare Technology shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Healthcare Technology's compliance with the relevant terms of the Order in a manner consistent with the purposes of the Order.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. A Monitor appointed pursuant to this Order may be the same person appointed as the Divestiture Trustee pursuant to the relevant provisions of this Order and may also be the same person appointed as the Manager pursuant to the Hold Separate.

**VII.****IT IS FURTHER ORDERED** that:

- A. If Respondent Healthcare Technology has not fully complied with the obligations as required by Paragraphs II, III, and IV of this Order, the Commission may appoint a Divestiture Trustee to divest the SDI Audit Business and enter into other agreements, assignments, and licenses, in a manner that satisfies the requirements of this Order.

In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or

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any other statute enforced by the Commission, Respondent Healthcare Technology shall consent to the appointment of a Divestiture Trustee in such action to effectuate the divestitures and other obligations as described in Paragraphs II, III, and IV. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph VII shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent Healthcare Technology to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Healthcare Technology, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Healthcare Technology has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent Healthcare Technology of the identity of any proposed Divestiture Trustee, Respondent Healthcare Technology shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent Healthcare Technology shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestitures required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VII, Respondent Healthcare Technology shall consent to the following terms and conditions regarding the

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Divestiture Trustee's powers, duties, authority, and responsibilities:

1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to divest the SDI Audit Business and enter into all agreements, licenses and assignments as described in Paragraph II of this Order.
2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to divest the SDI Audit Business and enter into all agreements, licenses and assignments as described in Paragraph II of this Order, absolutely and in good faith, at no minimum price, to one or more acquirers that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period or periods may be extended by the Commission; *Provided, however,* the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent Healthcare Technology shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent Healthcare Technology shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent

## Decision and Order

Healthcare Technology shall extend the time for divestiture under this Paragraph VII in an amount equal to the delay, as determined by the Commission.

4. The Divestiture Trustee shall use best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Healthcare Technology's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order.

*Provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring entity for assets and businesses to be divested pursuant to Paragraph II and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent Healthcare Technology from among those approved by the Commission;

*Provided, further, however,* that Respondent Healthcare Technology shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Healthcare Technology, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Healthcare Technology, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall

## Decision and Order

account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent Healthcare Technology, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent Healthcare Technology shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall act in a fiduciary capacity for the benefit of the Commission.
9. The Divestiture Trustee shall report in writing to Respondent Healthcare Technology and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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10. Respondent Healthcare Technology may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *Provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
  11. The Commission may, among other things, require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to Commission materials and information received in connection with the performance of the Divestiture Trustee's duties.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VII.
  - F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the obligations under Paragraph II of this Order.
  - G. The Divestiture Trustee(s) appointed pursuant to Paragraph VII of this Order may be the same Person appointed as the Monitor pursuant to Paragraph VI of this Order and may also be the same person appointed as the Manager pursuant to the Hold Separate.

**VIII.**

**IT IS FURTHER ORDERED** that for a period of ten (10) years from the date this Order becomes final:

## Decision and Order

- A. Respondent Healthcare Technology shall not, without the prior approval of the Commission, acquire, directly or indirectly, any assets divested pursuant to this Order; and
- B. Respondent Healthcare Technology shall not, without providing advance written notification to the Commission in the manner described in this Paragraph VIII.B, directly or indirectly, acquire:
  - 1. any stock, share capital, equity, or other interest in any Person, corporate or non-corporate, that produces, designs, manufactures, or sells Promotional Audit Products or Medical Audit Products in or into the United States; or
  - 2. any assets used at the time of the acquisition, or during the six (6) month period prior to the acquisition, in the design, manufacture, production, or sale of Promotional Audit Products or Medical Audit Products in or into the United States.

Said notification shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (herein referred to as “the Notification”), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such notification, notification shall be filed with the Secretary of the Commission, notification need not be made to the United States Department of Justice, and notification is required only of Respondent Healthcare Technology and not of any other party to the transaction. Respondent Healthcare Technology shall provide the Notification to the Commission at least thirty days prior to consummating the transaction (hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent Healthcare Technology shall not

## Decision and Order

consummate the transaction until thirty days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

*Provided, however,* that prior notification shall not be required by this paragraph for a transaction for which Notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

*Provided, further, however,* that prior notification shall not be required by this Paragraph VIII.B for any acquisition after which Respondent Healthcare Technology would hold not more than one percent of the outstanding securities or other equity interest in any Person described in this Paragraph VIII.B.

**IX.****IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondent Healthcare Technology has fully complied with Paragraphs II, III, and IV of this Order, Respondent Healthcare Technology shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent Healthcare Technology shall submit at the same time a copy of its report concerning compliance with this Order to the Monitor or Divestiture Trustee, if any Divestiture Trustee has been appointed pursuant to this Order. Respondent Healthcare Technology shall include in its report, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a description of all substantive contacts or negotiations

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related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent Healthcare Technology shall include in its report copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- B. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, for the next nine (9) years, Respondent Healthcare Technology shall submit to the Commission a verified written report setting forth in detail the manner and form in which it has complied, is complying, and will comply with this Order. Respondent Healthcare Technology shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Order and copies of all written communications to and from all persons Relating To this Order. Additionally, Respondent Healthcare Technology shall include in its compliance report whether or not it made any notifiable acquisitions pursuant to Paragraph VIII. Respondent Healthcare Technology shall include a description of such acquisitions including, but not limited to, the identity of the Person or assets acquired, the location of the Person or assets, and a detailed description of the assets or Person and its Medical Audit or Promotional Audit sales or development.

**X.****IT IS FURTHER ORDERED** that:

- A. Until the Effective Date, Respondent Healthcare Technology shall take such actions as are necessary to maintain the full economic viability, marketability, and competitiveness of the SDI Audit Business to minimize any risk of loss of competitive potential for the SDI Audit Business, and to prevent the destruction,

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removal, wasting, deterioration, or impairment of the SDI Audit Business, except for ordinary wear and tear. Respondent Healthcare Technology shall not sell, transfer, encumber or otherwise impair the SDI Audit Business (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the SDI Audit Business.

- B. Respondent Healthcare Technology shall retain all of Respondent Healthcare Technology's rights, title, and interest in the SDI Audit Business until the Effective Date.
- C. Until the Effective Date, Respondent Healthcare Technology shall maintain the operations of the SDI Audit Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets, as necessary) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the SDI Audit Business and shall use its best efforts to preserve the existing relationships with the following: suppliers, vendors, distributors, customers, governmental agencies, employees, and others having business relations with the SDI Audit Business. Respondent Healthcare Technology's responsibilities shall include, but are not limited to, the following:
  - 1. providing the SDI Audit Business with sufficient working capital to operate at least at current rates of operation and to meet all capital calls with respect to such business to carry on, at least at their scheduled pace, all planned maintenance and ordinary course activities for the SDI Audit Business;
  - 2. providing such resources as may be necessary to respond to competition and/or to prevent any diminution in sales of the SDI Audit Business after the Acquisition and prior to the complete

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divestiture, transfer and delivery of the SDI Audit Business to an Acquirer;

3. providing such resources and funding as may be necessary to maintain the competitive strength and positioning of the SDI Audit Business including such funds as are sufficient to:
    - a. perform all routine maintenance and all other maintenance as may be necessary to maintain or replace the assets related to the SDI Audit Business; and
    - b. provide appropriate levels of distribution, advertising, marketing, promotion, and sales expenditures for the SDI Audit Business;
  4. providing such support services to the SDI Audit Business as were being provided to such business by SDI as of the date the Consent Agreement was signed by Respondent;
  5. making any payment required to be paid under any contract, license, or lease when due, and otherwise paying all liabilities and satisfying all obligations, for the SDI Audit Business; and
  6. maintaining the books and records of the SDI Audit Business.
- D. Until the Effective Date, Respondent Healthcare Technology shall maintain a work force at the equivalent or larger size, and with equivalent or better training and expertise, to what has been associated with the SDI Audit Business as of the Effective Date.
- E. Until the Effective Date, Respondent Healthcare Technology shall provide Designated Employees with reasonable financial incentives to continue in their positions and to develop and sell the SDI Audit Business consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the SDI Audit Business

## Decision and Order

pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondent Healthcare Technology until the Effective Date has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to prevent any diminution of the competitiveness of the SDI Audit Business.

- F. The purpose of this Paragraph X is to maintain the full economic viability, marketability, and competitiveness of the SDI Audit Business until its Effective Date, to minimize any risk of loss of competitive potential for the SDI Audit Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the SDI Audit Business, except for ordinary wear and tear.

**XI.**

**IT IS FURTHER ORDERED** that Respondent Healthcare Technology shall notify the Commission at least thirty (30) days prior to any proposed:

- A. dissolution of the Respondent Healthcare Technology;
- B. acquisition of, merger with, or consolidation by Respondent Healthcare Technology; or
- C. other change in the Respondent Healthcare Technology, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**XII.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondent Healthcare Technology, Respondent Healthcare Technology shall, without restraint or interference, permit any duly authorized representative(s) of the Commission:

## Decision and Order

- A. access, during business office hours of Respondent Healthcare Technology and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent Healthcare Technology related to compliance with this Order, which copying services shall be provided by Respondent Healthcare Technology at its expense; and
- B. to interview officers, directors, or employees of Respondent Healthcare Technology, who may have counsel present, regarding such matters.

**XIII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on January 9, 2022.

By the Commission.

**CONFIDENTIAL EXHIBIT A****DESIGNATED EMPLOYEES**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

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**CONFIDENTIAL EXHIBIT A-1**

**EXCLUDED EMPLOYEES**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**CONFIDENTIAL EXHIBIT B**

**AUDIT CUSTOMER CONTRACTS**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

## Decision and Order

**EXHIBIT C****MONITOR AGREEMENT**

This Monitor Agreement (this "Agreement") entered into this 18<sup>th</sup> day of October 2011 by and between Stuart Samuels (the "Monitor") and Healthcare Technology Holdings, Inc., ("Healthcare Technology" or "Respondent") provides as follows:

**WHEREAS**, the United States Federal Trade Commission (the "Commission") has accepted or will shortly accept for Public Comment an Agreement Containing Consent Orders incorporated a Decision and Order ("Decision and Order"), which, among other things, requires Healthcare Technologies to divest the medial and promotional audits business, as defined in the Decision and Order, of SDI Health LLC and contemplates the appointment of a Monitor to monitor Healthcare Technology's compliance with its obligations under the Decision and Order;

**WHEREAS**, the Commission has appointed Stuart Samuels as Monitor pursuant to the Decision and Order, and Stuart Samuels has consented to such appointment;

**WHEREAS**, the Decision and Order further provides that Respondent shall execute an agreement, subject to the prior approval of the Commission, that confers all the rights and powers necessary to permit the Monitor to monitor Respondent's compliance with the terms of the Decision and Order as described in more detail in this Agreement; and

**WHEREAS**, the parties to this Agreement intend to be legally bound, subject only to the Commission's approval of this Agreement.

**NOW, THEREFORE**, the parties agree as follows:

All capitalized terms used in this Agreement and not specifically defined herein shall have the respective definitions given to them in the Decision and Order.

**ARTICLE I**

**1.1 Monitor's Areas of Responsibilities.** The Monitor shall be responsible for monitoring Respondent's compliance with the Decision and Order, the Order to Hold Separate and Maintain Assets, and the Divestiture Agreement, as defined in the Decision and Order (together, the "Monitor's Areas of Responsibilities").

**1.2 Access to Relevant Information and Facilities.** The Monitor shall have full and complete access to the personnel, facilities, books, and records of Respondent related to Respondent's obligations under the Decision and Order and Divestiture Agreements, as the Monitor may reasonably request. Respondent shall cooperate with any reasonable request of the Monitor. The Monitor shall give Respondent reasonable notice of any request for such access or such information and shall attempt to schedule any access or requests for information in such a manner as will not unreasonably interfere with Respondent's operations. At the request of the Monitor, Respondent shall promptly arrange meetings and discussions, including tours of relevant facilities, at reasonable times and locations between the Monitor and employees of

## Decision and Order

Respondent who have knowledge relevant to the proper discharge of his responsibilities under the Decision and Order.

**1.3 Compliance Reports.** Respondent shall provide the Monitor with copies of all compliance reports filed with the Commission in a timely manner, but in any event, no later than five (5) days after the date on which Respondents file such report with the Commission;

**1.4 Monitor's Obligations.** The Monitor shall:

- a. carry out the Monitor's duties and responsibilities within the Monitor's Areas of Responsibilities, including submission of periodic reports, and such additional written reports as may be requested by the Commission staff, to the Commission staff regarding Respondent's compliance with the Decision and Order;
- b. maintain the confidentiality of all confidential information, including Confidential Business Information, and any other information provided to the Monitor by Respondent, the Acquirers of the Divested Businesses, any supplier or customer of Respondent or the Divested Businesses, or the Commission, and shall use such information only for the purpose of discharging his obligations as Monitor and not for any other purpose, including, without limitation, any other business, scientific, technological, or personal purpose. The Monitor may disclose confidential information only to:
  - i. persons employed by or working with the Monitor under this Agreement; and
  - ii. persons employed at the Commission.
- c. require any consultants, accountants, attorneys, and any other representatives and/or assistants retained by the Monitor to assist in carrying out the duties and responsibilities of the Monitor to execute a confidentiality agreement, which Respondent will provide if requested, that requires such third parties to treat confidential or proprietary information, including Confidential Business Information, with the same standards of care and obligations of confidentiality to which the Monitor must adhere under this Agreement;
- d. maintain the confidentiality, for a period of five (5) years after the termination of this Agreement, of all other aspects of the performance of his duties under this Agreement and shall not disclose any confidential or proprietary information, including Confidential Business Information, relating thereto; and
- e. upon the termination of the Monitor's duties under this Agreement, promptly destroy all written and electronic materials (both originals and copies) that

## Decision and Order

relate to the performance of the Monitor's responsibilities under this Agreement.

**1.5 Monitor Payment.** Respondents will pay the Monitor the hourly fee specified in the attached fee schedule ("Hourly Fee") for all reasonable time spent in performance of the Monitor's duties under this Agreement. In addition, Respondent will pay: (a) out-of-pocket expenses reasonably incurred by the Monitor in the performance of the Monitor's duties; and (b) fees and disbursements reasonably incurred by such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities hereunder; however, all such out-of-pocket expenses and fees and disbursements shall be pre-approved by IMS, which shall not withhold approval unreasonably. The Monitor shall invoice Respondent on a monthly basis, within seven (7) days of the conclusion of the month, including details and an explanation of all matters for which the Monitor submits an invoice to Respondent. Respondent shall pay such invoices within 30 days of receipt. Any consultants, accountants, attorneys, and other representatives and assistants retained by the Monitor shall invoice their services to the Monitor who will review and approve such invoices and submit to Respondent for payment. At its own expense, Respondent may retain an independent auditor to verify such invoices. The Monitor and Respondent shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

**1.6 Monitor's Indemnification.** Respondent shall be liable to indemnify and hold harmless the Monitor against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties hereunder, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.

**1.7 Disputes.** In the event of a disagreement or dispute between Respondent and the Monitor concerning Respondent's obligations under the Decision and Order, and, in the event that such disagreement or dispute cannot be resolved by the parties, either party may seek the assistance of the individual in charge of the Commission's Compliance Division.

**1.8 Conflicts of Interest.** If the Monitor becomes aware during the term of this Agreement that he has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of his duties under this Agreement, the Monitor shall promptly inform Respondent and the Commission of any such conflict.

## ARTICLE II

**2.1 Termination.** This Agreement shall terminate upon the earlier of: (a) the expiration or termination of the Decision and Order; (b) Respondent's receipt of written notice from the Commission that the Commission has determined that Stuart Samuels has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; and (c) with at least thirty (30) days advance notice to be provided by the Monitor to Respondent and to the

## Decision and Order

Commission, upon resignation of the Monitor. If this Agreement is terminated for any reason, the confidentiality obligations set forth in Section 1.3 above will remain in force.

**2.2 Governing Law.** This Agreement and the rights and obligations of the parties hereunder shall in all respects be governed by the substantive laws of Pennsylvania, including all matters of construction, validity and performance. The Decision and Order shall govern this Agreement and any provisions herein which conflict or are inconsistent with it may be declared null and void by the Commission and any provision not in conflict shall survive and remain a part of this Agreement.

**2.3 Disclosure of Information.** Nothing in this Agreement shall require Respondent to disclose any material information that is subject to a legally recognized privilege or that Respondent is prohibited from disclosing by reason of law or an agreement with a third party.

**2.4 Assignment.** This Agreement may not be assigned or otherwise transferred by Respondent or the Monitor without the consent of Respondent and the Monitor and the approval of the Commission. Any such assignment or transfer shall be consistent with the terms of the Decision and Order.

**2.5 Modification.** No amendment, modification, termination, or waiver of any provision of this Agreement shall be effective unless made in writing, signed by all parties, and approved by the Commission. Any such amendment, modification, termination, or waiver shall be consistent with the terms of the Decision and Order.

**2.6 Approval by the Commission.** This Agreement shall have no force or effect until approved by the Commission.

**2.7 Entire Agreement.** This Agreement, and those portions of the Decision and Order incorporated herein by reference, constitute the entire agreement of the parties and supersede any and all prior agreements and understandings between the parties, written or oral, with respect to the subject matter hereof.

**2.8 Duplicate Originals.** This Agreement may be executed in several counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same document.

**2.9 Section Headings.** Any heading of the sections is for convenience only and is to be assigned no significance whatsoever as to its interpretation and intent.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

**MONITOR**

**RESPONDENT**

Healthcare Technology Holdings Inc.  
83 Wooster Heights Road

Decision and Order

Danbury, CT 06810

  
Stuart Samuels

  
By: Harvey Aspin  
Title: Senior Vice President, General  
Counsel and External Affairs

**CONFIDENTIAL EXHIBIT C-1**

**MONITOR FEE SCHEDULE**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

## Decision and Order

**EXHIBIT D**  
**Customer Notification Letter**

On Official IMS Letterhead  
Certified Mail, Return Receipt Requested

[Date]

Name  
Company Name  
Address  
City, State ZIP

Re: Notification of Your Right to Terminate IMS Medical and Promotional Audits Contract

Dear [IMS Customer]:

This letter is to inform you that pursuant to an agreement with the Federal Trade Commission ("FTC"), you have the right to terminate, without penalty or charge, your existing contract with IMS for medical or promotional audits that report on the United States pharmaceutical market (including NDTI, IPS, and Promo 360), unless your contract was a renewal.

**Background** - In October 2011, IMS acquired SDI Health LLC. IMS entered into an agreement with the FTC to resolve the FTC's competitive concerns with the acquisition in medical and promotional audits products. Without acknowledging that there was any problem with the acquisition, IMS agreed to an FTC Order requiring IMS to divest SDI's medical and promotional audits products, save those sold as SDI OSA and SDI SFSS. A copy of the Order is attached. The Order and related documents are also available at [insert url], if you would like more details about the settlement. [Insert name of relevant acquirer] was approved as the purchaser and will offer the SDI audit products going forward. IMS will also continue to offer its audits.

**Right to terminate - details** - Pursuant to the FTC Order, any customer that entered into a new contract with IMS for its medical and promotional audits offerings that report information on the United States pharmaceutical market between [insert relevant start date] and [insert date of divestiture] has the right to terminate, without penalty or charge, its existing contract for those audits. Please note that this right to terminate does not apply to renewal contracts for these audits and does not apply to any portion of IMS's contract other than the medical and promotional audits. Any time before [insert relevant date], you may exercise this termination right by notifying IMS. This termination right does not apply if, after receipt of this letter, you enter into a new medical or promotional audit contract with IMS. Nor does this termination right apply if, after receipt of this letter, you renew, extend, or materially modify your existing contract through agreement with IMS. Material modifications to your existing contract include changes you negotiate with IMS to the price, scope, or duration of your existing contract. Within thirty (30) days of receiving your request to terminate, IMS will terminate your contract. You must return any data received from IMS under that contract within thirty (30) days of termination. You should direct your request to terminate to [fill in IMS contact person name and address].

## Decision and Order

The FTC has appointed Stuart Samuels to monitor IMS's compliance with its obligations under the Order. We encourage you to raise any questions you may have with us by calling your IMS sales representative or me directly at \_\_\_\_\_. You may also contact the monitor, who may be reached by telephone at \_\_\_\_\_ or by e-mail at \_\_\_\_\_. In addition you may contact Karen Espaldon at the FTC at (202) 326-3726.

Sincerely,  
Name  
Title

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted from Healthcare Technology Holdings, Inc. (“Healthcare Technology”), subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”), which is designed to remedy the anticompetitive effects of Healthcare Technology’s proposed acquisition of SDI Health LLC (“SDI”) from SDI Health Holdings LLC (“SDI Holdings”). Under the terms of the proposed Consent Agreement, Healthcare Technology would be required, among other things, to divest SDI’s promotional audits and medical audits business.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments; any comments received will also become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make it final.

Pursuant to an agreement dated January 13, 2011, Healthcare Technology, through its wholly owned subsidiary, IMS Health Incorporated (“IMS”), proposes to acquire all of the membership interests in SDI (“Proposed Acquisition”). The Commission’s Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for promotional audits and medical audits. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the acquisition.

**II. The Parties**

Healthcare Technology is the private holding company of IMS. IMS produces and sells healthcare data and analytics to pharmaceutical, biotechnology, and other customers. IMS

Analysis to Aid Public Comment

maintains its headquarters in Danbury, Connecticut and has operations in over 100 countries.

SDI Holdings is the private holding company of SDI, which offers many of the same healthcare data and analytics products and services as IMS, and is headquartered in Plymouth Meeting, Pennsylvania.

### **III. The Products and Structure of the Markets**

Promotional audits provide estimates (based on data from physician panels) of pharmaceutical promotional activities for individual branded drugs in areas such as physician detailing, product sampling, and advertising. Pharmaceutical manufacturers and other customers use promotional audits to assess their “share of voice,” or their share of spending in various promotional categories, which helps them to determine their promotional budgets. The promotional audit market, however, does not include products that gauge physician reactions to promotional efforts or otherwise assess the effectiveness of promotional activities.

Medical audits provide estimates of disease-specific diagnoses made and therapies prescribed by physicians. The data underlying medical audits are also collected from panels of physicians. Customers use medical audits to assess, among other things, the size of therapeutic areas, which products are used to treat particular diseases, and prescribing and treatment trends.

The United States is the relevant geographic area in which to analyze the effects of the Proposed Acquisition in both the promotional audits and medical audits markets.

The \$16 million market for promotional audits is highly concentrated. Only IMS, SDI, and Cegedim S.A. offer promotional audits in the United States. IMS has a 30 percent share of the market, while SDI and Cegedim have shares of 68 percent and 2 percent, respectively. The \$9 million market for medical audits is also highly concentrated, with IMS accounting for 53 percent and SDI accounting for the remaining 47 percent of the market.

## Analysis to Aid Public Comment

**IV. Effects of the Acquisition**

The Proposed Acquisition would eliminate actual, direct, and substantial competition between IMS and SDI in the markets for promotional audits and medical audits. By increasing IMS's share in each market, while at the same time eliminating its only significant competitor, an acquisition of SDI likely would allow IMS to unilaterally charge significantly higher prices for promotional and medical audits. The Proposed Acquisition would also likely lead to a decrease in quality for such audits, resulting in substantial anticompetitive harm to consumers in the U.S. markets for promotional and medical audits.

**V. Entry**

Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to prevent the anticompetitive effects of the Proposed Acquisition. Entry would not take place in a timely manner because of the significant time required to recruit panels of physicians to provide the data underlying the estimates included in promotional and medical audits. In addition, the relevant markets are relatively small and mature, limiting sales opportunities for any potential new entrant. Given the size of the investment and the time needed to enter the relevant markets, relative to the sizes of those markets, it is unlikely that an entrant could obtain sufficient sales to make the investment profitable. As a result, new entry or repositioning by other firms sufficient to ameliorate the competitive harm from the Proposed Acquisition likely would not occur.

**VI. The Consent Agreement**

The proposed Consent Agreement remedies the acquisition's likely anticompetitive effects in the markets for promotional and medical audits. Pursuant to the Consent Agreement, Healthcare Technology will divest all of SDI's business relating to the production or sale of promotional and medical audits. The Consent Agreement provides that Healthcare Technology must find a buyer for the SDI audits business that is acceptable to the Commission (with no minimum price), no later than three months from the date on which Healthcare Technology consummates its acquisition of SDI.

Analysis to Aid Public Comment

Any acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating possible purchasers of divested assets is to maintain the competitive environment that existed prior to the acquisition. A proposed acquirer of divested assets must not present competitive problems. There are a number of parties interested in purchasing SDI's promotional and medical audits business, several of which appear to have the expertise, experience, and financial viability to successfully retain the current level of competition in the relevant markets.

If the Commission determines that Healthcare Technology has not provided an acceptable buyer for SDI's promotional and medical audits business within the required time period, or that the manner of the divestiture is not acceptable, the Commission may appoint a trustee to divest the assets. The trustee would have the exclusive power and authority to accomplish the divestiture, and would divest the business for no minimum price.

The Consent Agreement also contains an Order to Hold Separate and Maintain Assets, which will serve to protect the viability, marketability, and competitiveness of the divestiture asset package until the assets are divested to a buyer approved by the Commission.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

## Complaint

## IN THE MATTER OF

**POOL CORPORATION**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4345; File No. 101 0115*  
*Complaint, January 10, 2012 – Decision, January 10, 2012*

This consent order addresses Pool Corporation's threats to manufacturers that it would not deal with them if they also supplied new entrants in the pool product distribution market. The complaint alleges that PoolCorp effectively foreclosed new distributors from obtaining pool products from manufacturers that represented more than 70 percent of all pool product sales in violation of Section 5 of the Federal Trade Commission Act. The consent order prohibits PoolCorp from (1) conditioning the sale or purchase of pool products, or membership in PoolCorp's preferred vendor programs, on the intended or actual sale of pool products by a manufacturer to any distributor other than PoolCorp; (2) pressuring, urging or otherwise coercing manufacturers to refrain from selling, or to limit their sales, to any distributors other than PoolCorp; and (3) discriminating or retaliating against a manufacturer for selling, or intending to sell, pool products to any distributor other than PoolCorp.

*Participants*

For the *Commission: Matthew P. Accornero, Linda M. Holleran and Benjamin W. Jackson.*

For the *Respondent: Mark Cunningham, Jones Walker; and Cliff Aronson, Skadden, Arps, Slate, Meagher, and Flom LLP.*

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et seq.*, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Pool Corporation, Inc. ("PoolCorp" or "Respondent") has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

## Complaint

**NATURE OF THE CASE**

1. This action addresses PoolCorp's exclusionary acts and practices in the market for the distribution of residential and commercial swimming pool products. PoolCorp has unlawfully maintained its monopoly power by threatening to refuse to deal with any manufacturer that sells its pool products to a new distributor entering the market, thereby foreclosing potential rivals from an input necessary to compete. PoolCorp's conduct deters and impedes entry, raises its rivals' costs, and results in higher prices, reduced output and less consumer choice.

**RESPONDENT**

2. Respondent PoolCorp is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 109 Northpark Boulevard, Covington, Louisiana 70433.

3. Respondent distributes pool products through two distribution networks: SCP Distributors, LLC, formerly known as South Central Pools; and Superior Pool Products, LLC. Both distribution networks operate throughout the United States and distribute similar product lines.

**JURISDICTION**

4. At all times relevant herein, Respondent has been, and is now, a corporation as "corporation" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. The acts and practices of Respondent, including the acts and practices alleged herein, are in commerce or affect commerce in the United States, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

**RELEVANT MARKET**

6. There are over nine million residential pools in the United States, and over 250,000 commercial pools operated by hotels, country clubs, apartment buildings, municipalities, and others. In

## Complaint

2010, the distribution of pool products was an estimated \$3 billion industry in the United States.

7. The relevant product market is no broader than the wholesale distribution of residential and commercial swimming pool products. Pool products are the equipment, products, parts or materials used for the construction, renovation, maintenance, repair or service of residential and commercial swimming pools.

8. Pool products include, among others, pumps, filters, heaters, covers, cleaners, steps, rails, diving boards, pool liners, pool walls, and the “white goods” or parts necessary to maintain pool equipment. Pool products do not include pool toys or games, or products used solely for landscaping or irrigation, Olympic-style pools, or pools used in commercial water parks.

9. Pool products are designed and manufactured specifically for residential and commercial swimming pools. There are no close substitutes for pool products, and no other products significantly constrain their pricing.

10. Pool distributors purchase pool products from manufacturers, warehouse them, and then resell those products to pool builders, pool retail stores and pool service and repair companies (collectively, “pool dealers” or “dealers”). Pool dealers then sell the pool products to the ultimate consumer: owners of residential and commercial pools.

11. Pool product manufacturers consider wholesale distributors to be a unique and essential channel for the efficient distribution of their products. Distributors purchase and warehouse significant volumes of pool products throughout the year, allowing manufacturers to operate their factories year-round notwithstanding the seasonal nature of the pool industry. Distributors also provide one-stop shopping, timely delivery and the extension of credit to thousands of dealers, thereby providing dealers and manufacturers with significant transactional efficiencies. Additionally, distributors often help manufacturers administer their dealer rebate and warranty programs, and provide expertise to answer dealers’ product-related questions.

### Complaint

12. While manufacturers make some direct sales to larger dealers, they cannot easily expand their operations into distribution because of the costs, their lack of expertise in distribution, and the difficulty of obtaining products to distribute from competing manufacturers. Distributors are the only available source of pool products for the vast majority of dealers, which are small mom-and-pop operations that do not have the inventory size or resources to purchase pool products directly from manufacturers. Dealers that buy direct from manufacturers are not permitted by the manufacturers to participate more broadly in the wholesale distribution market and sell pool products to other dealers.

13. The relevant geographic markets are no larger than the United States, and numerous local geographic markets contained therein. With the exception of a few large national pool retail chains that purchase products for their retail centers throughout the United States, competition among distributors for sales to dealers occurs locally. The high cost of transportation and the general need for same-day or next-day delivery of pool products typically limits local geographic markets to 50 to 100 square miles, depending on the concentration of the population and pools in the local area.

### **RESPONDENT HAS MONOPOLY POWER**

14. Respondent is the world's largest distributor of pool products, and operates approximately half of all pool distribution facilities in the United States. Unlike other distributors that operate in a few local markets or a specific region, Respondent is the only U.S. distributor to operate nationwide. Through a series of acquisitions, Respondent has grown to operate over 200 distribution centers throughout the United States. By way of comparison, the next largest U.S. distributor operates less than 40 centers. In 2010, Respondent earned roughly \$1.5 billion in net sales.

15. Respondent has monopoly power in numerous local geographic markets across the country, including, among others, Austin TX, Baton Rouge LA, Mobile AL, Nashville TN, Oklahoma City OK, and Springfield MO. In these local markets, Respondent is the only or dominant distributor in the local

## Complaint

market, and has maintained a market share of approximately 80 percent or higher for at least the past five years.

16. Respondent's dominance in local markets is enhanced by its status as the largest nationwide buyer of pool products, commonly representing 30 to 50 percent of a manufacturer's total sales. Respondent obtains a significant competitive advantage in the downstream market by qualifying for large volume discounts from manufacturers that are not available to any other distributor.

17. Respondent's conduct of foreclosing new entrants from obtaining pool products directly from manufacturers, which is a necessary input to compete, represents a significant barrier to entering the pool distribution market.

**RESPONDENT EMPLOYED UNFAIR METHODS OF  
COMPETITION IN ORDER TO MAINTAIN ITS  
MONOPOLY**

18. Beginning in at least 2003 and continuing through to today, Respondent has engaged in unfair methods of competition by foreclosing access to essential inputs and impeding market entry by potential rivals. Respondent's conduct has the tendency and effect of improperly maintaining and enhancing Respondent's monopoly power. Respondent's conduct has caused injury to competition and to consumers. Respondent's conduct is likely to continue to harm competition absent the relief requested herein, and violates Section 5 of the FTC Act, as amended.

**A. The Wholesale Pool Product Distribution Industry**

19. The swimming pool industry is generally very fragmented. There are over 100 manufacturers that produce a small number of product lines, such as pool heaters or diving boards and rails. However, there are only three manufacturers that sell nearly all the pool products necessary to operate and maintain a pool: Pentair Water Pool and Spa, Inc.; Hayward Pool Products, Inc.; and Zodiac Pool Systems, Inc. Collectively, these three full-line manufacturers represent more than 50 percent of sales at the wholesale level.

20. Distributors generally carry all brands of pool products across all manufacturers in order to satisfy any and all orders from

### Complaint

their dealer customers. It is necessary to sell the products of at least one of the three full-line manufacturers in order to be able to compete effectively as a distributor. The products of the full-line manufacturers are “must have” products for wholesale distributors because of the volume of products they represent and the considerable consumer demand for their products. A positive relationship with these and other manufacturers is “critical” to the success of a pool distributor.

21. In general, manufacturers are willing to sell their products through any credit-worthy distributor that has a physical warehouse and personnel with knowledge of the pool industry. Manufacturers typically prefer to have two or more distributors selling their products in a local geographic market in order to ensure that their dealer customers receive competitive service and prices.

22. Manufacturers market their products directly to dealers in order to create pull-through demand at the distribution level, but also offer year-end rebates to distributors based on the volume of a distributors’ purchases. These year-end rebates represent a significant component of the ultimate price paid by distributors for pool products. Failure to qualify for these rebates can have a significant detrimental impact on a distributor’s ability to compete on price.

23. Dealers select a local distributor based on its level of service and the prices it offers. When a distributor increases its prices, dealers typically pass those increases on to their customers. Thus, the ultimate price paid by end consumers for pool products depends heavily on the prices that distributors charge to dealers.

### **B. Respondent’s Exclusionary Practices**

24. In August 2002, Respondent acquired Fort Wayne Pools, Inc. (“FWP”), a large regional pool distributor with operations in 16 states. FWP was Respondent’s then-largest, and sometimes only, competitor in numerous local markets.

25. Soon thereafter, Respondent closed a FWP distribution facility in Baton Rouge, LA. This left Respondent as the only

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remaining distributor in the area, and it implemented a five percent price increase. In Spring 2003, a former dealer with almost 20 years of experience in the industry opened a distribution business in Baton Rouge, LA to compete with Respondent.

26. Respondent responded to this new competition by notifying all major manufacturers that it would stop dealing with any manufacturer that sold any of its products to the new entrant. Respondent threatened to terminate not only its purchases and sales in the local Baton Rouge area, but across the entire country.

27. As the manufacturers' largest customer, Respondent's threat was significant. No other distributor could replace the large volume of potential lost sales to Respondent, particularly in those markets where Respondent was the only distributor. The loss of sales to Respondent could be "catastrophic" to the financial viability of even major manufacturers. Without expending tens of millions of dollars to enter dozens of markets simultaneously, it was impossible for the new entrant to offer any economic incentive to manufacturers that would offset the risks imposed by Respondent's threats.

28. The manufacturers, including the three "must-have" manufacturers, refused to sell pool products to the new entrant and canceled any pre-existing orders. Respondent effectively foreclosed the new entrant from obtaining pool products from manufacturers that represented more than 70 percent of all pool product sales. Without direct access to the manufacturers' pool products, the new entrant's business ultimately failed in 2005.

29. A new entrant cannot avoid the effects of Respondent's conduct by purchasing pool products from other distributors, rather than directly from manufacturers. As a general rule, distributors do not sell pool products to other distributors. Even when possible, this alternative is not a viable long-term strategy because it substantially increases a distributor's costs and lessens its quality of service.

30. For example, buying from a distributor forces the new entrant to pay transportation costs from the distributor's location rather than receiving free shipping under manufacturer programs.

### Complaint

The purchases are also at a marked-up price and do not qualify for key manufacturer year-end rebates. These higher costs would prevent the new entrant from being able to compete aggressively on price. Additionally, without full control of its inventory, this work-around hampers the entrant's ability to provide timely and quality service to its dealer customers.

31. Respondent has employed similar exclusionary strategies in other local markets, including against distributors that have entered the market since 2008, with the purpose and effect of excluding rivals, raising its rivals' costs, and maintaining its monopoly power. Respondent's exclusionary practices and policies target new entrants, rather than established rivals, because new entrants represent a unique competitive threat due to their likelihood to compete aggressively on price in order to earn new business.

### **ANTICOMPETITIVE EFFECTS OF RESPONDENT'S CONDUCT**

32. The acts and practices of Respondent as alleged herein have had the purpose, capacity, tendency, and effect of impairing the competitive effectiveness of Respondent's rivals, raising its rivals costs, and deterring and impeding entry. Respondent's conduct has contributed significantly to the enhancement and maintenance of Respondent's monopoly power.

33. Respondent's conduct adversely affects competition and consumers by:

- a. increasing the prices and reducing the output of pool products;
- b. deterring, delaying and impeding the ability of Respondent's actual or potential competitors to enter or to expand their sales in the wholesale distribution market; and
- c. reducing the choice of suppliers available to pool dealers.

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34. There are no legitimate procompetitive efficiencies that justify Respondent's conduct or outweigh its substantial anticompetitive effects.

**VIOLATION ALLEGED**

35. The acts and practices of Respondent, as alleged herein, constitute monopolization and unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this tenth day of January, 2012, issues its complaint against Respondent.

By the Commission, Commissioner Rosch dissenting.

**DECISION AND ORDER**

The Federal Trade Commission ("Commission") having initiated an investigation of certain acts and practices of Pool Corporation (hereinafter "PoolCorp" or Respondent), and Respondent having been furnished thereafter with a copy of a draft Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order ("Consent Agreement"), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute

## Decision and Order

an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from an interested person pursuant to section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent PoolCorp is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 109 Northpark Blvd, Covington, Louisiana 70433-5521.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

**THE PARTIES**

- A. "Respondent" or "PoolCorp" means Pool Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups

## Decision and Order

and affiliates controlled by PoolCorp; and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- B. “Commission” means the Federal Trade Commission.

**OTHER DEFINITIONS**

- C. “Analysis to Aid Public Comment” means the public statement provided by the Commission that describes the allegations in the Complaint in FTC File No. 101-0115 and the terms of this Order.
- D. “Antitrust Compliance Program” means the program to ensure compliance with this Order and with the Antitrust Laws, as required by Paragraph III of this Order.
- E. “Antitrust Laws” means the Federal Trade Commission Act, as amended, 15 U.S.C. § 41 *et. seq.*, the Sherman Act, 15 U.S.C. § 1 *et. seq.*, and the Clayton Act, 15 U.S.C. § 12 *et. seq.*
- F. “Business Segment” means, separately, pool builders; pool retailers; and pool service companies.
- G. “Confidentially” means that any documents or data that are produced by a Manufacturer to a third party are in an aggregated or other form such that the documents or data could not be used to identify the specific pricing or sales to any individual Distributor(s), and that will not be provided to or otherwise shared with Respondent.
- H. “Dealer” means any Person (*e.g.*, pool builders, pool service companies, and pool retail stores) that sells Pool Products directly to owners of residential or commercial pools.
- I. “Delivery Services” means all terms and services associated with a Distributor delivering Pool Products

## Decision and Order

to a specified location on behalf of a Manufacturer, Dealer or other Person, including but not limited to, delivery of Pool Products via truck or common carrier, delivery directly to a consumer's home or job site, the timely scheduling of the delivery, and the extension of credit to eligible Dealers.

- J. "Distribute" or "Distribution" means the wholesale purchase of Pool Products from a Manufacturer and the re-sale of those Pool Products to Dealers or others.
- K. "Distributor" means a Person that Distributes, or intends to Distribute, Pool Products.
- L. "Document" means all written, recorded, or graphic materials of every kind, prepared by any Person, that are in the possession, custody, or control of Respondent, and includes but is not limited to, letters, reports, memoranda, e-mails, notes, and presentations.
- M. "Executive Staff" means all Directors on the Board of Directors, the President, all Vice-Presidents, the Chief Financial Officer, Senior Directors, General Managers, and Regional Managers of Respondent, or their equivalent positions regardless of job title.
- N. "Favorable" means more economically advantageous Price Terms or Product Support, or more effective Delivery Services, to Dealers or to Manufacturers than Respondent makes Generally Available to other Dealers or to other Manufacturers.
- O. "Generally Available" means the standard or typical terms and conditions, including but not limited to Price Terms, Product Support and Delivery Services, that Respondent offers or provides on like grade, quality and quantity of goods to most, if not all, Manufacturers based on their designation as a Preferred Vendor, or to most, if not all, Dealers in the same Business Segment(s) in the local geographic market.

## Decision and Order

- P. “In-Person Training” means any educational session, seminar, or other meeting whereby individuals participate on a face-to-face basis or through a live, two-way video-conference feed as part of the Antitrust Compliance Program required in Paragraph III of this Order.
- Q. “Less Favorable” means economically disadvantageous Price Terms or Product Support or less effective Delivery Services, to Dealers or to Manufacturers than Respondent makes Generally Available to other Dealers or to other Manufacturers.
- R. “Manufacturer” means any Person that manufactures, develops, or produces one or more Pool Products.
- S. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or governmental entity, and any subsidiary, division, group or affiliate thereof.
- T. “Pool Product” means any equipment, product, part or material used for the construction, renovation, maintenance, repair or service of residential or commercial swimming pools (*e.g.*, pumps, filters, heaters, cleaners, covers, drains, fittings, diving boards, steps, rails, pool liners, pool walls, chemicals, and cleaning tools). This definition does not include: pool toys or games; generic building materials (*i.e.*, concrete, salt, sand, rebar, tiles, pavers, and electrical and plumbing products); or any equipment, product, part or material that is used solely for landscaping or irrigation, Olympic-style pools, or pools used in commercial water parks.
- U. “Preferred Vendor” means a Manufacturer that has been designated by Respondent as being eligible for favorable or preferential treatment by Respondent in connection with the sale, promotion, marketing, or purchase of the Manufacturer’s Pool Product(s).

## Decision and Order

- V. “Price Term” means the wholesale price, resale price, purchase price, price list, credit term, delivery term, service term, or any other term defining, setting forth, or relating to the money, compensation, or service paid by or received by a Manufacturer in connection with the sale of its Pool Products to Respondent.
- W. “Product Support” means any service, assistance or other support related to a Manufacturer’s Pool Product(s), including but not limited to, the processing or administration of Manufacturer warranties, Manufacturer rebates to Dealers, and training on the features of a Manufacturer’s Pool Product.
- X. “Sales Staff” means the officers, directors, employees, and contractors of Respondent whose duties primarily relate to the marketing, promotion, sale, or purchase of Pool Products.

**II.**

**IT IS ORDERED** that Respondent, acting directly or indirectly, or through any corporate or other device, in connection with the actual or potential purchase, sale, or Distribution of Pool Products, in or affecting commerce, as “commerce” is defined in the Federal Trade Commission Act, shall cease and desist from:

- A. Conditioning the sale, purchase, or Distribution of Pool Products by Respondent, or a Manufacturer’s Preferred Vendor status, based on a Manufacturer’s sale, or an intention to sell, Pool Products to any Distributor other than Respondent;
- B. Urging, inducing, coercing, threatening, or pressuring, or attempting thereto, a Manufacturer to refuse to sell Pool Products, or limit its sales of Pool Products, to any Distributor other than Respondent; and
- C. Discriminating against, penalizing, or otherwise retaliating against a Manufacturer because the Manufacturer sells, or intends to sell, Pool Products to any Distributor other than Respondent. Examples of

## Decision and Order

prohibited retaliation shall include, but not be limited to, the following when the conduct is substantially caused by the fact that the Manufacturer sells, or intends to sell, Pool Products to any Distributor other than Respondent:

1. Terminating, suspending, reducing, or delaying, or threatening or proposing thereto, purchases of a Manufacturer's Pool Products;
2. Terminating, suspending, reducing, or delaying, or threatening or proposing thereto, the sales or promotion of a Manufacturer's Pool Products to Dealers;
3. Increasing Respondent's sales price of a Manufacturer's Pool Product(s) to Dealers, provided there has been no corresponding increase in costs for Distributing such Pool Products;
4. Requiring, soliciting, requesting, or encouraging a Manufacturer to furnish information to Respondent relating to the price or quantity of any sales by the Manufacturer to any specific Distributor other than Respondent, provided that information that is provided Confidentially by a Manufacturer to a third party for compliance or audit purposes shall not be prohibited;
5. Withdrawing, terminating, or modifying, or threatening or proposing thereto, Favorable Price Terms, Product Support, or Preferred Vendor status for a Manufacturer that is otherwise eligible;
6. Providing, or threatening or proposing thereto, Less Favorable Price Terms or Product Support; and
7. Refusing to deal with a Manufacturer, or with Dealers of a Manufacturer's Pool Products, on terms and conditions that are Generally Available

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from Respondent to other Manufacturers or to other Dealers.

*Provided, however,* that nothing in this Order requires Respondent to continue purchasing the same volume of Pool Products from any Manufacturer as in previous years if there is a reduced demand for such Pool Products from Respondent's customers at Respondent's then current prices or margins in any local geographic market(s) where entry has occurred.

- D. Notwithstanding any provision of this Order, the following will not constitute, in and of itself, a violation of this Order:
1. Respondent's refusal to deal with a Manufacturer, or Respondent's engagement in any of the conduct described above in Paragraph II.C (1-7), when substantially caused by independent and verifiable business reasons unrelated to whether the Manufacturer sells, or intends to sell, Pool Products to any Distributor(s) other than Respondent; or
  2. Respondent's agreement(s) with a Manufacturer to be an exclusive Distributor of private-label Pool Products.
- E. Respondent, within ninety (90) days after the date this Order becomes final, shall waive or modify any condition, requirement, policy, agreement, contract, or understanding with any Manufacturer that is inconsistent with the terms of this Order.

**III.**

**IT IS FURTHER ORDERED** that Respondent shall design, maintain, and operate an Antitrust Compliance Program to assure compliance with this Order and with the Antitrust Laws. This program shall include, but not be limited to:

## Decision and Order

- A. Respondent's designation of an officer or director to supervise personally the design, maintenance, and operation of this program, and to be available on an ongoing basis to respond to any questions by employees of Respondent;
- B. Distribution of a copy of this Order to all Executive Staff and Sales Staff:
  - 1. Within thirty (30) days of the date this Order becomes final; and,
  - 2. Annually within thirty (30) days of the anniversary of the date this Order becomes final until the Order terminates;
- C. In-Person Training on the requirements of this Order and the Antitrust Laws for Respondent's Executive Staff to occur annually at either of Respondent's bi-annual management meetings;
- D. Training on the requirements of this Order and the Antitrust Laws for Respondent's Sales Staff to occur annually;
- E. Distribution within thirty (30) days after this Order becomes final of a copy of this Order and the Analysis to Aid Public Comment to all Manufacturers that have sold Pool Products to Respondent within twelve (12) months prior to the date this Order becomes final; and
- F. The retention of documents and records sufficient to record Respondent's compliance with its obligations under this Paragraph III of this Order.

**IV.****IT IS FURTHER ORDERED** that:

- A. Within sixty (60) days after the date this Order becomes final, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which the Respondent

## Decision and Order

has complied, is complying, and will comply with this Order. For the period covered by this report, the report shall include, but not be limited to:

1. The name, title, business address, e-mail address, and business phone number of the officer or director designated by Respondent to design, maintain, and operate Respondent's Antitrust Compliance Program;
  2. The name, title, business address, e-mail address, and business phone number of each Person to whom Respondent distributed a copy of this Order, and the date and manner of distribution to each; and
  3. The name, title, business address, e-mail address, and business phone number of each Person who received In-Person Training on the requirements of this Order and the Antitrust Laws; the date and location at which each Person was trained; the name, title, business address, e-mail address, and business phone number of the Person who conducted the training; and a description in reasonable detail of the In-Person Training.
- B. One (1) year after the date this Order becomes final, and annually for the following nine (9) years on the anniversary of the date this Order becomes final, as well as at any other such times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order. For the periods covered by these reports, these reports shall include, but not be limited to:
1. The name, title, business address, e-mail address, and business phone number of the officer or director designated by Respondent to design, maintain, and operate Respondent's Antitrust Compliance Program;

## Decision and Order

2. The name, title, business address, e-mail address, and business phone number of each Person to whom Respondent distributed a copy of this Order, and the date and manner of distribution to each;
3. The name, title, business address, e-mail address, and business phone number of each Person within Respondent's Executive Staff who received a copy of this Order and In-Person Training on the requirements of this Order and the Antitrust Laws during the reporting period, the date each Person received a copy of this Order and In-Person Training, and a description in reasonable detail of the In-Person Training;
4. The name, business address, e-mail address, and business phone number of each Person to whom Respondent required, solicited, requested or encouraged any Manufacturer to furnish information relating to the price or quantity of any sales by the Manufacturer to any Distributor other than Respondent;
5. The name, title, business address, e-mail address, and business phone number of each Person who has complained or alleged, orally or in writing (including, but not limited to, pleadings filed in any state or federal court), that Respondent has violated this Order or the Antitrust Laws, a description in reasonable detail of the complaint or allegation, and a description of any action or conduct by Respondent taken or proposed in response to the complaint or allegation; and
6. The names, business addresses, business phone numbers, and email addresses of the top ten Manufacturers that sold to Respondent the greatest dollar amounts of Pool Products in the United States in each of the following categories: pumps and filters, heaters, cleaners, covers, drains, fittings, diving boards, steps, rails, pool liners, and pool walls, during the most recently concluded

## Decision and Order

fiscal year and during the prior fiscal year; and for each such Person:

- a. State the total dollar amount of the Pool Products purchased by Respondent from the Manufacturer;
- b. Provide copies of all written agreements between Respondent and such Person in effect at any time during the most recently concluded fiscal year; and
- c. Provide copies of any Document that summarizes, memorializes, or otherwise reflects the terms of any oral agreement between Respondent and such Person that directly or indirectly require such Person to refrain from selling, limit its sales of, or delay its sales of, Pool Products to any other Distributor in effect at any time during the most recently concluded fiscal year.

**V.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent;
- B. Any proposed acquisition, merger or consolidation of Respondent; or
- C. Any other change in Respondent, including but not limited to, assignment, the creation or dissolution of subsidiaries, or if such change may affect compliance obligations arising out of this Order.

**VI.**

**IT IS FURTHER ORDERED** that for the purpose of determining or securing compliance with this order, upon written request, Respondent shall permit any duly authorized representative of the Commission:

## Concurring Statement

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent relating to any matters contained in this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of Respondent; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

**VII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on January 10, 2032.

By the Commission, Commissioner Rosch dissenting.

**STATEMENT OF****COMMISSIONERS JULIE BRILL, JON LEIBOWITZ  
AND EDITH RAMIREZ**

The Commission is today issuing for public comment a Complaint and Order that would resolve allegations that Pool Corporation (“PoolCorp”) used anticompetitive acts and practices to exclude rivals from, and to maintain its monopoly power in, several local pool product distribution markets, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

On the basis of staff’s investigation and as outlined in the Complaint, we have reason to believe that a violation of the antitrust laws has occurred — and that Commission action is in

## Concurring Statement

the public interest. 15 U.S.C. § 45(b). Specifically, the Complaint alleges that PoolCorp, which possesses monopoly power in many local distribution markets, threatened its suppliers (*i.e.*, pool product manufacturers) that it would no longer distribute a manufacturer's products on a nationwide basis if that manufacturer sold its products to a new distributor that was attempting to enter a local market. Although these manufacturers preferred to have a broad and diverse distribution network, they declined to add distributors because they feared retribution from PoolCorp. These decisions were not made for independent business reasons.<sup>1</sup>

As alleged in the Complaint, PoolCorp's actions foreclosed new entrants from obtaining pool products from manufacturers representing more than 70 percent of sales. Significantly, there is no efficiency justification for PoolCorp's conduct. That is, without any legitimate justification, PoolCorp dictated whether new competitors could access the full range of merchandise needed to compete effectively in the market. *Cf. Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 930 (7th Cir. 2000) (actions by dominant toy retailer to prevent would-be entrants from obtaining access to toys judged to be anticompetitive). Some of PoolCorp's targets were able to survive by purchasing pool products from other distributors rather than directly from the manufacturers. However, we assess consumer harm relative to market conditions that would have existed but for the respondent's allegedly unlawful conduct. Here, PoolCorp's strategy significantly increased a new entrant's costs of obtaining pool products. Conduct by a monopolist that raises rivals' costs can harm competition by creating an artificial price floor or deterring investments in quality, service and innovation.<sup>2</sup> The higher cost

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1 We disagree with Commissioner Rosch's conclusion that manufacturers refused to deal with new entrants for independent business reasons. In our view, the evidence demonstrates a causal relationship between the manufacturers' decisions and PoolCorp's alleged conduct.

2 *See, e.g.*, Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price*, 96 *YALE L.J.* 209, 224 (1986) (finding that a dominant firm's strategy of restraining rivals' access to supply can be a "particularly effective method of anticompetitive exclusion" because it allows the dominant firm to use its vertical relationships to create additional horizontal market power).

## Concurring Statement

structure PoolCorp imposed on new entrants prevented them from providing a competitive constraint to PoolCorp's alleged monopoly prices. And without full control of their inventory, the new distributors' ability to provide high quality service to their dealer customers was diminished. The harm to consumers that occurred as a result was substantial. In the end, consumers had fewer choices and were forced to pay higher prices for pool products.

Although we recognize that PoolCorp's alleged conduct did not target incumbent distributors, we nevertheless have reason to believe that the conduct harmed competition and consumers. Separate from PoolCorp, there are few, if any, incumbent distributors in the local markets at issue here. By targeting new distributor entrants, PoolCorp's conduct harmed the very companies that were most likely to compete aggressively on price and to introduce innovative services or ways of doing business.<sup>3</sup> The Commission has seen this pattern before. The targets of anticompetitive exclusion are often the new rivals that incumbents foresee as most likely to shake up the market and benefit consumers at the expense of incumbents.<sup>4</sup> We fail to do our job if we permit a monopolist to decide, without sufficient efficiency justification, whether or on what terms a rival will be permitted to enter the market.

Because we have reason to believe that PoolCorp's conduct had the purpose and effect of maintaining PoolCorp's monopoly power in numerous local markets where its dominance was threatened by new distributor entrants, we support the attached Complaint and Order.

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3 *See id.* at 246 (explaining that potential competition by new entrants can provide a "significant competitive check" distinct from established firms).

4 *See, e.g., Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 U.S. 492, 499-500 (1988) (condemning association action to prevent inclusion of plastic conduits in relevant standard); *Realcomp II, LTD. v. FTC*, 635 F.3d 815 (6th Cir. 2011) (condemning Multiple Listing Service rules that disadvantaged new brokerage model), *cert. denied*, 2011 U.S. Lexis 7292 (Oct. 11, 2011); *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928 (7th Cir. 2000) (condemning dominant toy company's actions that limited sources of toys available to new warehouse clubs).

## Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission has accepted for public comment an Agreement Containing Consent Order to Cease and Desist (“Agreement”) with Pool Corporation (“PoolCorp”). PoolCorp is the world’s largest distributor of products used in the construction, renovation, repair, service and maintenance of residential and commercial swimming pools. The Agreement resolves charges that PoolCorp used exclusionary acts and practices to maintain its monopoly power in the pool product distribution market in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45.

The administrative complaint that accompanies the Agreement (“Complaint”) alleges that PoolCorp used its monopoly power in local geographic markets to prevent manufacturers from supplying pool products to new entrants since at least 2003. As a result, PoolCorp foreclosed rival distributors from obtaining pool products – a necessary input to compete – and significantly raised its rivals’ costs, thereby lowering output, increasing prices, and diminishing consumer choice.

The Commission anticipates that the competitive issues described in the Complaint will be resolved by accepting the proposed Order, subject to final approval, contained in the Agreement. The Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and comments received, and will decide whether it should withdraw from the Agreement or make final the Order contained in the Agreement.

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment concerning the proposed Order. It is not intended to constitute an official interpretation of the Agreement and proposed Order or in any way to modify their terms.

The Agreement is for settlement purposes only and does not constitute an admission by PoolCorp that the law has been

## Analysis to Aid Public Comment

violated as alleged in the Complaint or that the facts alleged in the Complaint, other than jurisdictional facts, are true.

**I. The Complaint**

The Complaint makes the following allegations.

**A. Industry Background**

This case involves wholesale distribution in the swimming pool industry. There are over nine million residential pools in the United States, and over 250,000 commercial pools operated by hotels, country clubs, apartment buildings, municipalities, and others. In 2010, the distribution of pool products was an estimated \$3 billion industry in the United States.

Manufacturers use distributors to sell the products used to build, repair, service and maintain residential and commercial swimming pools (“pool products”). Pool products include, among others, pumps, filters, heaters, covers, cleaners, diving boards, steps, rails, pool liners, pool walls, and the parts necessary to maintain pool equipment. Distributors purchase pool products from manufacturers, warehouse them, and then resell the products to pool retail stores, pool service companies and pool builders (collectively, “pool dealers” or “dealers”). Dealers, in turn, sell the pool products to the ultimate consumer: owners of residential and commercial swimming pools.

The swimming pool industry is very fragmented and wholesale distributors make it more efficient for manufacturers and dealers to sell their products. Distributors purchase most, if not all, brands of pool products that are produced by manufacturers so that they can provide convenient one-stop shopping for their dealer customers. Distributors also extend credit and provide quick delivery of pool products to thousands of dealers. The vast majority of dealers are mom-and-pop operations that are too small to buy directly from manufacturers; for these dealers, distributors are their only source of pool products. Distributors also allow manufacturers to operate their factories year-round by purchasing large quantities of pool products throughout the year, even though the pool industry is seasonal.

### Analysis to Aid Public Comment

In general, manufacturers are willing to sell their products to any credit-worthy distributor that has a physical warehouse and personnel with knowledge of the pool industry. Manufacturers typically prefer to have two or more distributors selling their products in a local geographic market in order to ensure that the distributors compete and give competitive service and prices to their dealer customers.

To compete effectively as a distributor, a firm must be able to buy pool products directly from manufacturers. There are no cost-effective alternatives. While there are over 100 manufacturers of pool products, there are only three full-line manufacturers that produce almost all of the products used to operate or repair swimming pools: Pentair Water Pool & Spa; Zodiac Pool Systems, Inc.; and Hayward Pool Products. Collectively, these manufacturers represent more than 50 percent of all pool product sales. To be successful, a distributor must sell the products of at least one of these manufacturers. As recognized by PoolCorp, a positive relationship with these and other manufacturers is “critical” to the success of a distributor.

#### **B. PoolCorp’s Monopoly Power**

The relevant market is no broader than the wholesale distribution of pool products in the United States and numerous local geographic markets. With the exception of large national retail chains that purchase pool products for their retail centers located throughout the United States, competition among distributors for sales to dealers occurs locally. PoolCorp has monopoly power in numerous local markets, as evidenced by a persistently high market share of 80 percent or more for the past five years. PoolCorp’s conduct of foreclosing new distributor entrants from obtaining pool products directly from manufacturers represents a significant barrier to entry.

#### **C. PoolCorp’s Conduct**

Beginning in 2003 and continuing to today, PoolCorp has implemented an exclusionary policy that effectively impeded entry by new distributors by preventing them from being able to purchase pool products directly from manufacturers. Specifically, when a new distributor attempted to enter a local geographic

## Analysis to Aid Public Comment

market, PoolCorp threatened manufacturers that it would not deal with them if they also supplied the new entrant. PoolCorp threatened to terminate the purchase and sale of the manufacturer's pool products for all 200+ PoolCorp distribution centers located throughout the United States. PoolCorp's policy did not exclude existing rivals from obtaining pool products from manufacturers.

PoolCorp's threat was significant. The loss of sales to PoolCorp could be "catastrophic" to the financial viability of even major manufacturers. No other distributor could replace the large volume of potential lost sales to PoolCorp, particularly in markets where PoolCorp is the only distributor. New entrants could not offer any economic incentive to manufacturers that would offset the risks imposed by PoolCorp's threats.

After receiving these threats, manufacturers, including the three "must-have" manufacturers, refused to sell pool products to the new distributors and canceled any pre-existing orders. PoolCorp thus effectively foreclosed new distributors from obtaining pool products from manufacturers that represented more than 70 percent of all pool product sales.

In some cases, the new distributors were able to purchase pool products from other distributors. This counterstrategy, however, did not mitigate the effects of PoolCorp's conduct. As a general rule, distributors do not sell pool products to other distributors. Even when possible, this alternative is not a viable long-term strategy because it substantially increases the entrant's costs and lessens its quality of service. For example, buying pool products from a distributor forces the new distributor entrant to pay transportation costs from the distributor's location rather than receiving free shipping under manufacturer programs. The purchases are also at a marked-up price and do not qualify for key manufacturer year-end rebates.

By effectively increasing its rivals' costs, PoolCorp's exclusionary policy prevented the new distributor entrants from being able to compete aggressively on price. Additionally, without full control of their inventory, the entrants' ability to provide quality service to their dealer customers was diminished. PoolCorp specifically targeted new entrants, rather than

## Analysis to Aid Public Comment

established rivals, because the new distributors represented a significant competitive threat due to their likelihood to compete aggressively on price in order to earn new business. PoolCorp's conduct, therefore, had the purpose and effect of maintaining and enhancing PoolCorp's monopoly power in numerous local markets where its dominance would otherwise be threatened by new entrants. PoolCorp's exclusionary policy, therefore, has likely resulted in higher prices and reduced output.

There are no procompetitive efficiencies that justify PoolCorp's conduct.

## II. Legal Analysis

The offense of monopolization under § 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market; and (2) the willful acquisition, enhancement or maintenance of that power through exclusionary conduct.<sup>1</sup> A monopolist's refusal to deal with a firm if that firm also deals with a rival has long been recognized as exclusionary conduct. Exclusionary practices violate Section 2 of the Sherman Act when the challenged conduct significantly impairs the ability of rivals to compete effectively with the respondent and thus to constrain its exercise of monopoly power.<sup>2</sup>

The factual allegations in the complaint regarding market structure support a finding of monopoly power and competitive

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1 *Verizon Commun's. v. Law Offices of Curtis V. Trinko LLP.*, 540 U.S. 398, 407 (2004); *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

2 *E.g., Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 & n.32 (1985) (exclusionary conduct "tends to impair the opportunities of rivals" but "either does not further competition on the merits or does so in an unnecessarily restrictive way") (citations omitted); *see also Lorain Journal Co. v. United States*, 342 U.S. 143, 151-54 (1951) (condemning newspaper's refusal to deal with customers that also advertised on rival radio station because it harmed the radio station's ability to compete); *United States v. Microsoft*, 253 F.3d 34, 68-71 (D.C. Cir. 2001) (condemning exclusive agreements that prevented rivals from "pos[ing] a real threat to Microsoft's monopoly"); *United States v. Dentsply*, 399 F.3d 181, 191 (3d Cir. 2005) (condemning policy that kept competitors below "the critical level necessary for any rival to pose a real threat to Dentsply's market share").

## Analysis to Aid Public Comment

harm. PoolCorp's "all or nothing" threats acted as a powerful deterrent to manufacturers against dealing with new distributor entrants by jeopardizing a large and irreplaceable percentage of the manufacturer's sales. PoolCorp's conduct effectively foreclosed new entrants from manufacturers representing more than 70 percent of pool product sales. New entrants were unable to provide any economic incentive to manufacturers that could offset the risk posed by PoolCorp's threats. Raising rivals' costs by restraining their supply of inputs can be a "particularly effective method of anticompetitive exclusion."<sup>3</sup>

Additionally, the work-around strategy employed by some new entrants of purchasing pool products from other distributors significantly raised their costs and reduced their ability to provide quality service. PoolCorp's exclusionary policy therefore prevented these firms from providing a meaningful constraint on PoolCorp's monopoly prices.

Notably, PoolCorp's conduct targeted new entry and did not exclude existing rivals. The test for exclusionary conduct, however, is not total foreclosure, but "whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit."<sup>4</sup> New entrants may have a more disruptive impact on the market than established firms because they may have an increased incentive to compete aggressively on price in order to win business. Conduct that artificially raises entry barriers by increasing the scale, cost or time of entry harms

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3 See Thomas G. Krattenmaker & Steven C. Salop, *Anticompetitive Exclusion: Raising Rivals' Costs to Achieve Power Over Price*, 96 *YALE L.J.* 209, 224 (1986) (explaining that this method of exclusion allows a dominant firm to use its vertical relationships to create additional horizontal market power); see also *Dentsply*, 399 F.3d at 195 (holding "all or nothing" ultimatum exclusionary when it "created a strong economic incentive for dealers to reject competing lines in favor of Dentsply's teeth."); *In re Transitions Optical, Inc.*, 75 Fed. Reg. 10799 (Mar. 2010) (proposed complaint and analysis to aid public comment).

4 *LePage's, Inc. v. 3M*, 324 F.3d 141, 159 (3d Cir. 2003); see also *Dentsply*, 399 F.3d at 190 (explaining that "it is not necessary that all competition be removed from the market").

## Analysis to Aid Public Comment

consumers by providing a greater opportunity for monopoly pricing.<sup>5</sup>

A monopolist may rebut a *prima facie* showing of competitive harm by showing that the challenged conduct is reasonably necessary to achieve a procompetitive benefit. Any efficiency benefit, if proven, must be balanced against the harm caused by the challenged conduct.

There are no procompetitive efficiencies that justify PoolCorp's conduct. In some cases, for example, exclusive arrangements with suppliers could be necessary to prevent free-riding or to secure adequate supply. Here, however, PoolCorp did not offer any services upon which a new entrant could free-ride. Further, the pool industry is not subject to product shortfalls that could justify exclusive arrangements with suppliers. In short, PoolCorp's practice of foreclosing new entrants from supply did not help PoolCorp compete on the merits by improving its efficiency, quality or prices.

### III. The Order

The proposed Consent Order remedies PoolCorp's anticompetitive conduct. Paragraph II of the Order addresses the core of PoolCorp's conduct. Specifically, Paragraph II of the proposed Consent Order prohibits PoolCorp from:

- A. Conditioning the sale or purchase of pool products, or membership in PoolCorp's preferred vendor programs, on the intended or actual sale of pool products by a manufacturer to any distributor other than PoolCorp;

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<sup>5</sup> Herbert Hovenkamp, *ANTITRUST LAW* ¶ 1802c, at 64 (2d ed. 2002) ("Consumer injury results from the delay that the dominant firm imposes on the smaller rival's growth"); *see also Microsoft*, 253 F.3d at 79 ("it would be inimical to the purpose of the Sherman Act to allow monopolists free reign to squash nascent, albeit unproven, competitors at will"); *LePage's*, 324 F.3d at 159 ("When a monopolist's actions are designed to prevent one or more new or potential competitors from gaining a foothold in the market by exclusionary, *i.e.*, predatory, conduct, its success in that goal is not only injurious to the potential competitor but also to competition in general.").

## Analysis to Aid Public Comment

- B. Pressuring, urging or otherwise coercing manufacturers to refrain from selling, or to limit their sales, to any distributors other than PoolCorp; and
- C. Discriminating or retaliating against a manufacturer for selling, or intending to sell, pool products to any distributor other than PoolCorp.

The definition of “distributor” includes any entity that buys pool products directly from manufacturers and resells those products to dealers or others. The Order explicitly allows PoolCorp to enter into exclusive agreements with manufacturers to purchase private-label pool products.

Paragraph III of the Proposed Order requires PoolCorp to implement an antitrust compliance program. Paragraph IV- VI impose reporting and other compliance requirements. The Order will expire in 20 years.

\* \* \*

## Complaint

## IN THE MATTER OF

**TEVA PHARMACEUTICAL INDUSTRIES LTD.  
AND  
CEPHALON, INC.****CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT**

*Docket No. C-4335; File No. 111 0166*

*Complaint, October 7, 2011 – Decision, January 27, 2012*

This consent order addresses the \$6.8 billion acquisition by Teva Pharmaceutical Industries Ltd. of certain assets of Cephalon, Inc. The complaint alleges that the acquisition would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by significantly reducing competition in the U.S. markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil. The consent order requires Teva to divest to Par Pharmaceutical, Inc. (“Par”) all of Teva’s rights and assets relating to its generic transmucosal fentanyl citrate lozenges and generic extended release cyclobenzaprine hydrochloride capsules. The Order also requires Teva to enter into a supply agreement to allow Par to sell generic modafinil tablets for a period of at least one year; and Par has the option to extend that supply agreement for up to one additional year if it chooses.

*Participants*

For the *Commission: Stephanie C. Bovee, David Von Nirschl,*  
and *Kari A. Wallace.*

For the *Respondents: Ian R. Conner and Christine S. Wilson,*  
*Kirkland & Ellis LLP; Clifford H. Aronson and C. Scott Lent,*  
*Skadden, Arps, Slate, Meagher & Flom LLP.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Teva Pharmaceutical Industries Ltd. (“Teva”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Cephalon, Inc. (“Cephalon”), a corporation subject to the jurisdiction of the Commission, in violation of

## Complaint

Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

**I. RESPONDENTS**

1. Respondent Teva is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131, Israel and the address of its United States subsidiary, Teva Pharmaceuticals USA, located at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454.

2. Respondent Cephalon is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 145 Brandywine Parkway, West Chester, Pennsylvania 19380.

3. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

**II. THE PROPOSED ACQUISITION**

4. Pursuant to an Agreement and Plan of Merger (“Acquisition Agreement”) dated May 1, 2011, Teva proposes to acquire Cephalon for approximately \$6.2 billion (the “Acquisition”).

## Complaint

**III. THE RELEVANT MARKETS**

5. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. human pharmaceutical products containing fentanyl citrate delivered transmucosally in a lozenge;
- b. human pharmaceutical products containing extended release cyclobenzaprine hydrochloride; and
- c. human pharmaceutical products containing modafinil.

6. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

**IV. THE STRUCTURE OF THE MARKETS**

7. Transmucosal fentanyl citrate lozenges are a treatment for breakthrough cancer pain originally developed by Cephalon and marketed under the brand name Actiq. Only Teva, Cephalon/Watson Pharmaceuticals, Inc., and Covidien sell a generic version of the drug in the United States. Teva and Covidien both manufacture their own product while Watson's product is manufactured and supplied by Cephalon. Among the generic competitors, Teva is the leader with 43 percent share, Cephalon/Watson and Covidien have 40 percent and 17 percent, respectively. In that group, the Acquisition would increase the combined share of Teva/Cephalon/Watson to 83 percent and increase the Herfindahl-Hirschman Index concentration by 3,400 points to 7,178 points.

8. Cephalon developed and markets the branded formulation of extended release cyclobenzaprine hydrochloride, called Amrix, an extended release muscle relaxant. No companies currently market a generic version in the United States. Teva and Cephalon are two of a limited number of suppliers capable of entering with a generic version of the product in a timely manner.

## Complaint

9. Cephalon's branded modafinil product, Provigil, is used to treat excessive sleepiness caused by narcolepsy or shift work sleep disorder. No companies currently market a generic version in the United States. Teva and Cephalon are two of a limited number of suppliers capable of entering with a generic version of the product in a timely manner.

**V. ENTRY CONDITIONS**

10. Entry into the relevant markets described in Paragraphs 5 and 6 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of drug development times and U.S. Food and Drug Administration approval requirements take at least two years. In addition, entry is not likely because the relevant markets are relatively small, limiting sales opportunities for any potential new entrant.

**VI. EFFECTS OF THE ACQUISITION**

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Teva and Cephalon, and reducing the number of competitors, in the market for transmucosal fentanyl citrate lozenges thereby: (1) increasing the likelihood that Teva will be able to unilaterally exercise market power in these markets; (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating potential competition between Teva and Cephalon and reducing the number of generic competitors in the future thereby: (1) increasing the likelihood that the combined entity would forego or

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delay the launch of one of the extended release cyclobenzaprine hydrochloride products, and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from an additional supplier of extended release cyclobenzaprine hydrochloride products; and

- c. by eliminating potential competition between Teva and Cephalon and reducing the number of generic competitors in the future thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of one of the modafinil products, and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from an additional supplier of modafinil products.

**VII. VIOLATIONS CHARGED**

12. The Acquisition Agreement described in Paragraph 4 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

13. The Acquisition described in Paragraph 4, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this seventh day of October, 2011 issues its Complaint against said Respondents.

By the Commission.

## Order to Maintain Assets

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. (“Teva”) of Respondent Cephalon, Inc. (“Cephalon”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel and the address of its United States subsidiary, Teva Pharmaceuticals USA, Inc., located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454,

## Order to Maintain Assets

and its United States subsidiary, Barr Laboratories, Inc., located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.

2. Respondent Cephalon is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 41 Moores Road, Frazer, Pennsylvania 19355.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Teva” means Teva Pharmaceutical Industries Limited, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Barr Pharmaceuticals, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Teva shall include Cephalon.
- B. “Cephalon” means Cephalon, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Cephalon (including, but not limited to, Cima Labs Inc.), and the respective directors,

## Order to Maintain Assets

officers, employees, agents, representatives, successors, and assigns of each.

- C. “Respondents” means Teva and Cephalon, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Decision and Order” means the:
  - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
  - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- F. “Divestiture Assets” means the Generic Cyclobenzaprine Product Assets and the Generic Fentanyl Product Assets, as defined in the Decision and Order.
- G. “Divestiture Product Business(es)” means the business of Respondent Teva within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing, and sale of each Divestiture Product and the assets related to such business, including, without limitation, the Divestiture Assets.
- H. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph IV of the Decision and Order.
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

## Order to Maintain Assets

**II.**

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully transfer and deliver each of the respective Divestiture Assets to an Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Businesses except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair such Divestiture Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
  
- B. Until Respondents fully transfer and deliver each of the respective Divestiture Assets to an Acquirer, Respondents shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondents' responsibilities shall include, but are not limited to, the following:
  - 1. providing each of the respective Divestiture Product Businesses with sufficient working capital

## Order to Maintain Assets

to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for such Divestiture Product Business;

2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products at the related High Volume Accounts;
5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including without limitation, the Divestiture Assets;
6. providing each of the respective Divestiture Product Businesses with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of such Divestiture Product Business; and

## Order to Maintain Assets

7. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such business by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Until Respondents fully transfer and deliver the Divestiture Assets to an Acquirer, Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Until the Closing Date for the Divestiture Assets, Respondents shall provide all the related Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the relevant Divestiture Products consistent with past practices and as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the Divestiture Assets has occurred, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and additional incentives as may be necessary to prevent any diminution of the relevant Divestiture Product's competitiveness.
- E. Respondents shall:
1. for each Divestiture Product, for a period of six (6) months from the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by the relevant Acquirer, whichever occurs earlier, provide the relevant Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such Acquirer. Each of these periods is hereinafter

## Order to Maintain Assets

referred to as the “Divestiture Product Core Employee Access Period(s)”;

2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after written request by an Acquirer, provide such Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;
3. during the Divestiture Product Employee Access Period, not interfere with the hiring or employing by the Acquirer of Divestiture Product Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with such Acquirer, including, but not limited to, any noncompete provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the Acquirer;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.E.3. shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of such employee’s employment with Respondents prior to the date of the written offer of employment from the Acquirer to such employee.

## Order to Maintain Assets

- F. Pending divestiture of the Divestiture Assets, Respondents shall:
1. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Divestiture Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondents' obligations to the Acquirer of the particular Divestiture Product under the terms of any Remedial Agreement related to such Divestiture Product; or
    - c. applicable Law;
  2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer or other Persons specifically authorized by such Acquirer to receive such information;
  3. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; and
  4. institute procedures and requirements to ensure that the above-described employees:
    - a. do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Order to Maintain Assets; and

## Order to Maintain Assets

- b. do not solicit, access or use any Confidential Business Information that they are prohibited from receiving for any reason or purpose.
- G. Not later than thirty (30) days from the earlier of the Closing Date or the date that this Order to Maintain Assets becomes final and effective, Respondents shall provide to all of Respondents' employees and other personnel who may have access to Confidential Business Information related to the Divestiture Products notification of the restrictions on the use of such information by Respondents' personnel. Respondents shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel.
- H. Respondents shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondents shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondents' employees and other personnel.
- I. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents to the Acquirer under such

## Order to Maintain Assets

agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.

- J. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim

## Order to Maintain Assets

Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of the Decision and Order and until the earliest of:
    - a. with respect to each Divestiture Product, the date the Acquirer (or its Designee(s)) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents;
    - b. with respect to each Divestiture Product, the date the Acquirer notifies the Commission and the Respondents of its intention to abandon its

## Order to Maintain Assets

efforts to manufacture such Divestiture Product; or

- c. with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product;

*provided, however,* that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

*provided, further,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives

## Order to Maintain Assets

and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order;

*provided, however,* beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph IX.B. of the Decision and Order, and ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in

## Order to Maintain Assets

commercial quantities, in a manner consistent with cGMP, independently of Respondents.

8. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

**IV.**

**IT IS FURTHER ORDERED** that within thirty (30) days after the date this Order to Maintain Assets becomes final and effective, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant,

## Order to Maintain Assets

license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A. and II.B. of the related Decision and Order in this matter, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order to Maintain Assets and the related Decision and Order; *provided, however*, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph VIII of the Decision and Order.

**V.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

**VI.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, such Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books,

## Order to Maintain Assets

ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of such Respondent; and

- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

**VII.**

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The later of:
  - 1. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
  - 2. the day after the day the related Decision and Order becomes final and effective.

By the Commission.

## Decision and Order

**DECISION AND ORDER**  
**[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Teva Pharmaceutical Industries Ltd. (“Teva”) of Respondent Cephalon, Inc. (“Cephalon”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments filed by interested persons, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

## Decision and Order

1. Respondent Teva is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its corporate head office and principal place of business located at 5 Basel Street, P.O. Box 3190, Petach Tikva 49131 Israel and the address of its United States subsidiary, Teva Pharmaceuticals USA, Inc., located at 1090 Horsham Road, P.O.B. 1090, North Wales, Pennsylvania 19454, and its United States subsidiary, Barr Laboratories, Inc., located at 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey 07677.
2. Respondent Cephalon is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 41 Moores Road, Frazer, Pennsylvania 19355.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. "Teva" means Teva Pharmaceutical Industries Limited, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Teva (including, but not limited to, Barr Pharmaceuticals, LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Teva shall include Cephalon.
- B. "Cephalon" means Cephalon, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures,

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subsidiaries, divisions, groups and affiliates in each case controlled by Cephalon (including, but not limited to, Cima Labs Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- C. “Respondents” means Teva and Cephalon, individually and collectively.
- D. “Commission” means the Federal Trade Commission.
- E. “Acquirer(s)” means the following:
  - 1. a Person specified by name in this Order to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
  - 2. a Person approved by the Commission to acquire particular assets or rights that a Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Teva’s acquisition of fifty percent (50%) or more of the voting securities of Respondent Cephalon.
- G. “Acquisition Date” means the date on which the Acquisition occurs.
- H. Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes,

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without limitation, the United States Food and Drug Administration (“FDA”).

- I. “Amrix Patents” means the following United States patents: US 7387793, US 7544372, US 7790199, US 7820203, US 7829121, and any re-examinations and re-issues of the foregoing patents, and any patents claiming priority thereto.
- J. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SND A”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between a Respondent and the FDA related thereto.
- K. “Categorized Assets” means, for each specified Divestiture Product, all of the specified Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to the Divestiture Product to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Divestiture Product, including, without limitation, the following:
  - 1. all Product Intellectual Property related to the specified Divestiture Product;

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2. all Product Approvals related to the specified Divestiture Product;
3. all Product Manufacturing Technology related to the specified Divestiture Product;
4. all Product Marketing Materials related to the specified Divestiture Product;
5. all Website(s) related exclusively to the specified Divestiture Product;
6. the content related exclusively to the specified Divestiture Product that is displayed on Website that is not dedicated exclusively to the specified Divestiture Product;
7. a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
  - a. to require each Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Acquisition Date and *except* as may be required by applicable Law;
  - b. to prohibit each Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s);
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a Retained Product (including the right to receive notification from the specified Respondent of any such cross-referencing that is discovered by any Respondent);

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- d. to seek cross-referencing from a customer of the specified Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
  - e. to approve the timing of each Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Acquisition Date and *except* as may be required by applicable Law; and
  - f. to approve any notification(s) from each Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by that Respondent prior to such notification(s) being disseminated to the customer(s);
8. all rights to all of the specified Respondent's Applications related to the specified Divestiture Product;
  9. all Product Development Reports related to the specified Divestiture Product;
  10. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);
  11. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product;

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12. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
13. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
14. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
15. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
16. all of the specified Respondent's books, records, and files directly related to the foregoing;

*provided, however*, that "Categorized Assets" shall not include: (1) documents relating to a Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the

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specified Divestiture Product; (2) administrative, financial, and accounting records; (3) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (4) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing information that is exclusively related to the Retained Products; (5) any real estate and the buildings and other permanent structures located on such real estate; and (6) all Product Licensed Intellectual Property;

*provided further, however,* that in cases in which documents or other materials included in the assets to be divested contain information: (1) that relates both to the specified Divestiture Product and to Retained Products or businesses of a Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (2) for which a Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, a Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that a Respondent provides the Acquirer with the above-described information without requiring a Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- L. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.

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- M. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- N. “Closing Date” means, as to each Divestiture Product, the date on which a Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- O. “Confidential Business Information” means all information owned by, or in the possession or control of, a Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Divestiture Products;

*provided, however,* that the restrictions contained in this Order regarding a Respondent’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

1. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by a Respondent;
2. information related to the Divestiture Products that Respondent Cephalon can demonstrate it obtained without the assistance of Respondent Teva prior to the Acquisition;
3. information that is required by Law to be publicly disclosed;

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4. information relating to a Respondent's general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Divestiture Products;
  5. information specifically excluded from the Generic Fentanyl Product Assets or the Generic Cyclobenzaprine Product Assets;
  6. all intellectual property licensed on a non-exclusive basis to the Acquirer of the specified Divestiture Product; and
  7. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- P. "Contract Manufacture" means:
1. to manufacture a Contract Manufacture Product by a Respondent on behalf of an Acquirer;
  2. to manufacture a Product that is bioequivalent and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product by a Respondent on behalf of an Acquirer;
  3. to provide any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product by a Respondent on behalf of an Acquirer.
- Q. "Contract Manufacture Product(s)" means the following products:
1. Generic Fentanyl Products; and
  2. Generic Cyclobenzaprine Products; and/or any ingredient or component of any of the foregoing Divestiture Products, for which any part of the

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manufacturing process is performed by a Respondent prior to the Closing Date at a facility that is not subject to divestiture pursuant to this Order;

*provided however*, that with the consent of the affected Acquirer, a Respondent may substitute a bioequivalent form of such Products in performance of the Respondent's agreement to Contract Manufacture.

- R. "Development" means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. "Develop" means to engage in Development.
- S. "Direct Cost" means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. "Direct Cost" to the Acquirer for its use of any of a Respondent's employees' labor shall not exceed the average hourly wage rate for such employee;

*provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, "Direct Cost" means such cost as is provided in such Remedial Agreement for that Divestiture Product.

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- T. “Divestiture Products” means the Generic Fentanyl Products and the Generic Cyclobenzaprine Products, individually and collectively.
- U. “Divestiture Product Core Employee(s)” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- V. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
  2. any Person controlled by or under common control with that Acquirer; and
  3. any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- W. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- X. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- Y. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- Z. “Generic Cyclobenzaprine Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Teva

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pursuant to ANDA No. MR-090-864 and any supplements, amendments, or revisions thereto.

- AA. “Generic Cyclobenzaprine Product Assets” means all of Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to each of the respective Generic Cyclobenzaprine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Generic Cyclobenzaprine Product, including, without limitation, the Categorized Assets related to the Generic Cyclobenzaprine Products; and
1. all of Respondent Teva’s rights and interests in any patent infringement suit in which Respondent Teva is alleged to infringe any Amrix Patent, including without limitation:
    - a. all rights to all documentation created by or for, or in the possession of, Respondent Teva that is related exclusively to any pending patent litigation related to the Generic Cyclobenzaprine Products;
    - b. a right of access to any employee of Respondent Teva for the purposes of the suit;
    - c. a right of access to any witness under the control of Respondent Teva identified in the suit;
    - d. a waiver of any conflicts-of-interests or non-disclosure agreement(s) sufficient to allow Respondent Teva’s outside legal counsel to represent the Acquirer in the suit, to share all information and opinions created by or for Respondent Teva related exclusively to the suit with the Acquirer, and to provide any information gathered in connection with the suit with the Acquirer; and

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- e. all rights to all of the litigation files and any related attorney work-product created by or for, or in the possession of, Respondent Teva or in the possession of Respondent Teva's outside counsel relating exclusively to the Generic Cyclobenzaprine Product;

*provided however*, "Generic Cyclobenzaprine Product Assets" *excludes* the Amrix Patents.

BB. "Generic Cyclobenzaprine Product Divestiture Agreements" means all of the following agreements:

1. "Asset Purchase Agreement" between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and,
2. "Supply Agreement" between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

related to the Generic Cyclobenzaprine Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Cyclobenzaprine Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.B.

CC. "Generic Cyclobenzaprine Product License" means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Teva prior to the Acquisition:

1. to research and Develop the Generic Cyclobenzaprine Products for marketing,

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distribution or sale within the Geographic Territory;

2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Generic Cyclobenzaprine Products within the Geographic Territory;
3. to import or export the Generic Cyclobenzaprine Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Generic Cyclobenzaprine Products in the Geographic Territory; and
4. to have the Generic Cyclobenzaprine Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided however*, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by Respondent Teva prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent Teva; *provided further however*, the Generic Cyclobenzaprine Product License *excludes* a grant of rights in or to the Amrix Patents.

- DD. “Generic Fentanyl Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Teva pursuant to ANDA No. 77-312, and any supplements, amendments, or revisions thereto.
- EE. “Generic Fentanyl Product Assets” means all of Respondent Teva’s rights, title and interest in and to all assets related to Respondent Teva’s business within the Geographic Territory related to each of the respective Generic Fentanyl Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing,

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and sale of each such Product, including, without limitation, the Categorized Assets related to the Generic Fentanyl Products; and

1. an unlimited and unrestricted Right of Reference or Use to the Drug Master Files related to Oral Opioid Fentanyl granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the Commission Order C-4121 on a non-exclusive basis;
  2. all rights on a non-exclusive basis to Respondent Cephalon's Risk Evaluation Mitigation Strategy related to NDA Number 20-747 (Actiq<sup>®</sup>, fentanyl citrate), and all strategic safety programs, submitted to an Agency related to Actiq<sup>®</sup> that are designed to decrease product risk by using one or more interventions or tools beyond the package insert;
  3. all rights granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the Commission Order C-4121, including, without limitation, all rights granted by Respondent Cephalon to Barr Laboratories Inc. pursuant to the "License and Supply Agreement" by and between Cephalon Inc. and Barr Laboratories, Inc. dated July 7, 2004, and all amendments, exhibits, attachments, agreements, and schedules thereto;
  4. at the Acquirer's option, any of Respondent Teva's equipment that is used in the manufacture of Generic Fentanyl Products; and
  5. Respondent Teva's Risk MAP Program for the Generic Fentanyl Product.
- FF. "Generic Fentanyl Product Divestiture Agreements" means all of the following agreements:
1. "Asset Purchase Agreement" between Barr Laboratories, Inc. and Par Pharmaceutical, Inc.,

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dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and,

2. “Manufacturing Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;
3. “REMS Program License Agreement” by and among Cephalon, Inc., and Par Pharmaceutical, Inc., dated as of September 13, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto;

related to the Generic Fentanyl Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Generic Fentanyl Product Divestiture Agreements are attached to this Order and contained in non-public Appendix II.A.

GG. “Generic Fentanyl Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was used by Respondent Teva to manufacture the Generic Fentanyl Products prior to the Acquisition, which license may be limited in scope for use for the following purposes:

1. to research and Develop the Generic Fentanyl Products for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Generic Fentanyl Products within the Geographic Territory;
3. to import or export the Generic Fentanyl Products to or from the Geographic Territory to the extent

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related to the marketing, distribution or sale of the Generic Fentanyl Products in the Geographic Territory; and

4. to have the Generic Fentanyl Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided further however*, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party to Respondent Teva, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent Teva.

HH. “Generic Modafinil Products” means generic versions of all Products manufactured, marketed or sold by Respondent Cephalon prior to the Acquisition Date that contain the active pharmaceutical ingredient modafinil, including all dosage strengths, formulations and presentations of those Products. “Generic Modafinil Products” includes, without limitation, bioequivalent versions of all Products marketed or sold by Respondent Cephalon under the trademark Provigil<sup>®</sup>, but *excludes* the use of the Provigil<sup>®</sup> trademark on Product labels or packaging.

II. “Generic Modafinil Product Supply Agreement” means the “Modafinil Supply Agreement” between Barr Laboratories, Inc. and Par Pharmaceutical, Inc., dated as of September 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Generic Modafinil Products that have been approved by the Commission to accomplish the requirements of this Order. The Generic Modafinil Product Supply Agreement is attached to this Order and contained in non-public Appendix III;

*provided, however*, that, with the consent of Par, the Respondents may substitute Products that are bioequivalent to the Generic Modafinil Products in

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performance of Respondents' obligations to supply Par under this Order.

- JJ. "Geographic Territory" shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.
- KK. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- LL. "High Volume Account(s)" means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the specified Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent's U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition or the Closing Date.
- MM. "Interim Monitor" means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- NN. "Law" means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- OO. "Manufacturing Designee" means any Person other than a Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.

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- PP. “NDC Numbers” means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.
- QQ. “Order Date” means the date on which this Decision and Order becomes final and effective.
- RR. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- SS. “Par” means Par Pharmaceutical Companies, Inc., a corporation organized, existing and doing business under and by virtue of the laws of Delaware, with its headquarters address at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.
- TT. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by a Respondent as of the Closing Date (*except* where this Order specifies a different time).
- UU. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- VV. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or

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dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.

- WW. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.
- XX. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from a Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. pursuant to which a Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
  3. relating to any Clinical Trials involving the specified Divestiture Product;

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4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;
5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures or packages the specified Divestiture Product on behalf of a Respondent;
7. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to a Respondent;
8. pursuant to which a Third Party is licensed by a Respondent to use the Product Manufacturing Technology;
9. constituting confidentiality agreements involving the specified Divestiture Product;
10. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
11. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to a Respondent including, but not limited to, consultation arrangements; and/or
12. pursuant to which any Third Party collaborates with a Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the business related to such Divestiture Product;

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*provided, however*, that where any such contract or agreement also relates to a Retained Product(s), the Respondents shall assign the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

YY. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the specified Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the specified Divestiture Product sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing

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processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to such Divestiture Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

ZZ. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence to a Respondent from the FDA and from a Respondent to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event/serious adverse event summaries related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;
17. manufacturing batch records related to the specified Divestiture Product;

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18. stability testing records related to the specified Divestiture Product;
19. change in control history related to the specified Divestiture Product; and
20. executed validation and qualification protocols and reports related to the specified Divestiture Product.

AAA. "Product Employee Information" means the following, for each Divestiture Product Core Employee, as and to the extent permitted by Law:

1. a complete and accurate list containing the name of each Divestiture Product Core Employee (including former employees who were employed by the specified Respondent within ninety (90) days of the execution date of any Remedial Agreement);
2. with respect to each such employee, the following information:
  - a. the date of hire and effective service date;
  - b. job title or position held;
  - c. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, the specified Respondent may provide the employee's most recent performance appraisal;
  - d. the base salary or current wages;
  - e. the most recent bonus paid, aggregate annual compensation for the relevant Respondent's last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and

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- g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and
  3. at the Acquirer's option or the Proposed Acquirer's option (as applicable), copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant employees.
- BBB. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):
1. Patents;
  2. Product Copyrights;
  3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
  4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
- provided, however,* "Product Intellectual Property" does not include the corporate names or corporate trade dress of "Teva" "Barr" or "Cephalon", or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by Respondents or the related corporate logos thereof, or general registered images or symbols by which Teva, Barr or Cephalon can be identified or defined.
- CCC. "Product Licensed Intellectual Property" means the following:

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1. Patents that are related to a Divestiture Product that a Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition; and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that a Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by a Respondent within the two-year period immediately preceding the Acquisition.

DDD. “Product Manufacturing Employees” means all salaried employees of a Respondent who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.

EEE. “Product Manufacturing Technology” means:

1. all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the specified Divestiture Product, including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings,

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standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

2. all active pharmaceutical ingredients related to the specified Divestiture Product; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture the specified Divestiture Product.

FFF. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

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- GGG. “Product Research and Development Employees” means all salaried employees of a Respondent who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the eighteen (18) month period immediately prior to the Closing Date.
- HHH. “Product Trade Dress” means the current trade dress of the specified Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- III. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the specified Divestiture Product(s).
- JJJ. “Proposed Acquirer” means a Person proposed by a Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by a Respondent pursuant to this Order.
- KKK. “Remedial Agreement(s)” means the following:
1. any agreement between a Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including

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without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between a Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by a Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between a Respondent and a Third Party to effect the assignment of assets or rights of a Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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- LLL. “Retained Product” means any Product(s) other than a Divestiture Product.
- MMM. “Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.
- NNN. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.
- OOO. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,
1. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;

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2. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
  3. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and
  4. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
    - a. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
    - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
    - c. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.
- PPP. “Third Party(ies)” means any non-governmental Person other than the following: a Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

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QQQ. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by a Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by a Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that a Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

**II.**

**IT IS FURTHER ORDERED** that:

A. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Fentanyl Product Assets and grant the Generic Fentanyl Product License, absolutely and in good faith, to Par pursuant to, and in accordance with, the Generic Fentanyl Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Par or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Fentanyl Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however*, that if Respondents have divested the Generic Fentanyl Product Assets and granted the Generic Fentanyl Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Par is not an acceptable purchaser of the Generic Fentanyl Product Assets, then Respondents shall immediately rescind the transaction with Par, in whole or in part, as

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directed by the Commission, and shall divest the Generic Fentanyl Product Assets and grant the Generic Fentanyl Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Generic Fentanyl Product Assets and granted the Generic Fentanyl Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Fentanyl Product Assets or grant of the Generic Fentanyl Product License, as applicable, to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall divest the Generic Cyclobenzaprine Product Assets and grant the Generic Cyclobenzaprine Product License, absolutely and in good faith, to Par pursuant to, and in accordance with, the Generic Cyclobenzaprine Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Par or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Generic Cyclobenzaprine Product Assets is incorporated by reference into this Order and made a part hereof;

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*provided, however,* that if Respondents have divested the Generic Cyclobenzaprine Product Assets and granted the Generic Cyclobenzaprine Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Par is not an acceptable purchaser of the Generic Cyclobenzaprine Product Assets, then Respondents shall immediately rescind the transaction with Par, in whole or in part, as directed by the Commission, and shall divest the Generic Cyclobenzaprine Product Assets and grant the Generic Cyclobenzaprine Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have divested the Generic Cyclobenzaprine Product Assets and granted the Generic Cyclobenzaprine Product License to Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Generic Cyclobenzaprine Product Assets or grant of the Generic Cyclobenzaprine Product License, as applicable, to Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the research, Development, manufacture,

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sale, marketing or distribution of the Divestiture Product(s) being acquired by that Acquirer;

*provided, however,* Respondents may satisfy this requirement by certifying that the relevant Acquirer for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

- D. Respondents shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
  2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by a Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondents shall obtain any consents from Third Parties required to comply with this provision.

- E. Respondents shall:
1. upon reasonable written notice and request from an Acquirer to Respondent, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Respondent's Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of

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Respondents and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Respondent Teva's Application(s) for the Divestiture Product(s) acquired by that Acquirer from Persons other than the Respondents;

2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied by a Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by a Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondents under this Order;

*provided, however*, that Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondents' responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by a Respondent to the Acquirer;

*provided further* that in each instance where: (1) an agreement to divest relevant assets or to Contract

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Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement by a Respondent to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
4. make representations and warranties to each Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that their failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;

*provided, however,* that in each instance where: (1) an agreement to divest relevant assets or to Contract Manufacture is specifically referenced and attached to this Order and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on a Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture between a Respondent and an Acquirer, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;

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6. during the term of any agreement to Contract Manufacture between a Respondent and an Acquirer, maintain manufacturing facilities necessary to manufacture each of the relevant Contract Manufacture Products in finished form, *i.e.*, suitable for sale to the ultimate consumer/patient; and
7. during the term of any agreement to Contract Manufacture between a Respondent and an Acquirer, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by, or on behalf of, a Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondents and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, I.I.E.1. - 7., shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date each Acquirer (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Divestiture Product in the United States and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents; (2) the date the Acquirer of a particular Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has

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determined that the Acquirer of a particular Divestiture Product has abandoned its efforts to manufacture such Divestiture Product, or (4) the date four (4) years from the Closing Date.

## F. Respondents shall:

1. submit to each Acquirer, at Respondents' expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
2. deliver such Confidential Business Information to that Acquirer:
  - a. in good faith;
  - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all such Confidential Business Information to that Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Divestiture Products other than as necessary to comply with the following:

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- a. the requirements of this Order;
  - b. Respondent's obligations to the Acquirer of the Divestiture Product under the terms of any related Remedial Agreement; or
  - c. applicable Law;
5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Divestiture Product or other Persons specifically authorized by that Acquirer to receive such information; and
  6. not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the marketing or sales of the Divestiture Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products.
- G. Respondents shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.
- H. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to that Acquirer.

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- I. Respondents shall:
1. for each Divestiture Product, for a period of six (6) months from the Closing Date or until the hiring of twenty (20) Divestiture Product Core Employees by an Acquirer or its Manufacturing Designee, whichever occurs earlier, provide that Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees related to the Divestiture Products and assets acquired by that Acquirer. Each of these periods is hereinafter referred to as the “Divestiture Product Core Employee Access Period(s)”; and
  2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after written request by an Acquirer, provide that Acquirer or Proposed Acquirer(s) with the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Divestiture Product Core Employee within the time provided herein shall extend the Divestiture Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay;
  3. during the Divestiture Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of the Divestiture Product Core Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with that Acquirer or its Manufacturing Designee, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by

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that Acquirer or its Manufacturing Designee. In addition, Respondents shall not make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from that Acquirer or its Manufacturing Designee;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.I.3. shall not prohibit Respondents from continuing to employ any Divestiture Product Core Employee under the terms of that employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer or its Manufacturing Designee to that employee;

4. until the Closing Date, provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions and to research, Develop, and manufacture the Divestiture Product consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product and to ensure successful execution of the pre-Acquisition plans for that Divestiture Product. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

*provided, however,* that this Paragraph II.H. does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the Closing Date, not:

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- a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or
- b. hire any Divestiture Product Employee;

*provided, however,* Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondent, as long as that employee was not solicited in violation of the nonsolicitation requirements contained herein;

*provided further, however,* that Respondents may do the following: (1) advertise for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees; or (2) hire a Divestiture Product Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondent.

- J. Respondents shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each Divestiture Product Core Employee retained by Respondent, the direct supervisor(s) of any such employee, and any other employee retained by Respondents and designated by the Interim Monitor (if applicable) sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of

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Respondents (other than as necessary to comply with the requirements of this Order).

- K. Not later than thirty (30) days after the Closing Date, Respondents shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Divestiture Products;
  2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; and/or
  3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondents shall provide a copy of the notification to the relevant Acquirer. Respondents shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondents shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- L. Until Respondents complete the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology

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related to a particular Divestiture Product to the relevant Acquirer,

1. Respondents shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with that Divestiture Product;
    - b. minimize any risk of loss of competitive potential for that business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
    - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Divestiture Product;
    - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
  2. Respondents shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with that Divestiture Product.
- M. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer under the following:

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1. any Patent owned or licensed by Respondents as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;
2. any Patent owned or licensed by Respondents at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer;

if such suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product. Respondents shall also covenant to that Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the

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United States of America of a particular Divestiture Product;

*provided however*, that, for the purposes of this Paragraph II.M. only, and only with respect to any suit filed by Respondent Cephalon prior to May 13, 2011 involving the Generic Cyclobenzaprine Products, the term “Patent” shall *exclude* the Amrix Patents.

- N. Upon reasonable written notice and request from an Acquirer to Respondents, Respondents shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondents to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Products acquired by that Acquirer, if such litigation would have the potential to interfere with the Acquirer’s freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product within the Geographic Territory; *provided however*, these obligations do not apply to any matter involving the Amrix Patents.
- O. For any patent infringement suit in which a Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as a Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the relevant Acquirer’s freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product(s), Respondents shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance,

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documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving that Divestiture Product;

2. waive conflicts of interest, if any, to allow the Respondents' outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving that Divestiture Product; and
3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to that Divestiture Product;

*provided however*, these obligations do not apply to any matter involving the Amrix Patents.

P. Respondents shall not, in the Geographic Territory:

1. use the Product Trademarks contained in the Product Intellectual Property or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
2. attempt to register such Product Trademarks;
3. attempt to register any mark confusingly similar to such Product Trademarks;
4. challenge or interfere with the relevant Acquirer's use and registration of such Product Trademarks; or
5. challenge or interfere with the relevant Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

*provided however*, that this paragraph shall not preclude Respondents from continuing to use all trademarks, tradenames, or service marks that have

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been in use in commerce on a Retained Product at any time prior to the Acquisition Date.

- Q. The purpose of the divestiture of the Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of such assets in the research, Development, and manufacture of each Divestiture Product and for the purposes of the business associated with each Divestiture Product within the Geographic Territory;
  2. to provide for the future use of such assets for the distribution, sale and marketing of each Divestiture Product in the Geographic Territory;
  3. to create a viable and effective competitor, that is independent of the Respondents:
    - a. in the research, Development, and manufacture of each Divestiture Product for the purposes of the business associated with each Divestiture Product within the Geographic Territory; and
    - b. the distribution, sale and marketing of the each Divestiture Product in the Geographic Territory; and,
  4. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

**III.**

**IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (1) ten (10) days after the Acquisition Date or (2) ten (10) days after the Order Date, Respondents shall supply Generic Modafinil

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Products to Par, in a timely manner, pursuant to, and in accordance with, the Generic Modafinil Supply Agreement (which agreement shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Par or to reduce any obligations of Respondents under such agreement) for a period of at least one (1) year, and at Par's option, up to two (2) years.

*provided, however,* that if Respondents have executed the Generic Modafinil Product Supply Agreement with Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Par is not acceptable for the purposes of the agreement to supply Generic Modafinil Products, then Respondents shall immediately rescind the Generic Modafinil Supply Agreement and shall execute an agreement to supply Generic Modafinil Products within ninety (90) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondents have entered in to the Generic Modafinil Product Supply Agreement with Par prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the agreement to supply Generic Modafinil Products was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of the supply of Generic Modafinil Products, as applicable, with Par (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

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- B. Respondents shall, in connection with any Remedial Agreement by Respondents to supply Generic Modafinil Products to an Acquirer,
1. manufacture and deliver, absolutely and in good faith, to that Acquirer sufficient commercial quantities of Generic Modafinil Products in final finished and packaged form suitable for sale to the ultimate consumer/patient by the Acquirer (including all Acquirer approved packaging) in sufficient time to allow the Acquirer to market, distribute and sell the Generic Modafinil Products in commercial quantities not later than April 6, 2012;
  2. continue to manufacture and deliver such Generic Modafinil Products to the Acquirer in such quantities and in a timely manner to allow such Acquirer to continue to market, distribute and sell Generic Modafinil Products at least until April 6, 2013, and, at the Acquirer's option, a one (1) year extension of this obligation;
  3. make representations and warranties to that Acquirer that the Generic Modafinil Products supplied by the Respondents meet the relevant Agency-approved specifications;
  4. indemnify, defend and hold that Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Generic Modafinil Products supplied to that Acquirer by a Respondent to meet cGMP. This obligation may be made contingent upon that Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

*provided, however,* that Respondents may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondents'

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responsibilities to supply the Generic Modafinil Products in the manner required by this Order; *provided further* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by a Respondent to the Acquirer;

*provided further* that in each instance where: (1) an agreement to supply Generic Modafinil Products is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for the Generic Modafinil Products, each such agreement may contain limits on Respondent's aggregate liability resulting from the failure of the Generic Modafinil Products supplied to the Acquirer by Respondent to meet cGMP;

5. give priority to supplying Generic Modafinil Products to the Acquirer over manufacturing and supplying of Products for Respondents' own use or sale;
  6. hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Generic Modafinil Products in a timely manner as required by the Remedial Agreement(s) unless Respondents can demonstrate that its failure was entirely beyond the control of Respondents and in no part the result of negligence or willful misconduct by Respondents;
- C. Respondent shall maintain manufacturing facilities necessary to manufacture each of the Generic Modafinil Products for the term of the agreement to supply Generic Modafinil Products to the Acquirer of the agreement to supply Generic Modafinil Products.
- D. From September 26, 2012, Respondents shall not, directly or indirectly (i) enforce or seek to enforce

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against the FDA or any other Person, or (ii) seek to have the FDA enforce, any rights that Respondents may have to market on an exclusive basis any Product that is the subject of an ANDA that references or is based on Provigil (*i.e.*, Application Number N020717) as the Reference Listed Drug. Not later than ten (10) days after the Order Date, and at such time(s) as may be provided for under any applicable FDA rules or procedures, Respondents shall:

1. relinquish any and all claims to such exclusive marketing rights that Respondents may have after September 25, 2012;
2. provide written notification to the FDA and the Commission that Respondents relinquish any and all such exclusive marketing rights that Respondents may have after September 25, 2012; and
3. ensure that such notification(s) are made in a timely manner and in a manner consistent with all applicable FDA rules and procedures and sufficient to accomplish the requirements of this Paragraph of the Order;

*provided however*, this Paragraph shall not be interpreted to require Respondents to waive or relinquish their rights in the Provigil<sup>®</sup> trademark and copyrights.

- E. The purpose of requiring the Respondents to supply the Generic Modafinil Products and the related obligations imposed on the Respondents by this Order is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

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**IV.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondent Teva signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondents expeditiously complies with all of their obligations and performs all of their responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Teva, which consent shall not be unreasonably withheld. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Teva of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents’ compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondents’ compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and

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carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.

2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Interim Monitor shall serve until the date of completion by the Respondents of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
  - a. with respect to each Divestiture Product, the date the Acquirer of such Divestiture Product (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture such Divestiture Product and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of the Respondents;
  - b. with respect to each Divestiture Product, the date the Acquirer of that Divestiture Product notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
  - c. with respect to each Divestiture Product, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

*provided, however,* that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

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*provided, further*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross

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negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondents shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under the Order;

*provided, however,* beginning ninety (90) days after Respondents have filed their final report pursuant to Paragraph IX.B., and every ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the relevant Acquirer toward obtaining FDA approval to manufacture each Divestiture Product and obtaining the ability to manufacture each Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondents.

8. A Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission

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materials and information received in connection with the performance of the Interim Monitor's duties.

- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

**V.****IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief

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available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent Teva which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Teva has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.

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2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this

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Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties,

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including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be

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necessary or appropriate to accomplish the divestiture required by this Order.

**VI.**

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondents shall assure that Respondents' counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondents' compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and businesses associated with those Divestiture Products;

*provided, however,* that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph VI pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided further, however,* that pursuant to this Paragraph VI, Respondents shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a

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protective order to protect the confidentiality of such information during any adjudication.

**VII.****IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by a Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Divestiture Products or Generic Modafinil Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondents' obligations to the Acquirer pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement a representation from the Acquirer that that Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- E. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products or Generic Modafinil Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.

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- F. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

**VIII.****IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondents have fully complied with the following: Paragraphs II.A , II.B., II.C., II.D., II.E.1.-3., II.F., II.H., II.I.1.- 4., II.K., II.L. and III.A., Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondents shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and/or the agreement to supply relevant Products and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.
- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and

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form in which it has complied and is complying with the Order.

**IX.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of a Respondent;
- B. any proposed acquisition, merger or consolidation of a Respondent; or
- C. any other change in a Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**X.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, that Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of that Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of that Respondent; and

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- B. to interview officers, directors, or employees of that Respondent, who may have counsel present, regarding such matters.

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate on July 2, 2022.

By the Commission, Commissioner Ohlhausen not participating.

**NON-PUBLIC APPENDIX II.A.****GENERIC FENTANYL PRODUCT DIVESTITURE  
AGREEMENTS**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX II.B.****GENERIC CYCLOBENZAPRINE PRODUCT  
DIVESTITURE AGREEMENTS**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

Analysis to Aid Public Comment

### **NON-PUBLIC APPENDIX III**

#### **GENERIC MODAFINIL PRODUCT SUPPLY AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

#### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Teva Pharmaceutical Industries Ltd. (“Teva”) and Cephalon, Inc. (“Cephalon”) that is designed to remedy the anticompetitive effects of Teva’s acquisition of Cephalon. Under the terms of the proposed Consent Agreement, Teva would be required to divest to Par Pharmaceutical, Inc. (“Par”) all of Teva’s rights and assets relating to its generic transmucosal fentanyl citrate lozenges (“fentanyl citrate”) and generic extended release cyclobenzaprine hydrochloride capsules (“cyclobenzaprine hydrochloride”). Teva will also enter into a supply agreement to allow Par to sell generic modafinil tablets (“modafinil”) for a period of at least one year; Par has the option to extend that supply agreement for up to one additional year if it chooses.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

## Analysis to Aid Public Comment

Pursuant to an Asset Purchase Agreement dated May 1, 2011, Teva proposes to acquire Cephalon in a transaction valued at approximately \$6.8 billion (“Proposed Acquisition”). The Commission’s Complaint alleges that the Proposed Acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil. The proposed Consent Agreement will remedy the alleged violations by replacing the competition that would otherwise be eliminated by the acquisition.

**The Products and Structure of the Markets**

The Proposed Acquisition would reduce the number of suppliers in each of the relevant markets. In human pharmaceutical product markets with generic competition, price generally decreases as the number of generic competitors increases. Accordingly, the reduction in the number of suppliers within each relevant market has a direct and substantial effect on pricing.

Transmucosal fentanyl citrate lozenges are a treatment for breakthrough cancer pain originally developed by Cephalon and marketed under the brand name Actiq. Three companies – Teva, Cephalon/Watson Pharmaceuticals, Inc., and Covidien – manufacture and market a generic version of the product for sale in the United States. Teva and Covidien both manufacture their own products while Watson’s product is manufactured and supplied by Cephalon. In 2010, Teva had 43 percent of generic sales, while the Cephalon/Watson product had 40 percent and Covidien had 17 percent. Therefore, the proposed acquisition combines the two most competitively significant suppliers of generic fentanyl citrate.

Extended release cyclobenzaprine hydrochloride is an extended release version of Flexeril, a muscle relaxant. Cephalon acquired the North American rights to the branded formulation of extended release cyclobenzaprine hydrochloride, called Amrix, which was approved by the Food and Drug Administration (“FDA”) in 2007. No companies currently market a generic

### Analysis to Aid Public Comment

version of Amrix, but Teva and Cephalon (through an authorized generic product<sup>1</sup>) are two of a limited number of suppliers capable of entering with a generic cyclobenzaprine hydrochloride product in a timely manner.

Modafinil tablets treat excessive sleepiness caused by narcolepsy or shift work disorder. Cephalon markets modafinil tablets under the brand name Provigil, sales of which totaled approximately \$1 billion in 2010. No companies currently market a generic version of Provigil. Teva, Ranbaxy Pharmaceuticals, Inc., Mylan Pharmaceutical Inc., and Barr Laboratories, Inc. (now owned by Teva) each filed applications seeking FDA approval to market generic Provigil before expiration of Cephalon's patent. They all filed on the first day that the FDA would accept such an application, making them all eligible for the 180-day marketing exclusivity period provided under the Hatch-Waxman Act.<sup>2</sup> Subsequently, each of the companies agreed with Cephalon to refrain from marketing generic Provigil until April 2012. Cephalon (through an authorized generic product) and Teva are two of a limited number of suppliers best-positioned to enter with a generic modafinil product during the upcoming Hatch-Waxman exclusivity period for sales of generic modafinil.

### Entry

Entry into the markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. The combination of drug development times and regulatory requirements, including FDA approval, takes at least two years.

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<sup>1</sup> Authorized generic products are manufactured by branded pharmaceutical companies and marketed and sold under a non-brand label at generic prices.

<sup>2</sup> Under the Hatch-Waxman Act, if a generic company plans to launch a generic version of a pharmaceutical product before the patents covering the branded product expire it must certify that its product does not infringe the branded company's patents or that the branded company's patents are invalid. The certification usually results in patent litigation. If the generic company successfully challenges the patents held by the branded company, the generic company may be eligible to receive a 180-day period of market exclusivity for its generic product.

## Analysis to Aid Public Comment

And even companies for whom the FDA approval process is well underway face other regulatory barriers, including Hatch-Waxman regulatory exclusivity and pending patent litigation, that limit their ability to enter these markets in a timely manner.

**Effects**

The Proposed Acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for fentanyl citrate, cyclobenzaprine hydrochloride, and modafinil. In pharmaceuticals markets with generic competition, price generally decreases as the second, third, fourth, and even fifth competitors enter. Although generic versions of cyclobenzaprine hydrochloride and modafinil are not yet available in the United States, the FDA approval process provides information about the timeliness and likelihood of entry by generic products. In addition, substantial experience and empirical evidence of the impact of multiple generic suppliers on prices for other drugs provide a strong basis to draw conclusions about the likely effects of the Proposed Acquisition in the markets for these products. Moreover, for a drug with high dollar sales such as Provigil, the impact from a reduction of competition during the 180-day exclusivity period alone is substantial. The Proposed Acquisition, by reducing an already limited number of competitors or potential competitors in each of these markets, would cause anticompetitive harm to U.S. consumers by increasing the likelihood of higher post-acquisition prices.

**The Consent Agreement**

The proposed Consent Agreement effectively remedies the Proposed Acquisition's anticompetitive effects in the relevant markets by requiring Teva to divest certain rights and assets related to generic fentanyl citrate and generic cyclobenzaprine hydrochloride to a Commission-approved acquirer no later than ten days after the acquisition. In addition, to remedy the consolidation of marketers of generic modafinil during the exclusivity period, the Consent Agreement requires Teva to enter into a supply agreement to provide a Commission-approved acquirer with generic modafinil tablets to sell in the United States for at least one year. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's

## Analysis to Aid Public Comment

goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

The proposed Consent Agreement remedies the competitive concerns the acquisition raises by requiring Teva to divest its generic fentanyl citrate and generic cyclobenzaprine hydrochloride to Par, which will purchase all rights currently held by Teva. In addition, Teva will supply Par with at least a one-year supply of modafinil tablets. Par has the option to extend the modafinil supply agreement for an additional year. Par is a New Jersey-based generic pharmaceutical company with 115 active products and an active product development pipeline. With its experience in generic markets, Par is expected to replicate the competition that would otherwise be lost with the Proposed Acquisition.

If the Commission determines that Par is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, the parties must unwind the sale to Par and divest the products, within six months of the date the Order becomes final, to a Commission-approved acquirer. In that circumstance, the Commission may appoint a trustee to divest the products if Teva fails to divest the products as required.

The proposed Consent Agreement contains several provisions to help ensure that the divestitures are successful. The Order requires Teva to take all action to maintain the economic viability, marketability, and competitiveness of the products until such time as they are transferred to a Commission-approved acquirer. Teva must transfer the manufacturing technology for the fentanyl citrate and cyclobenzaprine hydrochloride products to Par and must supply Par with fentanyl citrate and cyclobenzaprine hydrochloride products during the transition period.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

**LABORATORY CORPORATION OF AMERICA  
HOLDINGS  
AND  
ORCHID CELLMARK INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4341; File No. 111 0155  
Complaint, December 6, 2011 – Decision, January 30, 2012*

This consent order addresses the \$85.4 million acquisition by Laboratory Corporation of America Holdings of certain assets of Orchid Cellmark Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act in U.S. markets for the provision of paternity testing services to state and local government agencies. The consent order requires LabCorp to divest Orchid's U.S. government paternity testing services business to DNA Diagnostics Center.

*Participants*

For the *Commission: Michael R. Barnett, David L. Inglefield, and Naomi Licker.*

For the *Respondents: Joseph G. Krauss and Leigh L. Oliver, Hogan Lovells US LLP; Farrah Short and Bruce D. Sokler, Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Laboratory Corporation of America Holdings ("LabCorp"), a corporation subject to the jurisdiction of the Commission, and Respondent Orchid Cellmark Inc. ("Orchid"), a corporation subject to the jurisdiction of the Commission, have agreed to merge in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to

### Complaint

the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

#### **I. RESPONDENTS**

1. Respondent LabCorp is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its corporate head office and principal place of business located at 358 South Main Street, Burlington, North Carolina 27215.

2. Respondent Orchid is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 4390 US Route One, Princeton, New Jersey 08540.

3. Respondents LabCorp and Orchid are engaged in, among other things, the provision of paternity testing services used to establish that two or more people are genetically related to federal, state, local, or governmental entities (including Native American tribal authorities) in the United States, its territories and possessions, including courts, legislatures, governmental agencies or governmental commissions or any judicial or regulatory authority of any government in the United States, its territories and possessions (collectively “government agencies”).

4. Respondents are, and at all times herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

#### **II. THE PROPOSED ACQUISITION**

5. Pursuant to an Agreement and Plan of Merger among LabCorp and Orchid dated as of April 5, 2011 (the “Merger Agreement”), LabCorp proposes to acquire all of the outstanding shares of Orchid’s common stock at a price per share of \$2.80 (the “Acquisition”).

## Complaint

**III. THE RELEVANT MARKET AND AREA**

6. For the purposes of this Complaint, the relevant market in which to analyze the effects of the Acquisition is the provision of paternity testing services to government agencies.

7. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition.

**IV. THE STRUCTURE OF THE MARKET**

8. The market for government paternity testing services is highly concentrated, with LabCorp and Orchid conducting an overwhelming majority of all paternity tests performed for government agencies in the United States. LabCorp and Orchid are each other's closest competitors and routinely are the top two choices and lowest-priced bidders for providing paternity testing services to government agencies.

**V. ENTRY CONDITIONS**

9. New entry into the relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition set forth in Paragraph 11 below. New entry into the relevant market is difficult because of, among other things, the time, cost, and risk associated with developing necessary economies of scale and experience needed to effectively compete to provide paternity testing services for government agencies. As a result, de novo entry or entry by laboratory services companies in adjacent markets sufficient to achieve a significant market impact within two years is unlikely.

10. Expansion by smaller competitors into the relevant market would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition set forth in Paragraph 11 below. Existing fringe competitors are decreasing their efforts in the government paternity testing services market and are unlikely to expand even in the event of a post-acquisition anticompetitive price increase.

## Complaint

**VI. EFFECTS OF THE ACQUISITION**

11. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between LabCorp and Orchid in the market for the provision of paternity testing services to government agencies in the United States;
- b. by increasing the likelihood that the merged entity will exercise market power unilaterally in the market for the provision of paternity testing services to government agencies in the United States;
- c. by increasing the likelihood that government agencies would be forced to pay higher prices for paternity testing services; and
- d. by creating a virtual monopoly in the market for the provision of paternity testing services to government agencies in the United States.

**VII. VIOLATIONS CHARGED**

12. The Acquisition described in Paragraph 5 above, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this sixth day of December, 2011, issues its Complaint against said Respondents.

By the Commission.

## Order to Maintain Assets

**ORDER TO MAINTAIN ASSETS**  
**[Public Record Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the acquisition of Respondent Orchid Cellmark Inc. (“Orchid”) by Respondent Laboratory Corporation of America Holdings (“LabCorp”), hereinafter referred to as Respondents, and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement containing the Decision and Order on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order to Maintain Assets:

1. Respondent Laboratory Corporation of America Holdings is a corporation organized, existing, and doing business under and by virtue of the laws of the

Order to Maintain Assets

State of Delaware, with its offices and principal place of business located at 358 South Main Street, Burlington, North Carolina.

2. Respondent Orchid Cellmark Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 4390 US Route One, Princeton, New Jersey.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and this proceeding is in the public interest.

**ORDER**

**I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, all definitions used in the Consent Agreement and the Decision and Order, shall apply.

**II.**

**IT IS FURTHER ORDERED** that Respondents shall, from the time Respondents execute the Agreement Containing Consent Orders until the Divestiture Assets are divested, the Assigned Agreements are assigned, and the Commission-approved Acquirer has assumed all responsibilities under the Assigned Agreements:

- A. Take all actions necessary to maintain, and ensure the continued maintenance of, the viability, marketability and competitiveness of the Government Paternity Testing Services Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets or the Government Paternity Testing Services Business, except for ordinary wear and tear, and shall not sell, transfer, encumber or otherwise impair the Government Paternity Testing Services Business (except as required by the Decision and Order);

## Order to Maintain Assets

- B. Perform Paternity Testing Services as required by each Assigned Agreement from the time Respondents execute the Agreement Containing Consent Orders:
1. in the performance of these services:
    - a. Respondents shall perform the services in a professional manner consistent with the terms of each Assigned Agreement, and
    - b. Respondents shall use a degree of care and diligence that is no less than the same degree of care and diligence used by Respondents when engaged in similar activities with respect to the performance of Paternity Testing Services;
  2. Respondents shall provide the services required by the Assigned Agreements at the Orchid facility at 5698 Springboro Pike, Dayton, Ohio 45449, until the earlier of:
    - a. thirty (30) days after the date on which DDC has assumed responsibilities under Assigned Agreements that represent 80% of the total number of tests performed under the Assigned Agreements during the twelve month period ending on September 30, 2011, or
    - b. September 30, 2012;
- C. Maintain relations and good will with all third party contractors, agents, and others having business with Orchid prior to the Acquisition and with Respondents after the Acquisition in connection with the Government Paternity Testing Services Business;
- D. No later than ten (10) days after Respondents execute the Agreement Containing Consent Orders appoint Kathy Leis, Director of Operations, to manage and operate the Government Paternity Testing Services Business in the regular and ordinary course of business and consistent with and in accordance with past

## Order to Maintain Assets

practices, and to monitor Respondents' compliance with their obligations under this Order to Maintain Assets, the Decision and Order, and the Divestiture Agreements:

1. such Manager shall report directly to the Commission staff on a regular basis (timing and method of reporting to be determined in consultation with Commission staff) with no interference from Respondents;
2. the Manager shall not be involved, in any way, in the operations of the other businesses of Respondents during the term of this Order to Maintain Assets;
3. the Manager shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, and other representatives and assistants as the Manager chooses and are reasonably necessary to carry out the Manager's duties and responsibilities;
4. Respondents shall assure that Commission staff shall have access to and be permitted to communicate with, contact, and be contacted by the Manager without prior notice to Respondents or the presence of Respondents' employees or counsel, except as expressly required by law;
5. No later than three (3) days after appointment of the Manager, Respondents shall enter into a management agreement with that Manager that, in consultation with the Commission staff, transfers all rights, powers, and authority necessary to permit the Manager to perform his or her duties and responsibilities pursuant to this Order to Maintain Assets, in a manner consistent with the purposes of the Order to Maintain Assets and the Decision and Order; and

## Order to Maintain Assets

6. Respondents shall provide the Manager with reasonable financial incentives to undertake this position. Such incentives shall include a continuation of all employee benefits, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by law), and additional incentives as may be necessary to assure the continuation and prevent any diminution of the Government Paternity Testing Services Business's viability, marketability and competitiveness until the Divestiture Assets are divested, the Assigned Agreements are assigned, and the Commission-approved Acquirer has assumed all responsibilities under the Assigned Agreements, and as may otherwise be necessary to achieve the purposes of the Order to Maintain Assets and the Decision and Order.
7. In the event that the Manager ceases to act as Manager, then Respondents shall select a substitute Manager, in consultation with and subject to the approval of Commission staff, and transfer to the substitute Manager all rights, powers and authorities necessary to permit the substitute Manager to perform his or her duties and responsibilities, pursuant to this Order to Maintain Assets.

**III.**

**IT IS FURTHER ORDERED** that Respondents shall:

- A. Not later than fifteen (15) days after signing the Divestiture Agreement, provide an opportunity for the proposed Commission-approved Acquirer:
  1. to meet personally, and outside the presence or hearing of any employee or agent of any Respondents, with any one or more of the Orchid Relevant Employees; and

## Order to Maintain Assets

2. to make offers of employment to any one or more of the Orchid Relevant Employees;
- B. Not interfere, directly or indirectly, with the proposed Commission-approved Acquirer's hiring or employing of the Orchid Relevant Employees;
  - C. Remove any impediments or incentives within the control of Respondents that may deter Orchid Relevant Employees from accepting employment with the proposed Commission-approved Acquirer or that may affect the ability of any Orchid Relevant Employee to work for the proposed Commission-approved Acquirer, including but not limited to removing any non-competes relating to Paternity Testing Services; and Respondents shall not make any counteroffer to an Orchid Relevant Employee who receives a written offer of employment from the proposed Commission-approved Acquirer; *provided, however*, that nothing in this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;
  - D. Provide all Orchid Relevant Employees with reasonable financial incentives to continue in their positions until those Orchid Relevant Employees that accept offers of employment from the Commission-approved Acquirer become employees of the Commission-approved Acquirer. Such incentives shall include but are not limited to a continuation of all employee benefits (including offering Orchid Relevant Employees the same employee benefits available to LabCorp employees prior to the Acquisition), including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by law and for those Orchid Relevant Employees covered by a pension plan), offered by Respondents; and
  - E. Not, for a period of one (1) year following the date that each Orchid Relevant Employee becomes an employee of the Commission-approved Acquirer, directly or

## Order to Maintain Assets

indirectly, solicit or otherwise attempt to induce any of those to terminate his or her employment with the Commission-approved Acquirer; *provided, however*, that Respondents may:

1. advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at Orchid Relevant Employees; or
2. hire Orchid Relevant Employees who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this Paragraph III.E.; *provided further, however*, that this Paragraph III.E. shall not prohibit Respondents from making offers of employment to or employing any Orchid Relevant Employee if the Commission-approved Acquirer has notified Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer.

F. Notwithstanding the above, Respondents shall:

1. provide the proposed Commission-approved Acquirer an opportunity to meet personally, and outside the presence or hearing of any employee or agent of any Respondents, with any person who was an employee of Orchid prior to the Acquisition, whose responsibilities related solely to the provision of Paternity Testing Services to private parties, and who has declined an offer of employment with Respondents;
2. provide the proposed Commission-approved Acquirer an opportunity to make offers of employment to such employees;

## Order to Maintain Assets

3. not interfere, directly or indirectly, with the proposed Commission-approved Acquirer's hiring or employing of such employees; and
4. remove any impediments or incentives within the control of Respondents that may deter such employees from accepting employment with the proposed Commission-approved Acquirer or may affect the ability of such employee to work for the proposed Commission-approved Acquirer, including but not limited to removing any non-competes relating to Paternity Testing Services.

**IV.****IT IS FURTHER ORDERED** that:

- A. Except as required by Paragraph II.B. of the Decision and Order, and Paragraph IV.B., below, Respondents shall not request, receive, solicit, or access, directly or indirectly, any Confidential Business Information of the Government Paternity Testing Services Business, or Books and Records (or any information contained therein), and shall not use, disclose, provide, discuss, exchange, circulate, convey, or otherwise furnish such information, directly or indirectly, to or with any Person other than as necessary to comply with and consistent with the requirements of the Decision and Order, the Order to Maintain Assets, or the Divestiture Agreement.
- B. To the extent any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) are made available to Respondents for the limited purposes identified in Paragraph IV.A. (and except as required by Paragraph II.B. of the Decision and Order):
  1. such information and Books and Records (or the information contained therein) shall be made available only to Respondents' employees who

## Order to Maintain Assets

have direct responsibilities for the Government Paternity Testing Services Business; and

2. no employee of Respondents who is an employee of Respondents after the Acquisition shall use any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) to formulate a bid in connection with the provision of Paternity Testing Services to a Governmental Entity by Respondents, to bid on the provision of such services by Respondents, or to provide such services by Respondents except as is required by the Decision and Order, the Order to Maintain Assets, or the Divestiture Agreement.

C. Respondents shall:

1. require, as a condition of continued employment post-divestiture, that each of Respondents' employees who had or have access to or possession, custody or control of any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) sign a confidentiality agreement no later than twenty (20) days after the Acquisition that complies with the restrictions, prohibitions and requirements of the Decision and Order and the Order to Maintain Assets and that prohibits Respondents' employees from using or disclosing such information in connection with Respondents' businesses; and
2. no later than ten (10) days after the Acquisition implement procedures and take such actions as are necessary to ensure that Respondents' employees comply with the restrictions, prohibitions and requirements of this Paragraph IV. , including all actions that Respondents would take to protect their own confidential information.

## Order to Maintain Assets

- D. Respondents shall provide access to the Commission-approved Acquirer, solely at the option of the Commission-approved Acquirer and in the manner determined by the Commission-approved Acquirer, to employees of Orchid as it existed prior to the Acquisition who have or had access to Confidential Business Information of the Government Paternity Testing Services Business or to Books and Records (or the information contained therein), who become employees of Respondents after the Acquisition, to obtain Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein).

**V.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and performs all of their responsibilities as required by this Order to Maintain Assets and the Divestiture Agreement.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers

## Order to Maintain Assets

necessary to permit the Monitor to monitor Respondents' compliance with the relevant requirements of this Order to Maintain Assets in a manner consistent with the purpose of this Order to Maintain Assets.

- D. If a Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondents' compliance with the Order to Maintain Assets and the Divestiture Agreement, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order to Maintain Assets and in consultation with the Commission.
  2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission and shall not be considered an employee or agent of Respondents.
  3. The Monitor shall serve until the Commission-approved Acquirer has assumed all responsibilities under the Assigned Agreements in a manner that fully satisfies the requirements of this Order to Maintain Assets and the Divestiture Agreement and notification by the Commission-approved Acquirer to the Monitor that it is fully capable of providing service under those agreements; *provided, however*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purpose of this Order to Maintain Assets.
  4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities, and technical information, and

## Order to Maintain Assets

such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with its obligations under this Order to Maintain Assets and the Divestiture Agreement, including but not limited to its obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order to Maintain Assets or the Divestiture Agreement.

5. The Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.
6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
7. Respondents shall report to the Monitor in accordance with the requirements of this Order to Maintain Assets and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer

## Order to Maintain Assets

with respect to the performance of Respondents' obligations under this Order to Maintain Assets or the Divestiture Agreement. Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under this Order to Maintain Assets and the Divestiture Agreement.

- E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph V.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order to Maintain Assets.
- I. The Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee under the Decision and Order or as a Monitor pursuant to the relevant provisions of the Decision and Order.

## Order to Maintain Assets

**VI.**

**IT IS FURTHER ORDERED** that within thirty (30) days after the Acquisition, and every thirty (30) days thereafter until Respondents have complied with the obligations of this Order to Maintain Assets, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order to Maintain Assets. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to Maintain Assets to the Monitor, if any Monitor has been appointed. Respondents shall include in their reports, among other things that the Commission may require from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of this Order to Maintain Assets;

**VII.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger or consolidation of Respondents, or (3) any other change in the Respondents that may affect compliance obligations arising out of this Order to Maintain Assets, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

**VIII.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondents, Respondents shall, without restraint or interference, permit any duly authorized representative(s) of the Commission:

- A. Access, during business office hours of the Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or

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under the control of the Respondents related to compliance with this Order to Maintain Assets, which copying services shall be provided by the Respondents at their expense; and

- B. To interview officers, directors, or employees of the Respondents, who may have counsel present, regarding such matters.

By the Commission.

**Non-Public Appendix A****Divestiture Agreement**

**[Incorporated By Reference, But Redacted From the Public Record Version]**

**DECISION AND ORDER****[Public Record Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the acquisition of Respondent Orchid Cellmark Inc. (“Orchid”) by Respondent Laboratory Corporation of America Holdings (“LabCorp”), hereinafter referred to as Respondents, and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments from an interested person pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, now in further conformity with the procedure described in Commission Rule 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Laboratory Corporation of America Holdings is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 358 South Main Street, Burlington, North Carolina.
2. Respondent Orchid Cellmark Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its offices and principal place of business located at 4390 US Route One, Princeton, New Jersey.
3. The Federal Trade Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and this proceeding is in the public interest.

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**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “LabCorp” means Laboratory Corporation of America Holdings, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by LabCorp, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, LabCorp includes Orchid.
- B. “Orchid” means Orchid Cellmark Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Orchid, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Acquisition” means the acquisition of Orchid by LabCorp.
- D. “Actual Costs” means the cost of labor, material, shipping, travel and other expenditures directly incurred to provide the relevant service. As used herein, the cost of labor for the use of the labor of an employee of Respondents shall not exceed the average hourly wage rate for such employee.
- E. “Alternative Divestiture Assets” means all assets relating to and used in the provision of Paternity Testing Services by Orchid in the United States, its territories and possessions, as those assets existed prior to the Acquisition, and includes but is not limited to the facility located at 5698 Springboro Pike, Dayton, Ohio 45449, all related real and personal property, the Assigned Agreements, and Books and Records.

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- F. “Assigned Agreements” means all contracts and agreements between Orchid and Customers, in effect as of November 10, 2011, for the provision of Paternity Testing Services, including those that are listed in Section 2.01(b) of the Disclosure Schedule attached to the Asset Purchase Agreement, between Respondent LabCorp and DDC, dated as of November 10, 2011, and attached hereto in Non-Public Appendix A.
- G. “Books and Records” means all information relating to the Government Paternity Testing Services Business, including but not limited to all originals and all copies of any books, records, documents, data, and files of any kind (regardless whether the information is stored or maintained in traditional paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media and regardless of where the information is stored or maintained) containing or pertaining to such information, including but not limited to operating information, technical information, financial information, accounting information, historic and current pricing and bid information, vendor information, collectors’ information, promotional and marketing information including website content and sales and marketing materials, employment information relating to any Orchid Relevant Employees, and statistical and other data bases. For the avoidance of doubt, Books and Records includes but is not limited to Case Specific Information and Customer Information; for the further avoidance of doubt, Books and Records includes all historical information and is not limited to information relating to the Assigned Agreements.
- H. “Case Specific Information” means all information relating to specific cases generated by Orchid under agreements and contracts with Governmental Entities for the provision of Paternity Testing Services, including but not limited to Samples and Results,

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chain of custody records, client authorization forms, court orders, affidavits, and other case specific correspondence; for the avoidance of doubt, Case Specific Information includes all case information relating to the Assigned Agreements and to all other past agreements and contracts between Orchid and Governmental Entities prior to the Acquisition for the provision of Paternity Testing Services as well as all case information generated by LabCorp as it maintains the Government Paternity Testing Services Business pursuant to the Order to Maintain Assets and the Transition Services Agreement.

- I. “Certifications” means all accreditations related to the collection, processing or analyzing of paternity tests currently held by Orchid that are necessary for the fulfilling of government paternity testing contracts including, but not limited to AABB (American Association of Blood Banks).
- J. “Commission” means the Federal Trade Commission.
- K. “Commission-approved Acquirer” means the following:
  - 1. DDC, if DDC has been approved by the Commission to acquire the Divestiture Assets pursuant to Paragraph II. of this Order in connection with the Commission’s determination to make this Order final; or
  - 2. a Person that receives the prior approval of the Commission to acquire the Alternative Divestiture Assets pursuant to Paragraph II. or Paragraph VI. of this Order.
- L. “Confidential Business Information” means any non-public, competitively sensitive, or proprietary information that is not independently known to a Person from sources other than the Person to which the information pertains, and includes, but is not limited to, pricing information, historic and current bid

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information, marketing methods, market intelligence, competitor information, management system information, business processes and practices, customer communications, bidding practices and information, procurement practices and information, supplier qualification and approval practices and information, and training practices.

- M. “Consent Agreement” means the Agreement Containing Consent Orders executed by Respondents on November 10, 2011.
- N. “Customer” means any Governmental Entity that is or was a purchaser of any Paternity Testing Services in the United States (including all U.S. territories and possessions) from Orchid, or any Governmental Entity to whom Orchid considered providing or sought to provide Paternity Testing Services in the United States regardless of whether that Governmental Entity purchased such services from Orchid or Orchid actually provided such services.
- O. “Customer Information” means all information relating to Customers, including all originals and all copies of any books, records, documents, data, and files of any kind (regardless of whether the information is stored or maintained in traditional paper format, by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media and regardless of where the information is stored or maintained) containing or pertaining to such information, including but not limited to, customer lists, rolodex, employee files, Requests for Proposals, Invitations to Bid, proposals, and draft and executed contracts; for the avoidance of doubt, Customer Information includes electronic files maintained on the computers of Orchid Relevant Employees even if the computers are to be retained by Respondents, and includes all historical information.

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- P. “DDC” means DNA Diagnostics Center, located at DNA Technology Park, One DDC Way (Formerly 205 Corporate Court) in Fairfield, Ohio.
- Q. “DDC Divestiture Agreement” means the Divestiture Agreement entered into between Respondent LabCorp and DDC.
- R. “Decision and Order” means:
1. the Proposed Decision and Order contained in the Consent Agreement in this matter until issuance and service of a final Decision and Order by the Commission; and
  2. the Final Decision and Order issued by the Commission following issuance and service of a final Decision and Order by the Commission.
- S. “Divestiture Agreement” means the following, which with respect to DDC is referenced in and attached to this Order as Non-Public Appendix A:
1. Asset Purchase and Sale Agreement;
  2. Transition Services Agreement; and
  3. all other agreements by the Commission-approved Acquirer and Respondents, including all amendments, exhibits, attachments, agreements and schedules thereto, related to the divestiture of the Divestiture Assets.
- T. “Divestiture Assets” means all right, title, interest of Respondents in and to the following:
1. Equipment;
  2. Books and Records; and
  3. at the option of the Commission-approved Acquirer and with the approval of the Commission, Certifications.

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- U. “Equipment” means all laboratory equipment and all other equipment and furniture located at Orchid’s facility relating to the provision of Paternity Testing Services to Governmental Entities as it existed prior to the Acquisition that the Commission-approved Acquirer chooses to acquire and that the Commission approves acquiring; for the avoidance of doubt, the Equipment to be divested to DDC shall not include computers, servers or other hardware, telephones, and phone systems.
- V. “Governmental Entity(ies)” means any federal, state, local, or governmental entity (including Native American tribal authorities) in the United States; any court, legislature, governmental agency or governmental commission; or any judicial or regulatory authority of any government in the United States, its territories and possessions.
- W. “Government Paternity Testing Services Business” means Orchid’s business of providing Paternity Testing Services to Governmental Entities, as that business existed prior to the Acquisition, and as that business is maintained by LabCorp after the Acquisition pursuant to the Order to Maintain Assets and the Transition Services Agreement. Government Paternity Testing Services Business includes any business that the Commission-approved Acquirer obtains during the term of the Transition Services Agreement. Government Paternity Testing Services Business also includes the formulation of bids and bidding for the business of providing Paternity Testing Services to Governmental Entities regardless of whether the bids are submitted or won.
- X. “Orchid Relevant Employees” means all employees of Orchid prior to the Acquisition who have responsibilities for Paternity Testing Services to Government Entities; for the avoidance of doubt, Orchid Relevant Employees may also have joint responsibilities for other businesses of Orchid,

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including Paternity Testing Services for private purposes.

- Y. “Order” means this Decision and Order.
- Z. “Paternity Testing Services” means DNA testing that is used to establish that two or more people are genetically related.
- AA. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business entity, and any subsidiaries, divisions, groups or affiliates thereof.
- BB. “Samples and Results” means DNA samples associated with the Government Paternity Testing Services Business and reports in hard copy and electronic form of results of tests conducted using those samples
- CC. “Respondents” means LabCorp and Orchid, individually and collectively.
- DD. “Third Party(ies)” means any Person other than the following: (1) the Respondents, or (2) the Commission-approved Acquirer.
- EE. “Transition Services” means any transitional services related to or necessary for the continuation of the provision of Paternity Testing Services to Governmental Entities by the Commission-approved Acquirer.
- FF. “Transition Services Agreement(s)” means any agreement or arrangement entered into by and between the Respondents and a Commission-approved Acquirer to provide Transition Services that receives the prior approval of the Commission and thereby becomes a Divestiture Agreement, or that is otherwise approved by the Commission in connection with the Commission’s determination to make this Order final.

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**II.****IT IS FURTHER ORDERED** that:

- A. Respondents shall:
1. divest the Divestiture Assets no later than ten (10) days after the Acquisition, absolutely and in good faith to DDC, pursuant to and in accordance with the DDC Divestiture Agreement; *provided, however,* that the timing of the delivery of specific Divestiture Assets to DDC shall be determined by DDC; and
  2. sell, assign, transfer, convey, and deliver all right, title and interest in the Assigned Agreements to the Commission-approved Acquirer, consistent with the terms of the Assigned Agreements, at a time determined in the sole discretion of the Commission-approved Acquirer (and, with respect to DDC, pursuant to and in accordance with the DDC Divestiture Agreement); and shall:
    - a. use good faith efforts to secure all necessary consents, orders, authorizations, and approvals in connection with the Assigned Agreements;
    - b. cooperate with the Commission-approved Acquirer's efforts to secure the required consents, orders, authorizations, and approvals;
    - c. not interfere with the efforts of the Commission-approved Acquirer to secure the required consents and approvals; and
    - d. indemnify, defend and hold harmless the Commission-approved Acquirer, its employees, officers, directors, shareholders, partners, members, attorneys, accountants, agents and representatives and their heirs, successors and permitted assigns against, and reimburse any such person for, any and all

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losses, damages, costs, expenses, liabilities, obligations, and claims of any kind that such person may at any time suffer or incur as a result of or in connection with Respondents' failure to comply with their obligations pursuant to the Assigned Agreements.

*provided further that:*

3. if Respondents have divested any of the Divestiture Assets or sold, assigned, transferred, conveyed, or delivered and rights, title, or interests in any Assigned Agreements to DDC prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that:
  - a. DDC is not an acceptable acquirer of the Divestiture Assets, then Respondents shall immediately rescind the transaction with DDC and shall:
    - i. divest the Divestiture Assets to a Commission-approved Acquirer no later than sixty (60) days from the date the Commission notifies Respondents that DDC is not an acceptable acquirer, and sell, assign, transfer, convey, and deliver all right, title and interest in the Assigned Agreements to the Commission-approved Acquirer and otherwise comply with the obligations of Paragraph II.A.2.; and
    - ii. if Respondents fail to divest to a Commission-approved Acquirer as required by Paragraph II.A.3.a.(1), then the Commission may appoint a Divestiture Trustee pursuant to Paragraph VI. to divest the Alternative Divestiture Assets, absolutely and in good faith, at no minimum price, and only in a manner that receives the prior approval of the

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Commission to a Commission-approved Acquirer; or

- b. the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee pursuant to Paragraph VI. of this Order, to effect such modifications to the manner of divesting the Divestiture Assets to DDC (including, but not limited to, entering into additional agreements or arrangements) as may be necessary to satisfy the requirements of this Order.
- B. Notwithstanding the divestiture obligations in Paragraph II.A above, after the transfer of all Books and Records, LabCorp may retain a copy of Case Specific Information but only under the following conditions:
1. all Case Specific Information retained by LabCorp shall be maintained in a secure location within the legal offices of LabCorp and accessible only through authorized members of the legal staff;
  2. Case Specific Information shall be used for the purpose only of defending lawsuits or responding to investigations, subpoenas or claims brought against LabCorp relating to the provision of Paternity Testing Services as verified by authorized members of the legal staff; for the avoidance of doubt, no Case Specific Information shall be used for bidding on the provision of Paternity Testing Services by LabCorp, for formulating such bids to provide Paternity Testing Services by LabCorp, for the provision of Paternity Testing Services by LabCorp, or for any other competitive purpose;
  3. if Respondents require access to Case Specific Information, Respondents shall provide notice to the Commission at the same time that Respondents

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request access from the legal staff. Such notice shall identify the specific information being requested and shall include an explanation of Respondents' need for the information. Such notice shall be made to the Commission's Secretary, pursuant to the Commission's Rules of Practice, and a copy of such notice shall be given simultaneously to the Commission's Bureau of Competition, Compliance Division; and

4. all Case Specific Information shall otherwise be maintained consistent with the document retention policies of LabCorp.
- C. Respondents shall provide Transition Services to the Commission-approved Acquirer, at the option of the Commission-approved Acquirer, and shall enter into an appropriate Transition Services Agreement to provide Transition Services to the Commission-approved Acquirer, subject to the approval of the Commission at no more than Respondent's Actual Cost; *provided, however*, that Respondents and the Commission-approved Acquirer shall not modify or amend such Transition Services Agreement without the prior approval of the Commission.
- D. For two (2) years after the Commission-approved Acquirer assumes the obligations under the Assigned Agreements, Respondents shall not join, file, or prosecute any suit, in law or equity, or initiate any other action (such as an action to protest the award of a bid), against a Governmental Entity with whom the Commission-approved Acquirer has entered into an agreement to provide Paternity Testing Services -- or against the Commission-approved Acquirer -- the subject of which is the legality or validity of such agreement entered into any time after the Respondents execute the Agreement Containing Consent Orders.
- E. The purpose of the divestiture of the Divestiture Assets and the additional requirements in this Order is to ensure the continuation of Orchid's Government

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Paternity Testing Services Business as a viable, ongoing, independent and competitive business, in the same line of commerce in which the business was engaged at the time of the Acquisition, and to ensure that the Commission-approved Acquirer is able to bid effectively in the future to provide Paternity Testing Services to Governmental Entities in order to remedy the lessening of competition alleged in the Commission's Complaint.

**III.**

**IT IS FURTHER ORDERED** that Respondents shall:

- A. Not later than fifteen (15) days after signing the Divestiture Agreement, provide an opportunity for the proposed Commission-approved Acquirer:
  - 1. to meet personally, and outside the presence or hearing of any employee or agent of any Respondents, with any one or more of the Orchid Relevant Employees; and
  - 2. to make offers of employment to any one or more of the Orchid Relevant Employees;
- B. Not interfere, directly or indirectly, with the proposed Commission-approved Acquirer's hiring or employing of the Orchid Relevant Employees;
- C. Remove any impediments or incentives within the control of Respondents that may deter Orchid Relevant Employees from accepting employment with the proposed Commission-approved Acquirer or that may affect the ability of any Orchid Relevant Employee to work for the proposed Commission-approved Acquirer, including but not limited to removing any non-competes relating to Paternity Testing Services; and Respondents shall not make any counteroffer to an Orchid Relevant Employee who receives a written offer of employment from the proposed Commission-approved Acquirer; *provided, however*, that nothing in

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this Order shall be construed to require Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of any employee;

- D. Provide all Orchid Relevant Employees with reasonable financial incentives to continue in their positions until those Orchid Relevant Employees that accept offers of employment from the Commission-approved Acquirer become employees of the Commission-approved Acquirer. Such incentives shall include but are not limited to a continuation of all employee benefits (including offering Orchid Relevant Employees the same employee benefits available to LabCorp employees prior to the Acquisition), including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by law and for those Orchid Relevant Employees covered by a pension plan), offered by Respondents; and
- E. Not, for a period of one (1) year following the date that each Orchid Relevant Employee becomes an employee of the Commission-approved Acquirer, directly or indirectly, solicit or otherwise attempt to induce any such Orchid Relevant Employee to terminate his or her employment with the Commission-approved Acquirer; *provided, however*, that Respondents may:
1. advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, in either case not targeted specifically at Orchid Relevant Employees; or
  2. hire Orchid Relevant Employees who apply for employment with Respondents, as long as such employees were not solicited by Respondents in violation of this Paragraph III.E.; *provided further, however*, that this Paragraph III.E. shall not prohibit Respondents from making offers of employment to or employing any Orchid Relevant Employee if the Commission-approved Acquirer

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has notified Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer.

- F. Notwithstanding the above, Respondents shall:
1. provide the proposed Commission-approved Acquirer an opportunity to meet personally, and outside the presence or hearing of any employee or agent of any Respondents, with any person who was an employee of Orchid prior to the Acquisition, whose responsibilities related solely to the provision of Paternity Testing Services to private parties, and who either was not offered employment with Respondents or has declined an offer of employment with Respondents;
  2. provide the proposed Commission-approved Acquirer an opportunity to make offers of employment to such employees;
  3. not interfere, directly or indirectly, with the proposed Commission-approved Acquirer's hiring or employing of such employees; and
  4. remove any impediments or incentives within the control of Respondents that may deter such employees from accepting employment with the proposed Commission-approved Acquirer or may affect the ability of such employee to work for the proposed Commission-approved Acquirer, including but not limited to removing any non-competes relating to Paternity Testing Services.

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**IV.****IT IS FURTHER ORDERED** that:

- A. Except as required by Paragraph II.B., above, and Paragraph IV.B., below, Respondents shall not request, receive, solicit, or access, directly or indirectly, any Confidential Business Information of the Government Paternity Testing Services Business, or Books and Records (or any information contained therein), and shall not use, disclose, provide, discuss, exchange, circulate, convey, or otherwise furnish such information, directly or indirectly, to or with any Person other than as necessary to comply with and consistent with the requirements of the Decision and Order, the Order to Maintain Assets, or the Divestiture Agreement.
- B. To the extent any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) are made available to Respondents for the limited purposes identified in Paragraph IV.A. (and except as required by Paragraph II.C, above):
1. such information and Books and Records (or the information contained therein) shall be made available only to Respondents' employees who have direct responsibilities for the Government Paternity Testing Services Business; and
  2. no employee of Respondents who is an employee of Respondents after the Acquisition shall use any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) to formulate a bid in connection with the provision of Paternity Testing Services to a Governmental Entity by Respondents, to bid on the provision of such services by Respondents, or to provide such services by Respondents except as

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is required by the Decision and Order, the Order to Maintain Assets, or the Divestiture Agreement.

- C. Respondents shall:
1. require, as a condition of continued employment post-divestiture, that each of Respondents' employees who had or have access to or possession, custody or control of any Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein) sign a confidentiality agreement no later than twenty (20) days after the Acquisition that complies with the restrictions, prohibitions and requirements of the Decision and Order and the Order to Maintain Assets and that prohibits Respondents' employees from using or disclosing such information in connection with Respondents' businesses; and
  2. no later than ten (10) days after the Acquisition implement procedures and take such actions as are necessary to ensure that Respondents' employees comply with the restrictions, prohibitions and requirements of this Paragraph IV., including all actions that Respondents would take to protect their own confidential information.
- D. Respondents shall provide access to the Commission-approved Acquirer, solely at the option of the Commission-approved Acquirer and in the manner determined by the Commission-approved Acquirer, to employees of Orchid as it existed prior to the Acquisition who have or had access to Confidential Business Information of the Government Paternity Testing Services Business or to Books and Records (or the information contained therein), who become employees of Respondents after the Acquisition, to obtain Confidential Business Information of the Government Paternity Testing Services Business or Books and Records (or the information contained therein).

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## V.

**IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor (“Monitor”) to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order and the Divestiture Agreement, including but not limited to using good faith efforts to secure all required consents and approvals.
- B. The Commission shall select the Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Monitor, Respondents shall be deemed to have consented to the selection of the proposed Monitor.
- C. Not later than ten (10) days after the appointment of the Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondents’ compliance with the relevant requirements of this Order and the Divestiture Agreement in a manner consistent with the purpose of this Order.
- D. If a Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - 1. The Monitor shall have the power and authority to monitor Respondents’ compliance with this Order and the Divestiture Agreement and shall exercise

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such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission and shall not be considered an employee or agent of Respondents.
3. The Monitor shall serve until the Commission-approved Acquirer has assumed all responsibilities under the Assigned Agreements in a manner that fully satisfies the requirements of this Order and the Divestiture Agreement and notification by the Commission-approved Acquirer to the Monitor that it is fully capable of providing service under those agreements; *provided, however*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purpose of this Order.
4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities, and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with their obligations under this Order and the Divestiture Agreement, including but not limited to their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with this Order or the Divestiture Agreement.
5. The Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of the

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Respondents, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities.

6. Respondents shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
  7. Respondents shall report to the Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondents, and any reports submitted by the Commission-approved Acquirer with respect to the performance of Respondents' obligations under this Order or the Divestiture Agreement. Within thirty (30) days from the date the Monitor receives these reports, the Monitor shall report in writing to the Commission concerning performance by Respondents of their obligations under this Order and the Divestiture Agreement.
- E. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Monitor from providing any information to the Commission.
- F. The Commission may, among other things, require the Monitor and each of the Monitor's consultants,

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accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph V.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.
- I. The Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order or as a Monitor pursuant to the Order to Maintain Assets.

**VI.****IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations imposed by Paragraph II. of this Order (or if the Commission determines that DDC is not an acceptable purchaser and Respondents have not complied with Paragraph II.A.3.a. of this Order), the Commission may appoint a trustee ("Divestiture Trustee") to divest the Alternative Divestiture Assets absolutely and in good faith, at no minimum price, and to comply with Respondents' other obligations in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to divest the required assets. Neither the appointment of a Divestiture Trustee nor a

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decision not to appoint a Divestiture Trustee under this Paragraph VI.A. shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to Section 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, and have stated in writing their reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effectuate the divestiture required by, and satisfy the additional obligations imposed by, this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VI, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to effectuate the divestiture required by, and satisfy the additional obligations imposed by, this Order.

## Decision and Order

2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan to satisfy the obligations of Paragraph II. or believes that such can be achieved within a reasonable time, the period may be extended by the Commission; *provided, however,* that the Commission may extend the period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays caused by Respondents shall extend the time under this Paragraph VI.D. in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than

## Decision and Order

one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such entity within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a Commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the

## Decision and Order

preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from malfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VI.
- F. The Commission may on its own initiative or at the request of the Divestiture Trustee, issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The Divestiture Trustee appointed pursuant to this Paragraph VI. may be the same person appointed as Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets.

## Decision and Order

**VII.****IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order or the Order to Maintain Assets, it being understood that nothing in this Order or the Order to Maintain Assets shall be construed to reduce any rights or benefits of any Commission-approved Acquirer or to reduce any obligations of Respondents under such agreement.
- B. The Divestiture Agreement, if approved by the Commission, shall be incorporated by reference into this Order and made a part hereof.
- C. Respondents shall comply with all terms of the Divestiture Agreement, and any breach by Respondents of any term of the Divestiture Agreement shall constitute a failure to comply with this Order. If any term of the Divestiture Agreement varies from the terms of this Order (“Order Term”), then to the extent that Respondents cannot fully comply with both terms, the Order Term shall determine Respondents’ obligations under this Order.

**VIII.****IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the Acquisition, and every thirty (30) days thereafter until Respondents have divested the Divestiture Assets and the Transition Services Agreement has terminated, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order and the Order to Maintain Assets. Respondents shall submit at the same time a copy of their report concerning compliance with this Order and the Order to Maintain Assets to the Monitor,

## Decision and Order

if any Monitor has been appointed under either this Order or the Order to Maintain Assets.

- B. Respondents shall include in their reports, among other things that are required from time to time:
1. a full description of the efforts being made to comply with this Order and the Order to Maintain Assets;
  2. if DDC is not approved by the Commission pursuant to Paragraph II.A., a description of all substantive contacts or negotiations related to the divestiture of the Divestiture Assets and the identity of all parties contacted and copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing their obligations pursuant to Paragraph II. of this Order.

**IX.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of the Respondents, (2) acquisition, merger or consolidation of Respondents, or (3) any other change in the Respondents that may affect compliance obligations arising out of this Order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

**X.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to Respondents, Respondents shall, without restraint or interference, permit any duly authorized representative(s) of the Commission:

- A. Access, during business office hours of the Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books,

## Analysis to Aid Public Comment

ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of the Respondents related to compliance with this Order, which copying services shall be provided by the Respondents at their expense; and

- B. To interview officers, directors, or employees of the Respondents, who may have counsel present, regarding such matters.

**XI.**

**IT IS FURTHER ORDERED** that this Order shall terminate on January 30, 2022.

By the Commission.

**Non-Public Appendix A****Divestiture Agreement**

**[Incorporated By Reference, But Redacted From Public Record Version]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing

## Analysis to Aid Public Comment

Consent Orders (“Consent Agreement”) with Laboratory Corporation of America Holdings (“LabCorp”), which is designed to remedy the anticompetitive effects of its proposed acquisition of Orchid Cellmark Inc. (“Orchid”). Under the terms of the Consent Agreement, LabCorp is required to divest Orchid’s U.S. government paternity testing services business to DNA Diagnostics Center (“DDC”). The Consent Agreement also requires LabCorp to facilitate the assignment of Orchid’s current government contracts to provide paternity testing services. The assets involved include all of the necessary relevant equipment, books and records, and other information necessary for DDC to bid competitively for future government paternity testing services business. With this Consent Agreement, the competition that would otherwise be eliminated through the proposed acquisition of Orchid by LabCorp will be fully preserved.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the accompanying Decision and Order (“Order”).

Pursuant to an Agreement and Plan of Merger dated April 5, 2011, LabCorp intends to acquire Orchid in a cash tender offer valued at approximately \$85.4 million. Both parties provide paternity testing services to government agencies, and are by far the largest providers of those services in the United States. The Commission’s complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in U.S. markets for the provision of paternity testing services to state and local government agencies. The proposed Consent Agreement remedies the alleged violations by replacing the lost competition in the relevant market that would result from the acquisition.

Analysis to Aid Public Comment

## **II. The Products and Structure of the Markets**

DNA paternity testing services for government agencies is a relevant product market in which to analyze the competitive effects of the proposed acquisition. No other types of paternity testing services, like blood testing, meet government agencies' requirements. LabCorp and Orchid are the two principal competitors in the United States for government paternity testing services contracts – they are the only two firms that consistently bid for these contracts, they account for the overwhelming majority of awarded contracts, and they have been the winner and runner-up in most of these bids. As a result, LabCorp and Orchid accounted for the overwhelming majority of the business in this roughly \$27 million market.

## **III. Entry**

The anticompetitive impact of LabCorp's acquisition of Orchid is not likely to be averted by entry or expansion from other DNA testing labs. Most other DNA testing laboratories do not have the scale or the experience needed to compete effectively for government contracts.

## **IV. Effects of the Acquisition**

The proposed acquisition likely would result in significant anticompetitive harm in the highly-concentrated relevant market for government paternity testing services. LabCorp and Orchid are the only significant competitors in this highly-concentrated market. Over the past five years, LabCorp and Orchid consistently participated in the vast majority of state and local government bids conducted in the United States, almost always as head-to-head competitors. They bid more often, and typically at lower prices, than any other labs. The acquisition will eliminate this significant head-to-head competition and is likely to result in higher prices for government paternity testing services contracts.

## **V. The Consent Agreement**

The proposed Consent Agreement remedies the competitive concerns raised by the transaction by requiring the parties to divest Orchid's U.S. government paternity testing business to

## Analysis to Aid Public Comment

DDC. LabCorp also must divest testing equipment along with contract and service information necessary to enable DDC to replicate Orchid's market position. LabCorp also must facilitate the assignment of all existing government paternity testing services contracts to DDC. This divestiture preserves competition that would otherwise be eliminated as a result of the acquisition.

The proposed Consent Agreement also contains several provisions designed to ensure that the divestiture is successful. LabCorp must provide lab testing services to DDC until the assets are fully transferred and Orchid's government contracts are assigned to DDC. In addition, DDC will have access to the personnel and information that are at Orchid's Dayton facility. Finally, LabCorp cannot use or retain any confidential business information except as necessary to maintain the assets for DDC's use during the transition period. To prevent improper sharing of information, a manager of the business being transferred who reports directly to Commission staff will be put in place.

DDC is a respected provider of paternity testing services for both private and government customers. DDC operates a testing laboratory located in Fairfield, Ohio that, with the divested assets and business, will enable DDC to effectively replace Orchid as the primary competitor to LabCorp. DDC has the resources and experience necessary to acquire the divested assets and assume responsibility for Orchid's existing government contracts.

If the Commission determines that either DDC is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, LabCorp must unwind the divestiture and divest the assets within six months of the date the Order becomes final to another Commission-approved acquirer. If LabCorp fails to divest the assets within the six months, the Commission may appoint a trustee to divest the relevant assets.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

Complaint

IN THE MATTER OF

**VALEANT PHARMACEUTICALS  
INTERNATIONAL, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4343; File No. 111 0216**Complaint, December 9, 2011 – Decision, February 8, 2012*

This consent order addresses the \$345 million acquisition by Valeant Pharmaceuticals International, Inc. of the Ortho Dermatologics division of Janssen Pharmaceuticals, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by significantly reducing competition in the market for tretinoin emollient cream. The consent order requires Valeant to return the marketing rights to two pharmaceutical products, Refissa, a branded tretinoin emollient cream, and a generic tretinoin emollient cream, to Spear Pharmaceuticals, the company that owns both products.

*Participants*

For the *Commission*: *Jacqueline K. Mendel, Catherine M. Sanchez, and David Von Nirschl.*

For the *Respondent*: *Michael Buchwald, Maria Raptis and Steven C. Sunshine, Skadden, Arps, Meagher & Flom LLP.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Ortho Dermatologics from Johnson & Johnson, a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in

## Complaint

the public interest, hereby issues its Complaint, stating its charges as follows:

**I. RESPONDENT**

1. Respondent is a corporation organized, existing, and doing business under and by virtue of the laws of Canada, with its headquarters address at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5 Canada. Respondent has offices in the United States at 14 Main Street, Suite 140, Madison, NJ 07940 and 700 Route 202/206, Bridgewater, NJ 08807, as well as locations in Irvine, CA, Petaluma, CA, Chantilly, VA and Durham, NC. Respondent develops, manufactures and markets branded, generic and over-the-counter pharmaceutical products, with an emphasis on dermatologic and neurologic therapeutic areas. Respondent employs approximately 3700 employees worldwide and had worldwide 2010 revenues of \$1.1 billion, the majority of which derived from U.S. sales.

2. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**II. PROPOSED ACQUISITION**

3. On July 15, 2011, Respondent and Johnson & Johnson entered into an Asset Purchase Agreement (“the Acquisition Agreement”) whereby Respondent proposes to acquire all rights, titles and interests of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a Johnson & Johnson company, in a transaction valued at approximately \$345 million (“the Acquisition”).

**III. RELEVANT MARKET**

4. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the manufacture and sale of tretinoin emollient cream.

## Complaint

5. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant line of commerce.

**IV. STRUCTURE OF THE MARKET**

6. The market for tretinoin emollient cream in the United States is highly concentrated. Respondent markets branded Refissa tretinoin emollient cream and generic tretinoin emollient cream pursuant to a licensing agreement between Respondent and Spear Pharmaceuticals. Johnson & Johnson's branded Renova is the only other tretinoin emollient cream product on the market. The Acquisition would create a monopoly in the market for tretinoin emollient cream in the United States.

**V. ENTRY CONDITIONS**

7. Entry into the relevant market would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of topical generic drug development times and the U.S. Food and Drug Administration's approval requirements take more than two years. Moreover, entry is not likely because the relevant market is relatively small, providing limited sales opportunities relative to the cost of entry for any potential entrant.

**VI. EFFECTS OF THE ACQUISITION**

8. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by eliminating actual, direct, and substantial competition between Respondent and Johnson & Johnson in the relevant market, thereby (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market, and (2) increasing the likelihood that customers would be forced to pay higher prices.

Order to Maintain Assets

**VII. VIOLATIONS CHARGED**

9. The Acquisition Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

10. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this ninth day of December, 2011, issues its Complaint against said Respondent.

By the Commission.

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent

## Order to Maintain Assets

Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Johnson & Johnson is a corporation organized, existing and doing business under and by virtue of the laws of New Jersey, with its headquarters address located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and the address of its wholly owned subsidiary, Janssen Pharmaceuticals, Inc., located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and

## Order to Maintain Assets

when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Decision and Order” means the:
  - 1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
  - 2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- D. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- E. “Orders” means the Decision and Order and this Order to Maintain Assets.
- F. “Refissa Product Business” means the business of the Respondent within the Geographic Territory specified in the Decision and Order related to each of the Refissa Products, including the research, Development, manufacture, distribution, marketing, and sale of each Refissa Product and the assets related to such business, including, without limitation, the Refissa Product Assets.

## Order to Maintain Assets

**II.**

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondent fully transfers and delivers the Refissa Product Assets to Spear, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness the Refissa Product Business, to minimize any risk of loss of competitive potential for such Refissa Product Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Refissa Product Business except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair such Refissa Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Refissa Product Business.
  
- B. Until Respondent fully transfers and delivers the Refissa Product Assets to Spear, Respondent shall maintain the operations of the Refissa Product Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Refissa Product Business and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Refissa Product Business. Respondent's responsibilities shall include, but are not limited to, the following:
  - 1. providing the Refissa Product Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at

## Order to Maintain Assets

least at their scheduled pace, all capital projects, business plans and promotional activities for such Refissa Product Business;

2. continuing, at least at their scheduled pace, any additional expenditures for the Refissa Product Business authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Refissa Products and/or to prevent any diminution in sales of each of the Refissa Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Refissa Product Assets to Spear;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Refissa Products at the related High Volume Accounts;
5. making available for use by the Refissa Product Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including without limitation, the Refissa Product Assets;
6. providing the Refissa Product Business with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of such Refissa Product Business; and
7. providing such support services to the Refissa Product Business as were being provided to such business by Respondent as of the date the Consent Agreement was signed by Respondent.

## Order to Maintain Assets

- C. Until Respondent fully transfers and delivers the Refissa Product Assets to Spear, Respondent shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Refissa Products for the relevant Refissa Product's last fiscal year.
- D. Pending divestiture of the Refissa Product Assets, Respondent shall:
1. not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Refissa Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondent's obligations to Spear under the terms of any Remedial Agreement; or
    - c. applicable Law;
  2. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except Spear or other Persons specifically authorized by Spear to receive such information;
  3. not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Refissa Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondent's obligations to Spear under the terms of any related Remedial Agreement; or
    - c. applicable Law;
  4. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person

## Order to Maintain Assets

except to Spear or other Persons specifically authorized by Spear to receive such information; and

5. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Refissa Products to the employees associated with business related to those Retained Products that contain the same active pharmaceutical ingredient as the Refissa Products.
- E. Not later than thirty (30) days from the earlier of the Closing Date or the date that this Order to Maintain Assets becomes final and effective, Respondent shall provide to all of Respondent's employees and other personnel who may have access to Confidential Business Information related to the Refissa Products notification of the restrictions on the use of such information by Respondent's personnel. Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to Spear. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Spear with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- F. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondent shall provide the Spear with

## Order to Maintain Assets

copies of all certifications, notifications and reminders sent to Respondent's employees and other personnel.

- G. Respondent shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondent to Spear under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- H. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Refissa Product Business within the Geographic Territory through their full transfer and delivery to Spear, to minimize any risk of loss of competitive potential for the Refissa Product Business within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Refissa Product Assets except for ordinary wear and tear.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be

## Order to Maintain Assets

deemed to have consented to the selection of the proposed Interim Monitor.

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Refissa Product Assets and the transfer and delivery of the related Confidential Business Information in a manner that fully satisfies the requirements of the Orders;

*provided, however,* that the Interim Monitor's service shall not exceed five (5) years from the Order Date;

## Order to Maintain Assets

*provided, further*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross

## Order to Maintain Assets

negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by Spear with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders.
  8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional

## Order to Maintain Assets

orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.

- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

**IV.**

**IT IS FURTHER ORDERED** that within thirty (30) days after the date this Order to Maintain Assets becomes final and effective, and every thirty (30) days thereafter until Respondent has fully complied with its obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A. of the related Decision and Order in this matter, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and the related Decision and Order; *provided, however,* that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII of the Decision and Order.

**V.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

## Order to Maintain Assets

**VI.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**VII.**

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The later of:
  - 1. The day after the divestiture of all of the Refissa Product Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor, in consultation with Commission

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staff and Spear, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or

2. the day after the day the related Decision and Order becomes final and effective.

By the Commission.

**DECISION AND ORDER**  
**[Public Record Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such

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Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Johnson & Johnson is a corporation organized, existing and doing business under and by virtue of the laws of New Jersey, with its headquarters address located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933, and the address of its wholly owned subsidiary, Janssen Pharmaceuticals, Inc., located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

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- A. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer(s)” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
  2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- D. “Acquisition” means Respondent’s acquisition of the rights, titles and interests of certain assets of the Ortho Dermatologics Division of Janssen Pharmaceuticals, Inc., a wholly owned subsidiary of Johnson & Johnson. The acquisition is contemplated pursuant to an Asset Purchase Agreement, by and among Janssen Pharmaceuticals, Inc., Valeant International (Barbados) SRL, and Valeant Pharmaceuticals North America LLC, dated as of July 15, 2011, submitted to the Commission.
- E. “Acquisition Date” means the date on which the Acquisition is consummated.

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- F. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term “Agency” includes, without limitation, the United States Food and Drug Administration (“FDA”).
- G. “Application(s)” means all of the following: “New Drug Application” (“NDA”), “Abbreviated New Drug Application” (“ANDA”), “Supplemental New Drug Application” (“SNDA”), or “Marketing Authorization Application” (“MAA”), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.
- H. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- I. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to the Acquirer pursuant to this Order.

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- J. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Refissa Products;

*provided, however,* that the restrictions contained in this Order regarding the Respondent’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

- a. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by the Respondent;
  - b. information that is required by Law to be publicly disclosed;
  - c. information relating to the Respondent’s general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Refissa Products;
  - d. information specifically excluded from the Refissa Product Assets; and
  - e. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.
- K. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage

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manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.

- L. “Divestiture Product Releasee(s)” means the following Persons:
1. the Acquirer for the assets related to a particular Divestiture Product;
  2. any Person controlled by or under common control with that Acquirer; and
  3. any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- M. “Divestiture Products” means the Refissa Products.
- N. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- O. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- P. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

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- Q. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- R. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- S. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- T. “Order Date” means the date on which this Decision and Order becomes final and effective.
- U. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- V. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by the Respondent as of the Closing Date (*except* where this Order specifies a different time).
- W. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

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- X. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- Y. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the Refissa Products and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Refissa Products from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. relating to any Clinical Trials involving the Refissa Products;
  3. relating to the particularized marketing of the Refissa Products or educational matters relating solely to the Refissa Products(s);
  4. constituting confidentiality agreements involving the Refissa Products;
  5. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the Refissa Products;
  6. pursuant to which a Third Party manufactures the specified Divestiture Product on behalf of the Respondent;
  7. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the

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Refissa Products to the Respondent including, but not limited to, consultation arrangements; and/or

8. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the Refissa Products or the business related to the Refissa Products;

*provided, however,* that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the Refissa Products, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- Z. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Divestiture Products and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the Divestiture Products sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all

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records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to such Divestiture Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

AA. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;
2. Product Copyrights;
3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;

*provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade

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dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

- BB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of the Divestiture Products in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Products.
- CC. “Product Trade Dress” means the current trade dress of the Divestiture Products, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.
- DD. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Divestiture Product(s);

*provided, however*, “Product Trademarks” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the

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corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

- EE. “Refissa Co-Marketing Agreement” means the “Co-Marketing Agreement” by and between Valeant Pharmaceuticals North America and Spear Pharmaceuticals, Inc., dated February 28, 2010, and all amendments, exhibits, attachments, agreements, and schedules thereto. The Refissa Co-Marketing Agreement is attached to this Order and contained in Non-Public Appendix I.
- FF. “Refissa Product(s)” means all products that are the subject of the Refissa Co-Marketing Agreement. “Refissa Products” includes all products marketed under the ANDA No. 76-498.
- GG. “Refissa Product Assets” means all rights, title and interest in and to all assets related to the research, Development, manufacture, distribution, marketing, and sale of the Refissa Products that are owned or controlled by, or licensed to Respondent on or before the Acquisition Date, to the extent legally transferable, including, without limitation, the following:
1. all rights, economic benefits, or other interests conveyed to Respondent pursuant to the Refissa Co-Marketing Agreement;
  2. all Product Intellectual Property related to the Refissa Products;
  3. all Product Marketing Materials related to the Refissa Products;
  4. all Website(s) related exclusively to the Refissa Products;

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5. the content related exclusively to the Refissa Products that is displayed on any Website that is not dedicated exclusively to the Refissa Products;
6. at the option of Spear, all Product Assumed Contracts related to the Refissa Products;
7. a list of all customers and targeted customers for the Refissa Products and a listing of the net sales (in either units or dollars) of the Refissa Products to such customers on either an annual, quarterly, or monthly basis;
8. a list of all physician sales calls related to Refissa Product made pursuant to the Refissa Product Co-Marketing Agreement;
9. a list of all prescribers of the Refissa Products;
10. at the option of Spear, and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the Refissa Products; and
11. all of the Respondent's books, records, and files directly related to the foregoing;

*provided, however,* that "Refissa Product Assets" shall not include: (1) documents relating to the Respondent's general business strategies or practices relating to research, Development, manufacture, marketing or sales of pharmaceutical Products, where such documents do not discuss with particularity the Refissa Products; (2) administrative, financial, and accounting records;

*provided further, however,* that in cases in which documents or other materials included in the assets to be divested contain information: (1) that relates both

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to the Refissa Products and to Retained Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Refissa Products; or (2) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to Spear, the Respondent shall provide Spear access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that the Respondent provides Spear with the above-described information without requiring the Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

HH. “Refissa Product Co-Marketing Termination Agreement” means the “Termination and Release Agreement” between Valeant Pharmaceuticals North America LLC, Spear Pharmaceuticals, Inc. and Spear Dermatology Products, Inc., dated as of November 22, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Refissa Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Refissa Product Co-Marketing Termination Agreement is attached to this Order and contained in non-public Appendix I.

- II. “Remedial Agreement(s)” means the following:
1. any agreement between the Respondent and the Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply

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specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of the Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;
3. any agreement between the Respondent and the Acquirer (or between a Divestiture Trustee and the Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of the Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

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- JJ. “Retained Product” means any Product(s) other than a Divestiture Product.
- KK. “Spear” means Spear Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Florida, with its headquarters address located at 11924 Fairway Lakes Drive, Ft. Myers, Florida 33913.
- LL. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.
- MM. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

**II.****IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Refissa Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Spear), to Spear and terminate the Refissa Product Co-Marketing Agreement, absolutely and in good faith, pursuant to the Refissa Product Co-Marketing Termination Agreement (which agreement shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits

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of Spear or to reduce any obligations of Respondent under such agreements);

*provided however*, that if Respondent has divested the Refissa Product Assets to Spear prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Refissa Product Assets to Spear (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the Refissa Product Assets to Spear, and to permit Spear to continue the research, Development, manufacture, sale, marketing or distribution of the Refissa Products;

*provided, however*, Respondent may satisfy this requirement by certifying that Spear has executed all such agreements directly with each of the relevant Third Parties.

- C. Respondent shall:
1. submit to Spear, at Respondent's expense, all Confidential Business Information related to the Refissa Products;
  2. deliver all Confidential Business Information to Spear:
    - a. in good faith;

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- b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
  - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;
3. pending complete delivery of all Confidential Business Information to Spear, provide Spear and the Interim Monitor (if any has been appointed) with access to all Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Refissa Products that contain Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Refissa Products other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondent's obligations to Spear under the terms of any related Remedial Agreement; or
  - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except Spear or other Persons specifically authorized by Spear to receive such information; and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the Refissa Products to the employees associated with business related to those Retained Products that

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contain the same active pharmaceutical ingredient as the Refissa Products and that are approved for the same indication as the Refissa Products.

- D. Respondent shall not enforce any agreement against a Third Party or Spear to the extent that such agreement may limit or otherwise impair the ability of Spear to acquire the Confidential Business Information related to the Refissa Products from the Third Party.
- E. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.D. that allows the Third Party to provide the Confidential Business Information to Spear. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to Spear.
- F. Until all of Respondent Spear's rights to enforce restrictions on the use, disclosure, conveyance or provision of Confidential Business Information are fully assigned or conveyed to Spear, Respondent shall enforce any agreement against a Third Party to the extent that such agreement prevents or limits the ability of the Third Party to provide any Confidential Business Information to any person or entity other than: (1) Spear or (2) any Person authorized by Spear to receive such information.
- G. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Refissa Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities to those Retained Products that contain the same active pharmaceutical ingredient and that are approved for the same indication as the Refissa Products and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to

## Decision and Order

maintain all Confidential Business Information related to the Refissa Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).

- H. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Refissa Products by Respondent's personnel to all of Respondent's employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Refissa Products;
  2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient and that are approved for the same indication as the Refissa Products; and/or
  3. may have Confidential Business Information related to the Refissa Products.

Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to Spear. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide Spear with copies of all certifications, notifications and reminders sent to Respondent's personnel.

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- I. Until Respondent completes the divestiture of the Refissa Product Assets to Spear,
  1. Respondent shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with the Refissa Products;
    - b. minimize any risk of loss of competitive potential for that business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Refissa Products;
    - d. ensure the Refissa Product Assets are provided to Spear in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with the Refissa Products; and
  2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with the Refissa Products.
- J. Respondent shall not, in the United States of America:
  1. use the Product Trademarks related to the Refissa Products or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
  2. attempt to register such Product Trademarks;
  3. attempt to register any mark confusingly similar to or resulting in dilution of such Product Trademarks;

## Decision and Order

4. challenge or interfere with Spear's use and registration of such Product Trademarks; or
5. challenge or interfere with Spear's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

*provided however*, this Paragraph shall only apply to those Product Trademarks conceived, registered, or developed prior to the Acquisition Date.

- K. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against Spear or the Divestiture Product Releasee(s) under the following:
1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Refissa Product(s), or that claims a device relating to the use thereof;
  2. any Patent owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Refissa Products;

if such suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa Products anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Refissa Product. Respondent shall also covenant to Spear that as a

## Decision and Order

condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue Spear or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with Spear's freedom to practice the following: (1) the research, Development, or manufacture of the Refissa Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a Refissa Product.

- L. The purpose of the divestiture of the Refissa Product Assets, the termination of the Refissa Product Co-Marketing Agreement and the related obligations imposed on the Respondent by this Order is to ensure the continued research, Development, manufacture, distribution, sale and marketing of the Refissa Products independently of Respondent and for the purposes of the business associated with each Refissa Product within the Geographic Territory and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreement(s).
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has

## Decision and Order

not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Refissa Product Assets and the transfer and delivery of the related Confidential Business Information in a manner that fully satisfies the requirements of this Order; *provided, however,* that, with respect to each Refissa Product, the

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Interim Monitor's service shall not exceed five (5) years from the Order Date; *provided, further*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Order.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.
5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to

## Decision and Order

the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.
  8. The Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.

## Decision and Order

- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

**IV.****IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Refissa Product Assets or to terminate the Refissa Product Co-Marketing Agreement as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.

## Decision and Order

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be

## Decision and Order

achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to the Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5)

## Decision and Order

days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

## Decision and Order

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however*, that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to this Order or the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

## V.

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that Respondent's counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain

## Decision and Order

unredacted copies of documents or other materials provided to Spear or access original documents provided to Spear, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Refissa Products or the assets and businesses associated with the Refissa Products;

*provided, however,* that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided further, however,* that pursuant to this Paragraph V, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with Spear (but shall not be deemed to have violated this requirement if Spear withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

**VI.**

**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.

## Decision and Order

- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligations to Spear pursuant to this Order.
- D. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Refissa Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- E. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

**VII.****IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with Paragraphs II.A, and II.C.1.-3., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the

## Decision and Order

efforts being made to comply with the relevant paragraphs of the Order, including a full description of all substantive contacts related to the termination of the Refissa Co-Marketing Agreement and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

**VIII.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**IX.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

## Decision and Order

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of that Respondent related to compliance with this Order, which copying services shall be provided by that Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate on February 8, 2022.

By the Commission.

**NON-PUBLIC APPENDIX I****REFISSA CO-MARKETING AGREEMENT****AND****REFISSA PRODUCT CO-MARKETING TERMINATION  
AGREEMENT**

**[Redacted From the Public Record Version But Incorporated  
By Reference]**

## Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Valeant Pharmaceuticals International, Inc. (“Valeant”), which is designed to remedy the anticompetitive effects of Valeant’s acquisition of the Ortho Dermatologics division of Janssen Pharmaceuticals, Inc. (“Janssen”), a wholly owned subsidiary of Johnson & Johnson.

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Valeant intends to acquire Ortho Dermatologics from Janssen, a Johnson & Johnson company, in a transaction valued at approximately \$345 million. Both parties sell topical pharmaceuticals in the United States. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the market for tretinoin emollient cream. The proposed Consent Agreement remedies the loss of competition that would result from the merger in this market. Specifically, the Consent Agreement requires that Valeant return the marketing rights to two pharmaceutical products, Refissa, a branded tretinoin emollient cream, and a generic tretinoin emollient cream, to Spear Pharmaceuticals (“Spear”), the company that owns both products.

**II. The Products and the Structure of the Market**

Valeant’s proposed acquisition of Ortho Dermatologics from Johnson & Johnson would create a monopoly in the market for

## Analysis to Aid Public Comment

tretinoin emollient cream. Tretinoin emollient cream is a topical retinoid cream used for the treatment of fine line wrinkles (retinoids are chemical compounds derived from Vitamin A, most commonly used in the treatment of acne, but also used to treat fine line wrinkles). This market includes branded and generic tretinoin emollient cream, and is highly concentrated. Pursuant to a co-marketing agreement between Valeant and Spear Pharmaceuticals, Valeant markets branded Refissa tretinoin emollient cream as well as a generic tretinoin emollient cream. Johnson & Johnson's Renova is the only other tretinoin emollient cream product on the market. The proposed acquisition would create a monopoly in the market for tretinoin emollient cream in the United States.

### **III. Entry**

As with most pharmaceutical products, entry into the manufacture and sale of tretinoin emollient cream is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration ("FDA") approval for the manufacture and sale of topical pharmaceuticals takes at least two years due to substantial regulatory, technological and intellectual property barriers. Moreover, entry is not likely because the relevant market is relatively small, providing limited sales opportunities relative to the cost of entry for any potential entrant.

### **IV. Effects of the Acquisition**

The proposed acquisition would cause significant anticompetitive harm in the U.S. market for tretinoin emollient cream by eliminating actual, direct and substantial competition between Valeant and Johnson & Johnson. The evidence indicates that the loss of head to head competition between Renova and the products co-marketed by Valeant ( Refissa and generic tretinoin emollient cream) would result in higher prices for tretinoin emollient cream.

### **V. The Consent Agreement**

The proposed Consent Agreement would remedy the competitive concerns raised by the proposed acquisition by requiring that (1) Valeant terminate its agreement with Spear

Analysis to Aid Public Comment

Pharmaceuticals, returning all its marketing rights to Refissa and generic tretinoin emollient cream and allowing Spear to take over its role in the market and (2) Valeant and Johnson & Johnson take steps to ensure that confidential business information relating to Refissa and generic tretinoin emollient cream will not be obtained or used by Valeant.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

Complaint

IN THE MATTER OF

**VALEANT PHARMACEUTICALS  
INTERNATIONAL, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT*Docket No. C-4342; File No. 111 0215  
Complaint, December 9, 2011 – Decision, February 21, 2012*

This consent order addresses the \$425 million acquisition by Valeant Pharmaceuticals International, Inc. of certain assets of Sanofi. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by significantly reducing competition in the markets for BenzaClin and topical fluorouracil cream. The consent order requires Valeant to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex.

*Participants*

For the *Commission*: *Jacqueline K. Mendel, Catherine M. Sanchez, and David Von Nirschl.*

For the *Respondent*: *Michael Buchwald, Maria Raptis and Steven C. Sunshine, Skadden, Arps, Meagher & Flom LLP.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets from Sanofi, a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

## Complaint

**I. RESPONDENT**

1. Respondent is a corporation organized, existing, and doing business under and by virtue of the laws of Canada, with its headquarters address at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5 Canada. Respondent has offices in the United States at 14 Main Street, Suite 140, Madison, NJ 07940 and 700 Route 202/206, Bridgewater, NJ 08807, as well as locations in Irvine, CA, Petaluma, CA, Chantilly, VA and Durham, NC. Respondent develops, manufactures and markets branded, generic and over-the-counter (“OTC”) pharmaceutical products, with an emphasis on dermatologic and neurologic therapeutic areas. Respondent employs approximately 3700 employees worldwide and had worldwide 2010 revenues of \$1.1 billion, the majority of which derived from U.S. sales.

2. Respondent is, and at all times relevant herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and is a company whose business is in or affects commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

**II. THE PROPOSED ACQUISITION**

3. Pursuant to an Asset Purchase Agreement (“the Acquisition Agreement”) dated July 8, 2011, Respondent proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”).

**III. THE RELEVANT MARKETS**

4. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of:

- a. BenzaClin; and
- b. Topical fluorouracil cream (“topical 5FU”).

## Complaint

5. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

**IV. THE STRUCTURE OF THE MARKETS**

6. Sanofi's Dermik unit manufactures and markets BenzaClin, a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. Respondent owns the only Abbreviated New Drug Application ("ANDA") for the generic version of BenzaClin, which it licenses to Mylan, Inc. ("Mylan"). Pursuant to this licensing agreement, Mylan sells the only generic of BenzaClin and Respondent receives royalties from those sales. Currently Dermik's BenzaClin sales account for approximately 50 per cent of unit sales in the BenzaClin market, while Mylan's generic version accounts for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

7. Topical 5FU products are used to treat actinic keratosis, a pre-cancerous lesion that can result from years of repeated sun exposure. There are three branded topical 5FUs currently on the market: (1) Respondent's Efudex; (2) Dermik's Carac; and (3) Allergan, Inc.'s Fluoroplex. Two generic companies, Spear Pharmaceuticals and Taro Pharmaceuticals U.S.A., Inc., market generic equivalents of Efudex, and Respondent also markets an authorized generic of the drug. Efudex sales have been almost completely displaced by sales of the three generic versions of the drug. Branded Carac is priced directly against the three generics of branded Efudex. Post-acquisition, Respondent's market share in the topical 5FU market would be over 50 per cent.

**V. ENTRY CONDITIONS**

8. Entry into the relevant markets would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of topical drug development times and U.S. Food and Drug Administration approval requirements take more than two years. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a

## Complaint

new entrant would likely be insufficient to justify the time and investment necessary to enter.

**VI. EFFECTS OF THE ACQUISITION**

9. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Respondent and Sanofi and creating a monopoly in the market for BenzaClin thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices; and
- b. by eliminating actual, direct, and substantial competition between Respondent and Sanofi in the market for topical 5FUs and reducing the number of competitors in the market for topical 5FUs thereby: (1) increasing the likelihood that Respondent will be able to exercise unilaterally market power in this market; and (2) increasing the likelihood that customers would be forced to pay higher prices.

**VII. VIOLATIONS CHARGED**

10. The Acquisition Agreement described in Paragraph 3 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

11. The Acquisition described in Paragraph 3, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this ninth day of December, 2011, issues its Complaint against said Respondent.

## Order to Maintain Assets

By the Commission.

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of the assets relating to the business of Sanofi’s dermatology unit, Dermik, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

## Order to Maintain Assets

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.
2. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its global headquarters located at 174 Avenue de France, 75013 Paris, France and the address of its United States subsidiary, Sanofi-Aventis US LLC, located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.

## Order to Maintain Assets

- C. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final and effective Decision and Order by the Commission; and
  2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission in this matter.
- D. “Divestiture Assets” means the Clindamycin-Benzoyl Peroxide Product Assets and the Fluorouracil Product Assets, as defined in the Decision and Order.
- E. “Divestiture Product Business(es)” means the business of the Respondent within the Geographic Territory specified in the Decision and Order related to each of the Divestiture Products, including the research, Development, manufacture, distribution, marketing, and sale of each Divestiture Product and the assets related to such business, including, without limitation, the Divestiture Assets.
- F. “Divestiture Products” means the Clindamycin-Benzoyl Products and the Fluorouracil Products, individually and collectively, as defined in the Decision and Order.
- G. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- H. “Orders” means the Decision and Order and this Order to Maintain Assets.

**II.**

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final and effective:

## Order to Maintain Assets

- A. Until Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of each of the related Divestiture Product Businesses, to minimize any risk of loss of competitive potential for such Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of such Divestiture Product Businesses except for ordinary wear and tear. Respondent shall not sell, transfer, encumber or otherwise impair such Divestiture Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the related Divestiture Product Businesses.
- B. Until Respondent fully transfers and delivers each of the respective Divestiture Assets to an Acquirer, Respondent shall maintain the operations of the related Divestiture Product Businesses in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of such Divestiture Product Businesses and shall use its best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors; the High Volume Accounts; customers; Agencies; employees; and others having business relations with each of the respective Divestiture Product Businesses. Respondent's responsibilities shall include, but are not limited to, the following:
1. providing each of the respective Divestiture Product Businesses with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such business and to carry on, at least at their scheduled pace, all

## Order to Maintain Assets

capital projects, business plans and promotional activities for such Divestiture Product Business;

2. continuing, at least at their scheduled pace, any additional expenditures for each of the respective Divestiture Product Businesses authorized prior to the date the Consent Agreement was signed by Respondent including, but not limited to, all research, Development, manufacturing, distribution, marketing and sales expenditures;
3. providing such resources as may be necessary to respond to competition against each of the Divestiture Products and/or to prevent any diminution in sales of each of the Divestiture Products during and after the Acquisition process and prior to the complete transfer and delivery of the related Divestiture Assets to an Acquirer;
4. providing such resources as may be necessary to maintain the competitive strength and positioning of each of the Divestiture Products at the related High Volume Accounts;
5. making available for use by each of the respective Divestiture Product Businesses funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including without limitation, the Divestiture Assets;
6. providing each of the respective Divestiture Product Businesses with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of such Divestiture Product Business; and
7. providing such support services to each of the respective Divestiture Product Businesses as were being provided to such business by Respondent as

## Order to Maintain Assets

of the date the Consent Agreement was signed by Respondent.

- C. Until Respondent fully transfers and delivers the Divestiture Assets to the Acquirer, Respondent shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Product's last fiscal year.
- D. Pending divestiture of the Divestiture Assets, Respondent shall:
  - 1. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Clindamycin-Benzoyl Peroxide Products other than as necessary to comply with the following:
    - a. the requirements of this Order;
    - b. Respondent's obligations to the Acquirer of the the Clindamycin-Benzoyl Peroxide Products under the terms of any related Remedial Agreement; or
    - c. applicable Law;
  - 2. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Clindamycin-Benzoyl Peroxide Products or other Persons specifically authorized by that Acquirer to receive such information; and
  - 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the the Clindamycin-Benzoyl Peroxide Products to the employees associated with business related to those Retained Products that contain the same

## Order to Maintain Assets

active pharmaceutical ingredient as the Clindamycin-Benzoyl Peroxide Products.

- E. Not later than thirty (30) days from the earlier of the Closing Date or the date that this Order to Maintain Assets becomes final and effective, Respondent shall provide to all of Respondent's employees and other personnel who may have access to Confidential Business Information related to the Divestiture Products notification of the restrictions on the use of such information by Respondent's personnel. Respondent shall give such notification by e-mail with return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the Closing Date. Respondent shall provide a copy of such notification to the Acquirer. Respondent shall maintain complete records of all such agreements at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that such acknowledgment program has been implemented and is being complied with. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.
- F. Respondent shall monitor the implementation by its employees and other personnel of all applicable restrictions, and take corrective actions for the failure of such employees and personnel to comply with such restrictions or to furnish the written agreements and acknowledgments required by this Order to Maintain Assets. Respondent shall provide the Acquirer with copies of all certifications, notifications and reminders sent to Respondent's employees and other personnel.
- G. During the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s), including, without limitation, such actions as are necessary to ensure the production of the Build-Up Inventory.

## Order to Maintain Assets

- H. Respondent shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondent to the Acquirer under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses within the Geographic Territory through their full transfer and delivery to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses within the Geographic Territory, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor (“Interim Monitor”) to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Orders and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.

## Order to Maintain Assets

- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission.
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
    - a. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Fluorouracil Products and able to manufacture the Fluorouracil Products in commercial quantities, in a manner consistent with cGMP, independently of the Respondent;

## Order to Maintain Assets

- b. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Fluorouracil Products; or
- c. with respect to the Fluorouracil Products, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Fluorouracil Products;

*provided, however,* that, with respect to the Fluorouracil Products, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

*provided, further,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- 4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations under the Orders, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Orders.
- 5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The

## Order to Maintain Assets

Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.

6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of the Orders and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders.
8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor

## Order to Maintain Assets

from providing any information to the Commission.

- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- H. The Interim Monitor appointed pursuant to this Order to Maintain Assets may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

**IV.**

**IT IS FURTHER ORDERED** that within thirty (30) days after the date this Order to Maintain Assets becomes final and effective, and every thirty (30) days thereafter until Respondent has fully complied with its obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A. and II.B. of the related Decision and Order in this matter, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order to Maintain Assets and the related Decision and Order; *provided, however*, that, after the Decision and Order in this matter becomes final and effective, the reports due under this Order to Maintain Assets may be consolidated

## Order to Maintain Assets

with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent pursuant to Paragraph VII of the Decision and Order.

**V.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Orders.

**VI.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

Order to Maintain Assets

- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**VII.**

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The later of:
  - 1. The day after the divestiture of all of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and the Interim Monitor, in consultation with Commission staff and the Acquirer(s), notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
  - 2. the day after the day the related Decision and Order becomes final and effective.

By the Commission.

Decision and Order

**DECISION AND ORDER**  
**[Public Record Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Valeant Pharmaceuticals International, Inc. (“Respondent”) of the assets relating to the business of Sanofi’s dermatology unit, Dermik, and Respondent having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Valeant is a corporation organized, existing and doing business under and by virtue of the

## Decision and Order

laws of Canada, with its corporate head office and principal place of business located at 7150 Mississauga Road, Mississauga, Ontario L5N 8M5, Canada.

2. Sanofi is a corporation organized, existing and doing business under and by virtue of the laws of the French Republic, with its global headquarters located at 174 Avenue de France, 75013 Paris, France and the address of its United States subsidiary, Sanofi-Aventis US LLC, located at 55 Corporate Drive, Bridgewater, New Jersey 08807.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. “Valeant” or “Respondent” means Valeant Pharmaceuticals International Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Valeant, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer(s)” means the following:
  1. a Person specified by name in this Order to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to

## Decision and Order

accomplish the requirements of this Order in connection with the Commission's determination to make this Order final and effective; or

2. a Person approved by the Commission to acquire particular assets or rights that the Respondent is required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- D. "Acquisition" means Respondent's acquisition of the assets relating to Sanofi's dermatology unit, Dermik. The acquisition is contemplated pursuant to an Asset Purchase Agreement among Sanofi, Valeant International (Barbados) SRL and Valeant Pharmaceuticals International, Inc., dated as of July 8, 2011, submitted to the Commission.
- E. "Acquisition Date" means the date on which the Acquisition is consummated.
- F. "Agency(ies)" means any government regulatory authority or authorities in the world responsible for granting approval(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing, distribution, or sale of a Product. The term "Agency" includes, without limitation, the United States Food and Drug Administration ("FDA").
- G. "Application(s)" means all of the following: "New Drug Application" ("NDA"), "Abbreviated New Drug Application" ("ANDA"), "Supplemental New Drug Application" ("SNDA"), or "Marketing Authorization Application" ("MAA"), the applications for a Product filed or to be filed with the FDA pursuant to 21 C.F.R. Part 314 et seq., and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto. The term "Application" also includes an "Investigational New Drug Application" ("IND")

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filed or to be filed with the FDA pursuant to 21 C.F.R. Part 312, and all supplements, amendments, and revisions thereto, any preparatory work, drafts and data necessary for the preparation thereof, and all correspondence between the Respondent and the FDA related thereto.

- H. “Build-Up Inventory” has the meaning set forth in Appendix II. The purpose of the Build Up Inventory is to ensure that there is a sufficient number of units of saleable inventory of a Contract Manufacture Product available to supply the Acquirer with all of the Acquirer’s requirements of the Contract Manufacture Products until the earlier of the following dates:
1. the date the Respondent establishes a facility (other than the Legacy Facility) that is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate customer/patient) and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP for the purposes of sale within the United States; or
  2. the date the Acquirer of that Contract Manufacture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate customer/patient) and able to manufacture such Contract Manufacture Product in commercial quantities, in a manner consistent with cGMP for the purposes of sale within the United States, independently of Respondent.
- I. “Categorized Assets” means, for each specified Divestiture Product, all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to the Divestiture Product to the extent legally transferable, including the research,

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Development, manufacture, distribution, marketing, and sale of the Divestiture Product, including, without limitation, the following:

1. all Product Intellectual Property related to the specified Divestiture Product;
2. all Product Approvals related to the specified Divestiture Product;
3. all Product Manufacturing Technology related to the specified Divestiture Product;
4. all Product Marketing Materials related to the specified Divestiture Product;
5. all Website(s) related exclusively to the specified Divestiture Product;
6. the content related exclusively to the specified Divestiture Product that is displayed on any Website that is not dedicated exclusively to the specified Divestiture Product;
7. a list of all of the NDC Numbers related to the specified Divestiture Product, and rights, to the extent permitted by Law:
  - a. to require Respondent to discontinue the use of those NDC Numbers in the sale or marketing of the specified Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Product sold prior to the Acquisition Date and *except* as may be required by applicable Law;
  - b. to prohibit Respondent from seeking from any customer any type of cross- referencing of those NDC Numbers with any Retained Product(s);
  - c. to seek to change any cross-referencing by a customer of those NDC Numbers with a

## Decision and Order

Retained Product (including the right to receive notification from the Respondent of any such cross-referencing that is discovered by Respondent);

- d. to seek cross-referencing from a customer of the Respondent's NDC Numbers related to such Divestiture Product with the Acquirer's NDC Numbers related to such Divestiture Product;
  - e. to approve the timing of Respondent's discontinued use of those NDC Numbers in the sale or marketing of such Divestiture Product *except* for returns, rebates, allowances, and adjustments for such Divestiture Product sold prior to the Acquisition Date and *except* as may be required by applicable Law; and
  - f. to approve any notification(s) from Respondent to any customer(s) regarding the use or discontinued use of such NDC numbers by the Respondent prior to such notification(s) being disseminated to the customer(s);
  - g. all rights to all of the Respondent's Applications related to the specified Divestiture Product;
8. all Product Development Reports related to the specified Divestiture Product;
  9. at the option of the Acquirer of the specified Divestiture Product, all Product Assumed Contracts related to the specified Divestiture Product (copies to be provided to that Acquirer on or before the Closing Date);
  10. all patient registries related to the specified Divestiture Product, and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and

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identification information required to be maintained by the FDA to facilitate the investigation of adverse effects related to the specified Divestiture Product;

11. a list of all customers and targeted customers for the specified Divestiture Product and a listing of the net sales (in either units or dollars) of the specified Divestiture Product to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the specified Divestiture Product on behalf of the High Volume Account and his or her business contact information;
12. at the option of the Acquirer of the specified Divestiture Product and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to the specified Divestiture Product;
13. copies of all unfilled customer purchase orders for the specified Divestiture Product as of the Closing Date, to be provided to the Acquirer of the specified Divestiture Product not later than five (5) days after the Closing Date;
14. at the option of the Acquirer of the specified Divestiture Product, all unfilled customer purchase orders for the specified Divestiture Product; and
15. all of the Respondent's books, records, and files directly related to the foregoing;

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*provided, however,* that “Categorized Assets” shall not include: (1) documents relating to the Respondent’s general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the specified Divestiture Product; (2) administrative, financial, and accounting records; (3) quality control records that are determined not to be material to the manufacture of the specified Divestiture Product by the Interim Monitor or the Acquirer of the specified Divestiture Product; (4) formulas used to determine the final pricing of any Divestiture Product and/or Retained Products to customers and competitively sensitive pricing information that is exclusively related to the Retained Products; (5) any real estate and the buildings and other permanent structures located on such real estate; and (6) all Product Licensed Intellectual Property;

*provided further, however,* that in cases in which documents or other materials included in the assets to be divested contain information: (1) that relates both to the specified Divestiture Product and to Retained Products or businesses of the Respondent and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the specified Divestiture Product; or (2) for which the Respondent has a legal obligation to retain the original copies, the Respondent shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer of the specified Divestiture Product, the Respondent shall provide that Acquirer access to original documents under circumstances where copies of documents are insufficient for evidentiary or regulatory purposes. The purpose of this proviso is to ensure that the Respondent provides the Acquirer with the above-described information without requiring the

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Respondent completely to divest itself of information that, in content, also relates to Retained Product(s).

- J. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- K. “Clinical Trial(s)” means a controlled study in humans of the safety or efficacy of a Product, and includes, without limitation, such clinical trials as are designed to support expanded labeling or to satisfy the requirements of an Agency in connection with any Product Approval and any other human study used in research and Development of a Product.
- L. “Clindamycin-Benzoyl Peroxide Products” means the following: all Products in Development, manufactured, marketed, sold, owned or controlled by Respondent Valeant pursuant to ANDA No. 065443, and any supplements, amendments, or revisions thereto.
- M. “Clindamycin-Benzoyl Peroxide Product Assets” means all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to each of the respective Clindamycin-Benzoyl Peroxide Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such Clindamycin-Benzoyl Peroxide Product, including, without limitation, the Categorized Assets related to the Clindamycin-Benzoyl Peroxide Products.
- N. “Clindamycin-Benzoyl Peroxide Product Divestiture Agreements” means “Asset Purchase Agreement” between Valeant Pharmaceuticals International, Valeant Pharmaceuticals North America, LLC, Mylan Pharmaceuticals Inc. and solely for the purposes set forth herein Dow Pharmaceutical Sciences, Inc., dated as of November 28, 2011, and all amendments,

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exhibits, attachments, agreements, and schedules thereto; related to the Clindamycin-Benzoyl Peroxide Product Assets that have been approved by the Commission to accomplish the requirements of this Order, including the “First Amendment To Asset Purchase Agreement,” dated as of February 3, 2012.

- O. “Closing Date” means, as to each Divestiture Product, the date on which the Respondent (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey assets related to such Divestiture Product to an Acquirer pursuant to this Order.
- P. “Confidential Business Information” means all information owned by, or in the possession or control of, the Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of each of the Divestiture Products;

*provided, however,* that the restrictions contained in this Order regarding the Respondent’s use, conveyance, provision, or disclosure of “Confidential Business Information” shall not apply to the following:

- a. information that subsequently falls within the public domain through no violation of this Order or breach of confidentiality or non-disclosure agreement with respect to such information by the Respondent;
- b. information that is required by Law to be publicly disclosed;
- c. information relating to the Respondent’s general business strategies or practices relating to research, Development, manufacture, marketing, or sales of Products that does not discuss with particularity the Divestiture Products;

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- d. information specifically excluded from the Divestiture Product Assets;
- e. all intellectual property licensed on a non-exclusive basis to the Acquirer of the specified Divestiture Product; and
- f. information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws.

Q. “Contract Manufacture” means:

1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer;
2. to manufacture, or to cause to be manufactured, a Product that is bioequivalent and in the identical dosage strength, formulation and presentation as a Contract Manufacture Product on behalf of an Acquirer;
3. to provide, or to cause to be provided, any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of a Contract Manufacture Product on behalf of an Acquirer.

R. “Contract Manufacture Product(s)” means the Fluorouracil Products; and/or

any ingredient or component of any of the Fluorouracil Products;

*provided however*, that with the consent of the Acquirer of the Fluorouracil Products, the Respondent may substitute a bioequivalent form of such Products in performance of the Respondent’s agreement to Contract Manufacture.

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- S. “Development” means all preclinical and clinical drug development activities (including formulation), including test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting Clinical Trials for the purpose of obtaining any and all approvals, licenses, registrations or authorizations from any Agency necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals), Product approval and registration, and regulatory affairs related to the foregoing. “Develop” means to engage in Development.
- T. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of the Respondent’s employees’ labor shall not exceed the average hourly wage rate for such employee;
- provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Divestiture Product.
- U. “Divestiture Agreements” means the Clindamycin-Benzoyl Peroxide Product Divestiture Agreements and the Fluorouracil Product Divestiture Agreements, individually and collectively. The Divestiture Agreements are attached to this Order and contained in non-public Appendix I.
- V. “Divestiture Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s)

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with rights to sublicense to all Product Licensed Intellectual Property and all Product Manufacturing Technology related to general manufacturing know-how that was owned, licensed, or controlled by Respondent Valeant prior to the Acquisition:

1. to research and Develop the Divestiture Products for marketing, distribution or sale within the Geographic Territory;
2. to use, make, have made, distribute, offer for sale, promote, advertise, or sell the Divestiture Products within the Geographic Territory;
3. to import or export the Divestiture Products to or from the Geographic Territory to the extent related to the marketing, distribution or sale of the Divestiture Products in the Geographic Territory; and
4. to have the Divestiture Products made anywhere in the World for distribution or sale within, or import into the Geographic Territory;

*provided however*, that for any Product Licensed Intellectual Property that is the subject of a license from a Third Party entered into by Respondent Valeant prior to the Acquisition, the scope of the rights granted hereunder shall only be required to be equal to the scope of the rights granted by the Third Party to Respondent Valeant.

- W. “Divestiture Products” means the Clindamycin-Benzoyl Peroxide Products and the Fluorouracil Products, individually and collectively.
- X. “Divestiture Product Assets” means the Clindamycin-Benzoyl Peroxide Product Assets and the Flouroucil Product Assets, individually and collectively.
- Y. “Divestiture Product Releasee(s)” means the following Persons:

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1. the Acquirer for the assets related to a particular Divestiture Product;
  2. any Person controlled by or under common control with that Acquirer; and
  3. any Manufacturing Designees, licensees, sublicensees, manufacturers, suppliers, distributors, and customers of that Acquirer, or of such Acquirer-affiliated entities.
- Z. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- AA. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any Person or authority that issues and maintains the domain name registration. “Domain Name” shall not include any trademark or service mark rights to such domain names other than the rights to the Product Trademarks required to be divested.
- BB. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.
- CC. “Fluorouracil Product(s)” means the following: all Products in Development, manufactured, marketed or sold by Respondent Valeant pursuant to NDA No. 016831, and any supplements, amendments, or revisions thereto.
- DD. “Fluorouracil Product Assets” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all of Respondent Valeant’s rights, title and interest in and to all assets related to Respondent Valeant’s business within the Geographic Territory related to each of the respective Fluorouracil Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each such

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Fluorouracil Product, including, without limitation, a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to the Categorized Assets related to the Fluorouracil Products, and an unlimited and unrestricted Right of Reference or Use to the Drug Master Files related to NDA 016831; *provided however*, “Fluorouracil Product Assets” excludes all rights to the Efudex® trademark.

EE. “Fluorouracil Product Divestiture Agreements” means, the following agreements:

1. “Asset Purchase Agreement” between Valeant Pharmaceuticals International, Valeant Pharmaceuticals North America, LLC, Mylan Pharmaceuticals Inc. and solely for the purposes set forth herein Dow Pharmaceutical Sciences, Inc., dated as of November 28, 2011; and
2. “Supply Agreement” between Mylan Pharmaceuticals Inc. and Valeant Pharmaceuticals International, Inc., as entered into as of February 3, 2012; and

all amendments, exhibits, attachments, agreements, and schedules thereto; related to the Fluorouracil Product Assets that have been approved by the Commission to accomplish the requirements of this Order, including the “First Amendment To Asset Purchase Agreement,” dated as of February 3, 2012.

FF. “Geographic Territory” shall mean the United States of America, including all of its territories and possessions, unless otherwise specified.

GG. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

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- HH. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States of America from the Respondent was, or is projected to be among the top twenty highest of such purchase amounts by the Respondent’s U.S. customers on any of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition; (2) the end of the last quarter that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the relevant assets; or (4) the end of the last quarter following the Acquisition or the Closing Date.
- II. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- JJ. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- KK. “Legacy Facility” means the facility operated by Legacy Pharmaceuticals Puerto Rico, LLC, that supplies Fluorouracil Products and Efudex to Respondent.
- LL. “Manufacturing Designee” means any Person other than the Respondent that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- MM. “Mylan” means Mylan Laboratories Inc., a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its headquarters address at 1500 Corporate Drive, Suite 400, Canonburg, Pennsylvania 15317.

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- NN. “NDC Numbers” means the National Drug Code numbers, including both the labeler code assigned by the FDA and the additional numbers assigned by an Application holder as a product code for a specific Product.
- OO. “Order Date” means the date on which this Decision and Order becomes final and effective.
- PP. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- QQ. “Patent(s)” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Product of or owned by the Respondent as of the Closing Date (*except* where this Order specifies a different time).
- RR. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- SS. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient and/or that is the subject of an Application.
- TT. “Product Approval(s)” means any approvals, registrations, permits, licenses, consents,

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authorizations, and other approvals, and pending applications and requests therefor, required by applicable Agencies related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Product within the United States of America, and includes, without limitation, all approvals, registrations, licenses or authorizations granted in connection with any Application.

- UU. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to the specified Divestiture Product and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the specified Divestiture Product from the Respondent unless such contract applies generally to the Respondent’s sales of Products to that Third Party;
  2. pursuant to which the Respondent purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of the specified Divestiture Product;
  3. relating to any Clinical Trials involving the specified Divestiture Product;
  4. with universities or other research institutions for the use of the specified Divestiture Product in scientific research;

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5. relating to the particularized marketing of the specified Divestiture Product or educational matters relating solely to the specified Divestiture Product(s);
6. pursuant to which a Third Party manufactures the specified Divestiture Product on behalf of the Respondent;
7. pursuant to which a Third Party provides any part of the manufacturing process including, without limitation, the finish, fill, and/or packaging of the specified Divestiture Product on behalf of Respondent;
8. pursuant to which a Third Party provides the Product Manufacturing Technology related to the specified Divestiture Product to the Respondent;
9. pursuant to which a Third Party is licensed by the Respondent to use the Product Manufacturing Technology;
10. constituting confidentiality agreements involving the specified Divestiture Product;
11. involving any royalty, licensing, covenant not to sue, or similar arrangement involving the specified Divestiture Product;
12. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the specified Divestiture Product to the Respondent including, but not limited to, consultation arrangements; and/or
13. pursuant to which any Third Party collaborates with the Respondent in the performance of research, Development, marketing, distribution or selling of the specified Divestiture Product or the business related to such Divestiture Product;

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*provided, however*, that where any such contract or agreement also relates to a Retained Product(s), the Respondent shall assign the Acquirer all such rights under the contract or agreement as are related to the specified Divestiture Product, but concurrently may retain similar rights for the purposes of the Retained Product(s).

- VV. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the specified Divestiture Product and any registrations and applications for registrations thereof within the Geographic Territory, including, but not limited to, the following: all such rights with respect to all promotional materials for healthcare providers, all promotional materials for patients, and educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of such Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of such Divestiture Product, including all copyrights in raw data relating to Clinical Trials of such Divestiture Product, all case report forms relating thereto and all statistical programs developed (or modified in a manner material to the use or function thereof (other than through user references)) to analyze clinical data, all market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information, promotional and marketing materials, the specified Divestiture Product sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, reimbursement data, speaker lists, manufacturing records, manufacturing

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processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to such Divestiture Product or relating to its biology; all copyrights in adverse experience reports and files related thereto (including source documentation) and all copyrights in periodic adverse experience reports and all data contained in electronic databases relating to adverse experience reports and periodic adverse experience reports; all copyrights in analytical and quality control data; and all correspondence with the FDA.

WW. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product;
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product;
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product;
4. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with the FDA relating to the Application(s) related to the specified Divestiture Product;
5. annual and periodic reports related to the above-described Application(s), including any safety update reports;
6. FDA approved Product labeling related to the specified Divestiture Product;
7. currently used or planned product package inserts (including historical change of controls summaries) related to the specified Divestiture Product;

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8. FDA approved patient circulars and information related to the specified Divestiture Product;
9. adverse event reports, adverse experience information, descriptions of material events and matters concerning safety or lack of efficacy related to the specified Divestiture Product;
10. summary of Product complaints from physicians related to the specified Divestiture Product;
11. summary of Product complaints from customers related to the specified Divestiture Product;
12. Product recall reports filed with the FDA related to the specified Divestiture Product, and all reports, studies and other documents related to such recalls;
13. investigation reports and other documents related to any out of specification results for any impurities found in the specified Divestiture Product;
14. reports related to the specified Divestiture Product from any consultant or outside contractor engaged to investigate or perform testing for the purposes of resolving any product or process issues, including without limitation, identification and sources of impurities;
15. reports of vendors of the active pharmaceutical ingredients, excipients, packaging components and detergents used to produce the specified Divestiture Product that relate to the specifications, degradation, chemical interactions, testing and historical trends of the production of the specified Divestiture Product;
16. analytical methods development records related to the specified Divestiture Product;

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17. manufacturing batch records related to the specified Divestiture Product;
  18. stability testing records related to the specified Divestiture Product;
  19. change in control history related to the specified Divestiture Product; and
  20. executed validation and qualification protocols and reports related to the specified Divestiture Product.
- XX. “Product Intellectual Property” means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):
1. Patents;
  2. Product Copyrights;
  3. Product Trademarks, Product Trade Dress, trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development and other information; and
  4. rights to obtain and file for patents, trademarks, and copyrights and registrations thereof and to bring suit against a Third Party for the past, present or future infringement, misappropriation, dilution, misuse or other violations of any of the foregoing;
- provided, however,* “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.
- YY. “Product Licensed Intellectual Property” means the following:

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1. Patents that are related to a Divestiture Product that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition; and
2. trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, research, Development, and other information, and all rights in the Geographic Territory to limit the use or disclosure thereof, that are related to a Divestiture Product and that the Respondent can demonstrate have been routinely used, prior to the Acquisition Date, for Retained Product(s) that has been marketed or sold on an extensive basis by the Respondent within the two-year period immediately preceding the Acquisition.

ZZ. “Product Manufacturing Technology” means:

1. all technology, trade secrets, know-how, formulas, and proprietary information (whether patented, patentable or otherwise) related to the manufacture of the specified Divestiture Product, including, but not limited to, the following: all product specifications, processes, analytical methods, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory communications, control history, current and historical information associated with the FDA Application(s) conformance and cGMP compliance, and labeling and all other information related to the manufacturing process, and supplier lists;

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2. all active pharmaceutical ingredients related to the specified Divestiture Product; and,
3. for those instances in which the manufacturing equipment is not readily available from a Third Party, at the Acquirer's option, all such equipment used to manufacture the specified Divestiture Product.

AAA. "Product Marketing Materials" means all marketing materials used specifically in the marketing or sale of the specified Divestiture Product in the Geographic Territory as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to the specified Divestiture Product.

BBB. "Product Trade Dress" means the current trade dress of the specified Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

CCC. "Product Trademark(s)" means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and

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associated therewith, for the specified Divestiture Product(s);

*provided, however*, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Valeant”, or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondent or the related corporate logos thereof, or general registered images or symbols by which Valeant can be identified or defined.

DDD. “Proposed Acquirer” means a Person proposed by the Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets or rights required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by the Respondent pursuant to this Order.

EEE. “Remedial Agreement(s)” means the following:

1. any agreement between the Respondent and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
2. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments,

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agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission's determination to make this Order final and effective;

3. any agreement between the Respondent and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, including without limitation, any agreement by the Respondent to supply specified products or components thereof, and that has been approved by the Commission to accomplish the requirements of this Order; and/or
4. any agreement between the Respondent and a Third Party to effect the assignment of assets or rights of the Respondent related to a Divestiture Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

FFF. "Retained Product" means any Product(s) other than a Divestiture Product.

GGG. "Right of Reference or Use" means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining approval of an Application or to defend an Application, including the ability to make available the underlying raw data from the investigation for FDA audit.

HHH. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United

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States dollars of manufacturing the specified Divestiture Product for the twelve (12) month period immediately preceding the Acquisition Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, “Supply Cost” means the cost as specified in such Remedial Agreement for that Divestiture Product.

- III. “Technology Transfer Standards” means requirements and standards sufficient to ensure that the information and assets required to be delivered to an Acquirer pursuant to this Order are delivered in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring no unreasonable delays in transmission), and meaningful manner. Such standards and requirements shall include, *inter alia*,
- a. designating employees knowledgeable about the Product Manufacturing Technology (and all related intellectual property) related to each of the Divestiture Products who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee, and the Interim Monitor (if one has been appointed), for the purpose of effecting such delivery;
  - b. preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the specified Divestiture Product that are acceptable to the Acquirer;
  - c. preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all

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such Product Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee; and

- d. providing, in a timely manner, assistance and advice to enable the Acquirer or its Manufacturing Designee to:
  - i. manufacture the specified Divestiture Product in the quality and quantities achieved by the Respondent, or the manufacturer and/or developer of such Divestiture Product;
  - ii. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell the specified Divestiture Product in commercial quantities and to meet all Agency-approved specifications for such Divestiture Product; and
  - iii. receive, integrate, and use all such Product Manufacturing Technology and all such intellectual property related to the specified Divestiture Product.

JJJ. “Third Party(ies)” means any non-governmental Person other than the following: the Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

KKK. “Website” means the content of the Website(s) located at the Domain Names, the Domain Names, and all copyrights in such Website(s), to the extent owned by the Respondent; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by the Respondent that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that the Respondent

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can convey its rights, if any, therein; or (2) content unrelated to any of the Divestiture Products.

**II.****IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Clindamycin-Benzoyl Peroxide Product Assets (to the extent that such assets are not already owned, controlled or in the possession of Mylan) and grant the related Divestiture Product License, absolutely and in good faith, to Mylan pursuant to, and in accordance with, the Clindamycin-Benzoyl Peroxide Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mylan or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Clindamycin-Benzoyl Peroxide Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondent has divested the Clindamycin-Benzoyl Peroxide Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that Mylan is not an acceptable purchaser of the Clindamycin-Benzoyl Peroxide Product Assets, then Respondent shall immediately rescind the transaction with Mylan, in whole or in part, as directed by the Commission, and shall divest the Clindamycin-Benzoyl Peroxide Product Assets and grant the related Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that

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receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondent has divested the Clindamycin-Benzoyl Peroxide Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Clindamycin-Benzoyl Peroxide Product Assets or grant of the related Divestiture Product License, as applicable, to Mylan (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondent shall divest the Fluorouracil Product Assets and grant the related Divestiture Product License, absolutely and in good faith, to Mylan pursuant to, and in accordance with, the Fluorouracil Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to vary or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Mylan or to reduce any obligations of Respondent under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Fluorouracil Product Assets is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondent has divested the Fluorouracil Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission

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determines to make this Order final and effective, the Commission notifies Respondent that Mylan is not an acceptable purchaser of the Fluorouracil Product Assets, then Respondent shall immediately rescind the transaction with Mylan, in whole or in part, as directed by the Commission, and shall divest the Fluorouracil Product Assets and grant the related Divestiture Product License within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer that receives the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further* that if Respondent has divested the Fluorouracil Product Assets and granted the related Divestiture Product License to Mylan prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Fluorouracil Product Assets or grant of the related Divestiture Product License, as applicable, to Mylan (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- C. Prior to the Closing Date, Respondent shall secure all consents and waivers from all Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to an Acquirer, and to permit the relevant Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Product(s) being acquired by that Acquirer;

*provided, however,* Respondent may satisfy this requirement by certifying that the relevant Acquirer

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for the Divestiture Product has executed all such agreements directly with each of the relevant Third Parties.

- D. Respondent shall provide, or cause to be provided to each Acquirer in a manner consistent with the Technology Transfer Standards the following:
1. all Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Product(s) being acquired by that Acquirer; and
  2. all rights to all Product Manufacturing Technology (including all related intellectual property) that is owned by a Third Party and licensed by the Respondent related to the Divestiture Products being acquired by that Acquirer.

Respondent shall obtain any consents from Third Parties required to comply with this provision.

- E. Respondent shall:
1. submit to each Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer;
  2. deliver all Confidential Business Information related to the Divestiture Products being acquired by that Acquirer to that Acquirer:
    - a. in good faith;
    - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
    - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness;

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3. pending complete delivery of all such Confidential Business Information to the relevant Acquirer, provide that Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the relevant Divestiture Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order;
4. not use, directly or indirectly, any such Confidential Business Information related to the research, Development, manufacturing, marketing, or sale of the Clindamycin-Benzoyl Peroxide Products other than as necessary to comply with the following:
  - a. the requirements of this Order;
  - b. Respondent's obligations to the Acquirer of the Clindamycin-Benzoyl Peroxide Products under the terms of any related Remedial Agreement; or
  - c. applicable Law;
5. not disclose or convey any Confidential Business Information, directly or indirectly, to any Person except the Acquirer of the Clindamycin-Benzoyl Peroxide Products or other Persons specifically authorized by that Acquirer to receive such information; and
6. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the marketing or sales of the the Clindamycin-Benzoyl Peroxide Products to the employees associated with business related to those Retained Products that contain the same

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active pharmaceutical ingredient as the Clindamycin-Benzoyl Peroxide Products.

- F. Respondent shall:
1. upon reasonable written notice and request from an Acquirer to the Respondent, Contract Manufacture and deliver to the requesting Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products related to the Divestiture Products acquired by that Acquirer at Respondent's Supply Cost, for a period of time sufficient to allow that Acquirer (or the Manufacturing Designee of the Acquirer) to obtain all of the relevant Product Approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the finished drug product independently of Respondent and to secure sources of supply of the active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in Respondent's Application(s) for the Divestiture Product(s) acquired by that Acquirer from Persons other than the Respondent;
  2. make representations and warranties to the Acquirer(s) that the Contract Manufacture Product(s) supplied by the Respondent pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Contract Manufacture Product(s) to be marketed or sold in the Geographic Territory, the Respondent shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by the Respondent to meet cGMP. This obligation may be made contingent upon the Acquirer giving the Respondent prompt written notice of such claim and cooperating fully in the defense of such claim. The Remedial

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Agreement shall be consistent with the obligations assumed by Respondent under this Order;

*provided, however,* that Respondent may reserve the right to control the defense of any such claim, including the right to settle the claim, so long as such settlement is consistent with Respondent's responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further* that this obligation shall not require Respondent to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by the Respondent to the Acquirer;

*provided further* that in each instance where: (1) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability resulting from the failure of the Contract Manufacture Products supplied to the Acquirer pursuant to such Remedial Agreement by the Respondent to meet cGMP;

3. give priority to supplying a Contract Manufacture Product to the relevant Acquirer over manufacturing and supplying of Products for Respondent's own use or sale;
4. make representations and warranties to each Acquirer that Respondent shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement(s) unless Respondent can demonstrate that their failure was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

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*provided, however,* that in each instance where: (1) an agreement to divest relevant assets or Contract Manufacture is specifically referenced and attached to this Order and (2) such agreement becomes a Remedial Agreement for a Divestiture Product, each such agreement may contain limits on the Respondent's aggregate liability for such a failure;

5. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, upon written request of that Acquirer or the Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, Respondent shall take all actions as are reasonably necessary to ensure an uninterrupted supply of the Contract Manufacture Product(s);
7. produce or cause to be produced the Build-Up Inventory and ensure that, within ten (10) days of March 9, 2012, at least the number of units of Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate consumer/patient) specified as the Build-Up Inventory is physically in existence and available for supply to the Acquirer;

*provided however,* that if the Respondent or the Interim Monitor notifies the Commission that, due to circumstances beyond the control of the Respondent, the Build-Up Inventory will be deficient in any respect, then the Respondent shall: (i) in consultation with the Interim Monitor and staff of the Commission, take such steps as are reasonably necessary to address the effects of any deficiency in Build-Up Inventory and otherwise mitigate the competitive and other

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effects from any failure to comply with the requirements of this Paragraph II.F.7.; and (ii) bear the burden of establishing to the Commission that any failure to comply with the requirements of this Paragraph II.F.7. was beyond the control of Respondent and in no part the result of negligence or willful misconduct by Respondent;

8. on January 15, 2012, February 1, 2012, February 15, 2012, March 1, 2012, and March 15, 2012, respectively, notify the Commission of the number of units of Build Up Inventory that is physically in existence and available for supply to the Acquirer;
9. provide access to all information and facilities, and make such arrangements with Third Parties, as are necessary to allow the Interim Monitor to monitor Respondent's compliance with its obligations pursuant to Paragraph II.F.7;
10. not later than June 30, 2013, and for the purposes of supplying the Acquirer, establish a facility that is approved by the FDA to manufacture each of the Contract Manufacture Products in finished form (*i.e.*, suitable for sale to the ultimate consumer/patient) in commercial quantities, in a manner consistent with cGMP for the purposes of sale of the Contract Manufacture Products within the United States; the obligation to establish a manufacturing facility, shall include, without limitation, ensuring that, at all times after June 30, 2013, there is a facility fully capable of manufacturing in commercial quantities, and in a manner consistent with cGMP, the Contract Manufacture Products in finished form;
11. within (10) days of the Order Date, absolutely and in good faith, begin the technical transfer and other processes that are necessary for Respondent to obtain all Product Approvals that are required to ensure that Respondent can comply with the requirements of Paragraph II.A.10;

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12. during the term of any agreement to Contract Manufacture between the Respondent and an Acquirer, provide consultation with knowledgeable employees of the Respondent and training, at the written request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling that Acquirer (or the Manufacturing Designee of that Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by, or on behalf of, the Respondent and in commercial quantities, and in a manner consistent with cGMP, independently of Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Manufacturing Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, II.F.1. - 12., shall remain in effect with respect to each Divestiture Product that is a Contract Manufacture Product until the earliest of: (1) the date the Acquirer of that Divestiture Product (or the Manufacturing Designee(s) of that Acquirer), respectively, is approved by the FDA to manufacture and sell such Divestiture Product in the United States and able to manufacture such Divestiture Product in commercial quantities, in a manner consistent with cGMP, independently of Respondent; (2) the date the Acquirer of a particular Divestiture Product notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture such Divestiture Product; (3) the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer of a particular Divestiture Product has abandoned its efforts to manufacture such Divestiture Product, or (4) the date four (4) years from the Closing Date.

- G. Respondent shall not enforce any agreement against a Third Party or an Acquirer to the extent that such agreement may limit or otherwise impair the ability of

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that Acquirer to use or to acquire from the Third Party the Product Manufacturing Technology (including all related intellectual property) related to the Divestiture Products acquired by that Acquirer. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Product Manufacturing Technology.

- H. Not later than ten (10) days after the Closing Date, Respondent shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Product Manufacturing Technology to that Acquirer. Within five (5) days of the execution of each such release, Respondent shall provide a copy of the release to that Acquirer.
- I. Respondent shall require, as a condition of continued employment post-divestiture of the assets required to be divested pursuant to this Order, that each employee that has had responsibilities related to the marketing or sales of the Divestiture Products within the one (1) year period prior to the Closing Date and each employee that has responsibilities to those Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products and the direct supervisor(s) of any such employee sign a confidentiality agreement pursuant to which that employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of that information to all other employees, executives or other personnel of Respondent (other than as necessary to comply with the requirements of this Order).
- J. Not later than thirty (30) days after the Closing Date, Respondent shall provide written notification of the restrictions on the use and disclosure of the Confidential Business Information related to the Divestiture Products by Respondent's personnel to all of Respondent's employees who:

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1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of any of the Divestiture Products;
2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that contain the same active pharmaceutical ingredient as the Divestiture Products; and/or
3. may have Confidential Business Information related to the Divestiture Products.

Respondent shall give the above-described notification by e-mail with return receipt requested or similar transmission, and keep a file of those receipts for one (1) year after the Closing Date. Respondent shall provide a copy of the notification to the relevant Acquirer. Respondent shall maintain complete records of all such notifications at Respondent's registered office within the United States and shall provide an officer's certification to the Commission stating that the acknowledgment program has been implemented and is being complied with. Respondent shall provide the relevant Acquirer with copies of all certifications, notifications and reminders sent to Respondent's personnel.

- K. Until Respondent completes the divestitures required by this Order and fully provides, or causes to be provided, the Product Manufacturing Technology related to a particular Divestiture Product to the relevant Acquirer,
1. Respondent shall take actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with that Divestiture Product;
    - b. minimize any risk of loss of competitive potential for that business;

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- c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to that Divestiture Product;
  - d. ensure the assets related to each Divestiture Product are provided to the relevant Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to the business associated with each Divestiture Product;
  - e. ensure the completeness of the transfer and delivery of the Product Manufacturing Technology; and
2. Respondent shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with that Divestiture Product.
- L. Respondent shall not join, file, prosecute or maintain any suit, in law or equity, against an Acquirer or the Divestiture Product Releasee(s) of that Acquirer for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer under the following:
1. any Patent owned or licensed by Respondent as of the day after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claims a method of making, using, or administering, or a composition of matter, relating to the Divestiture Product(s) acquired by that Acquirer, or that claims a device relating to the use thereof;

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2. any Patent owned or licensed by Respondent at any time after the Acquisition Date (*excluding* those Patents that claim inventions conceived by and reduced to practice after the Acquisition Date) that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) acquired by that Acquirer;

if such suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product. Respondent shall also covenant to that Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue that Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the suit would have the potential to interfere with that Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) anywhere in the World for the purposes of marketing or sale in the United States of America; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of America of a particular Divestiture Product.

- M. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation brought by a Third Party related to the Product Intellectual Property related to any of the Divestiture Products acquired by

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that Acquirer, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product within the Geographic Territory.

- N. For any patent infringement suit in which the Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date or for such suit as the Respondent has prepared or is preparing as of the Closing Date to defend against such infringement claim(s), and where such a suit would have the potential to interfere with the relevant Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Divestiture Product(s) acquired by that Acquirer; or (2) the use, import, export, supply, distribution, or sale of that Divestiture Product(s), Respondent shall:
1. cooperate with that Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondent in connection with obtaining resolution of any pending patent litigation involving that Divestiture Product;
  2. waive conflicts of interest, if any, to allow the Respondent's outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving that Divestiture Product; and
  3. permit the transfer to that Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondent's outside counsel relating to that Divestiture Product.
- O. The purpose of the divestiture of the Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing Technology and the

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related obligations imposed on the Respondent by this Order is:

1. to ensure the continued use of such assets in the research, Development, and manufacture of each Divestiture Product and for the purposes of the business associated with each Divestiture Product within the Geographic Territory;
2. to provide for the future use of such assets for the distribution, sale and marketing of each Divestiture Product in the Geographic Territory;
3. to create a viable and effective competitor, that is independent of the Respondent:
  - a. in the research, Development, and manufacture of each Divestiture Product for the purposes of the business associated with each Divestiture Product within the Geographic Territory; and
  - b. the distribution, sale and marketing of the each Divestiture Product in the Geographic Territory; and,
4. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

**III.**

**IT IS FURTHER ORDERED** that:

- A. At any time after the Respondent signs the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that the Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order, the Order to Maintain Assets and the Remedial Agreements.

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- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Interim Monitor, Respondent shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondent shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondent's compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.
- D. If an Interim Monitor is appointed, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
  - 1. The Interim Monitor shall have the power and authority to monitor Respondent's compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission.
  - 2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  - 3. The Interim Monitor shall serve until the date of completion by the Respondent of the divestiture of all Divestiture Product Assets and the transfer and delivery of the related Product Manufacturing

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Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:

- a. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products (or that Acquirer's Manufacturing Designee(s)) is approved by the FDA to manufacture and sell the Fluorouracil Products and able to manufacture the Fluorouracil Products in commercial quantities, in a manner consistent with cGMP, independently of the Respondent;
- b. with respect to the Fluorouracil Products, the date the Acquirer of the Fluorouracil Products notifies the Commission and the Respondent of its intention to abandon its efforts to manufacture the Fluorouracil Products; or
- c. with respect to the Fluorouracil Products, the date of written notification from staff of the Commission that the Interim Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture the Fluorouracil Products;

*provided, however,* that, with respect to the Fluorouracil Products, the Interim Monitor's service shall not exceed five (5) years from the Order Date;

*provided, further,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

4. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondent's personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondent's compliance with its obligations

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under the Order, including, but not limited to, its obligations related to the relevant assets. Respondent shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondent's compliance with the Order.

5. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
6. Respondent shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
7. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days

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from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

8. Respondent may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
  - F. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
  - G. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
  - H. The Interim Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

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**IV.****IT IS FURTHER ORDERED** that:

- A. If Respondent has not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Product Assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent to comply with this Order.
- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.

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- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
  3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall

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develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondent from among those approved by the Commission; *provided further, however*, that Respondent shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture

## Decision and Order

Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
  - F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

**V.**

**IT IS FURTHER ORDERED** that, in addition to any other requirements and prohibitions relating to Confidential Business Information in this Order, Respondent shall assure that Respondent's counsel (including in-house counsel under appropriate confidentiality arrangements) shall not retain unredacted copies of documents or other materials provided to an Acquirer or access original documents provided to an Acquirer, except under circumstances where copies of documents are insufficient or otherwise unavailable, and for the following purposes:

- A. To assure Respondent's compliance with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals, and rules promulgated by the Commission), any data retention requirement of any applicable Government Entity, or any taxation requirements; or

## Decision and Order

- B. To defend against, respond to, or otherwise participate in any litigation, investigation, audit, process, subpoena or other proceeding relating to the divestiture or any other aspect of the Divestiture Products or the assets and businesses associated with those Divestiture Products;

*provided, however,* that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph V pursuant to an appropriate confidentiality order, agreement or arrangement;

*provided further, however,* that pursuant to this Paragraph V, Respondent shall: (1) require those who view such unredacted documents or other materials to enter into confidentiality agreements with the relevant Acquirer (but shall not be deemed to have violated this requirement if that Acquirer withholds such agreement unreasonably); and (2) use best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

**VI.**

**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by the Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to each of the Divestiture Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of the Respondent's obligations to the Acquirer pursuant to this Order.
- D. Respondent shall also include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to

## Decision and Order

secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each such Divestiture Product, as applicable, and to have any such manufacture to be independent of Respondent, all as soon as reasonably practicable.

- E. Respondent shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of this Order or the remedial purposes thereof.
- F. Respondent shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

**VII.****IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the Order Date, and every sixty (60) days thereafter until Respondent has fully complied with the following: Paragraphs II.A , II.B., II.C., II.D. II.E.1.-3., II.F., and II.K., Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondent shall include in its reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant paragraphs of the Order, including a full description of

## Decision and Order

all substantive contacts or negotiations related to the divestiture of the relevant assets and/or the agreement to supply relevant Products and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- C. One (1) year after the Order Date, annually for the next nine years on the anniversary of the Order Date, and at other times as the Commission may require, Respondent shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

**VIII.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of the Respondent;
- B. any proposed acquisition, merger or consolidation of the Respondent; or
- C. any other change in the Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**IX.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to the Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, the Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

Decision and Order

- A. access, during business office hours of the Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of the Respondent related to compliance with this Order, which copying services shall be provided by the Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of the Respondent, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that this Order shall terminate on February 21, 2022.

By the Commission.

**NON-PUBLIC APPENDIX I**

**DIVESTITURE AGREEMENTS**

**[Redacted From the Public Record Version But Incorporated  
By Reference]**

Analysis to Aid Public Comment

## **NON-PUBLIC APPENDIX II**

### **BUILD-UP INVENTORY**

**[Redacted From the Public Record Version But Incorporated  
By Reference]**

## **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

### **I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Order (“Consent Agreement”) from Valeant Pharmaceuticals International, Inc. (“Valeant”), which is designed to remedy the anticompetitive effects of Valeant’s acquisition of certain assets of Sanofi’s dermatology unit, Dermik (“Dermik”)

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Valeant proposes to acquire certain assets of Sanofi’s dermatology unit, Dermik, in a transaction valued at approximately \$425 million (“the Acquisition”). Both parties sell topical pharmaceutical products in the United States. The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the markets for 1) BenzaClin and 2) topical fluorouracil cream (“topical 5FU”). The proposed

## Analysis to Aid Public Comment

Consent Agreement remedies the loss of competition in these markets that would result from the Acquisition. Specifically, under the terms of the Consent Agreement, Valeant would be required to (1) divest all rights and assets related to generic BenzaClin, and (2) grant a perpetual, unrestricted license for the authorized generic of Efudex (“AG Efudex”). Valeant has proposed Mylan Inc. (“Mylan”) as the buyer of generic BenzaClin and AG Efudex assets.

## II. The Products and the Structure of the Market

Valeant’s proposed acquisition of Dermik from Sanofi would create a monopoly in the BenzaClin market. Dermik manufactures and markets BenzaClin, which is a topical pharmaceutical product used to treat acne vulgaris, commonly known as acne. BenzaClin is a combination of clindamycin, an antibiotic, and benzoyl peroxide, an antimicrobial. Valeant owns the only Abbreviated New Drug Application (“ANDA”) for the generic version of BenzaClin, which it licenses to Mylan. Pursuant to that license, Mylan sells the only generic equivalent of BenzaClin in the United States and Valeant receives the vast majority of royalties from those sales. Currently Dermik’s BenzaClin sales account for approximately 50 per cent of sales, while sales of Mylan’s generic version account for the other approximate 50 per cent. The Acquisition would create a monopoly in this market.

In addition, Valeant’s proposed acquisition of Dermik is likely to result in anticompetitive effects in the market for topical 5FU products. Topical 5FU products are used to treat actinic keratosis (“AK”), which is a pre-cancerous lesion that can result from years of repeated sun exposure. Three branded topical 5FUs are currently on the market, including Valeant’s Efudex and Dermik’s Carac. There are also two generic versions of Efudex, as well as an “authorized” generic, also sold by Valeant. The price of the generic drugs in this market determines the pricing of branded Carac. Post-acquisition, Valeant’s market share in the topical 5FU market would be over 50 per cent. Other treatments for AKs are not viable substitutes for topical 5FUs because they are more costly, less efficacious or impracticable.

## Analysis to Aid Public Comment

**III. Entry**

Entry into the manufacture and sale of both BenzaClin and topical 5FU products is difficult, expensive and time consuming. Developing and obtaining U.S. Food and Drug Administration approval for the manufacture and sale of topical pharmaceuticals takes over two years due to substantial regulatory, technological and intellectual property barriers. Furthermore, entry would not be likely because the markets are relatively small, so the limited sales opportunities available to a new entrant would likely be insufficient to justify the time and investment necessary to enter.

**IV. Effects of the Acquisition**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of both BenzaClin and topical 5FU products by eliminating actual, direct and substantial competition between Valeant and Sanofi in those markets. With respect to the BenzaClin market, the transaction would combine BenzaClin and its only generic equivalent, eliminating BenzaClin's closest competitor and creating a monopoly. The impact of eliminating the competition between BenzaClin and its only currently-marketed generic equivalent, is highly likely to result in consumers paying higher prices.

In the topical 5FU market, the transaction would give Valeant control over three linked treatments for AK – Dermik's branded Carac and Valeant's branded and AG Efudex products. The combination of these products at Valeant would eliminate head to head competition between Carac and the Efudex AG and is thus likely to result in higher prices for topical 5FUs.

**V. The Consent Agreement**

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant markets by requiring Valeant to (1) divest its ANDA for generic BenzaClin to Mylan, and (2) supply an authorized generic of Efudex, pursuant to a license to Mylan. If approved, Mylan will acquire all rights and assets currently held by Valeant, including any existing

## Analysis to Aid Public Comment

inventory. The assets to be transferred include all manufacturing and research and development rights in the divested products.

Mylan is a particularly well-suited acquirer of generic BenzaClin because it has been manufacturing and marketing the product, pursuant to an agreement with Valeant, since it was introduced in August 2009. Mylan is the second-largest generic pharmaceutical manufacturer in the United States, and is well-positioned to replicate the competition that would be lost with the proposed Valeant/Dermik acquisition. Headquartered in Pittsburgh, Pennsylvania, Mylan employs more than 18,000 employees and generated approximately \$5.45 billion in revenue in 2010. Mylan sells approximately 270 products and has a manufacturing facility where BenzaClin is manufactured. It is in the process of upgrading that facility to handle compounds such as 5FU.

Mylan expects to begin manufacturing generic Efudex at that facility in 2013. Until that time, the proposed Consent Agreement contemplates Mylan's purchase of topical 5FU from Valeant pursuant to a supply agreement. In order to ensure that there is no supply interruption, the proposed Consent Agreement would require that Valeant build up a two-year inventory and establish its own manufacturing as a back-up supply until Mylan is able to manufacture Efudex commercially. Valeant would also be required to assist Mylan with developing its manufacturing capabilities and securing the necessary FDA approvals. With these provisions, Mylan will be able to compete in the 5FU market immediately following the divestiture and establish independent manufacturing as soon as practicable.

The Commission has appointed Francis J. Civile as the Interim Monitor to oversee the asset transfer and to ensure Valeant's compliance with the provisions of the proposed Consent Agreement. Mr. Civile has over 27 years of experience in the pharmaceutical industry. He has extensive experience in areas such as pharmaceutical research and development, regulatory approval, manufacturing and supply, and marketing. Mr. Civile will oversee the transfer of Efudex manufacturing technology to the acquirer and ensure that Valeant is diligent in building up the required inventory of the product and establishing its own back-up supply capabilities. In order to ensure that the Commission

*Analysis to Aid Public Comment*

remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

## Complaint

## IN THE MATTER OF

**OMNICARE, INC.**COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED  
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION  
ACT AND SECTION 7 OF THE CLAYTON ACT*Docket No. 9352; File No. 111 0239**Complaint, January 27, 2012 – Decision, February 22, 2012*

This case addresses the \$760 million acquisition by Omnicare, Inc. of certain assets of PharMerica Corporation. The complaint alleges that the acquisition, if consummated, would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by substantially increasing Omnicare's bargaining leverage and otherwise reducing competition in the sale of long term care pharmacy services to Plan Sponsors. The Order dismisses the Administrative Complaint without prejudice, because Respondent has announced that it is abandoning the proposed acquisition of PharMerica, and has withdrawn its Hart-Scott-Rodino Notification and Report Form filed for the proposed transaction.

*Participants*

For the *Commission*: Jordan S. Andrew, Stephanie C. Bovee, Gerald A. Stein, Lore Unt, Mark Seidman, Christine L. White, and Daniel Zach.

For the *Respondent*: John D. Harkrider and Michael L. Keeley, Axinn, Veltrop & Harkrider, LLP, and Jacqueline I. Grise and Roxann E. Henry, Dewey & LeBoeuf.

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by the Act, the Federal Trade Commission, having reason to believe that Respondent Omnicare, Inc.'s ("Omnicare") cash tender offer to acquire PharMerica Corporation ("PharMerica"), if consummated, would violate Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

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**I.****NATURE OF THE CASE**

1. Twenty-nine million elderly or disabled Americans participate in federally subsidized Medicare Part D Plans (“Part D Plans”) to help pay for their prescription drugs; approximately 1.6 million of those beneficiaries reside in skilled nursing facilities (“SNFs”). Part D beneficiaries residing in SNFs receive their medications from the long-term care pharmacy (“LTC Pharmacy”) with which the SNF has contracted on an exclusive basis. The beneficiaries’ Part D Plan sponsors (“Part D sponsors”) reimburse the LTC Pharmacy for that service under contracts that the LTC Pharmacy negotiates directly with the Part D sponsors. Omnicare, the nation’s largest LTC Pharmacy, has made a hostile tender offer for its largest competitor, PharMerica (the “Acquisition”). The Acquisition, if successful, threatens to increase substantially Omnicare’s negotiating leverage with Part D sponsors, and is likely to result in higher reimbursement rates paid by the Part D sponsors, their beneficiaries, and ultimately, American taxpayers who subsidize the vast majority of the Part D Plans’ costs.

2. LTC Pharmacies are specialized pharmacies that do not cater to retail traffic. Instead, they package and deliver prescription medications primarily to SNFs for their residents who are receiving nursing care. Omnicare is already, by far, the largest LTC Pharmacy in the United States, controlling % of the country’s licensed SNF beds. As a result of this market position, it already enjoys considerable leverage in its negotiations with Part D sponsors. Omnicare seeks to extend its market-leading position by acquiring its largest, and only, national competitor, PharMerica, which controls % of the country’s licensed SNF beds. PharMerica’s board of directors has rejected Omnicare’s offer (and has recommended, in a publicly issued statement, that shareholders not tender their shares to Omnicare), in part because, in PharMerica’s words: “Antitrust clearance to combine competitors with #1 and #2 market share in institutional pharmacy is likely to be difficult to achieve and involve lengthy administrative and court proceedings.” Post-Acquisition, the combined firm’s only competitors would be small, regional and

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local pharmacies, none of which currently possesses substantial market share or operates in more than a few states.

3. The Centers for Medicare and Medicaid Services (“CMS”) requires Part D sponsors to provide “convenient access” to LTC Pharmacies for their beneficiaries residing in SNFs. SNFs contract exclusively with a single LTC Pharmacy to meet the prescription medication needs of all their residents. Thus, the larger the LTC Pharmacy (measured by number of SNF beds served), the more likely CMS is to require a Part D sponsor to include it in its Part D network. Sponsors that fail to satisfy CMS’s “convenient access” requirement risk being barred from offering their Part D Plans to any beneficiaries, even though SNF residents make up only a small portion of their enrollees.

4. Omnicare’s exclusive contractual relationships with a large number of the nation’s 16,000-plus SNFs are the source of its market-leading position. Because Omnicare serves far more SNF beds than any other LTC Pharmacy, it is often able to extract higher prices and other more favorable contract terms from Part D sponsors. As Omnicare’s CEO recently explained to investors, “[Omnicare] basically control[s] 50% of the patient . . . population in the nursing home agencies. . . . So with that type of leverage and market share, you know, we’re in a different and unique position when we’re negotiating our contracts with [Part D sponsors].”

5. Omnicare has explicitly and successfully invoked the risk that Part D sponsors face if they fail to contract with it in its negotiations with several Part D sponsors. Indeed, Omnicare’s standard negotiating practice is to threaten to terminate its participation in the Part D sponsor’s LTC Pharmacy network if the sponsor refuses its demand for higher rates or better terms. To drive home that risk, Omnicare has repeatedly threatened to bring the impasse to CMS’s attention, placing CMS approval of the sponsor’s entire Part D business at risk. A number of the largest Part D sponsors have capitulated to Omnicare’s demands to avoid the risk that CMS would refuse to approve their Part D Plan network without Omnicare.

6. Post-Acquisition, Omnicare would control approximately 57% of all of the licensed SNF beds in the United States. The

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high pre- and post-merger market shares and concentration levels render the Acquisition presumptively unlawful under the relevant case law and the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (“Merger Guidelines”). Evidence from CMS, as well as market participants including Part D sponsors, Pharmacy Benefit Managers (“PBMs”) (which assemble LTC Pharmacy networks on their own behalf and on behalf of other Part D sponsors), SNFs, other LTC Pharmacies, and Omnicare and PharMerica themselves, confirms this strong presumption of illegality.

7. The combined firm would have unparalleled power in its negotiations with the Part D sponsors. Already a “should have,” Omnicare’s post-Acquisition market share will almost certainly make it a “must have” for every Part D Plan seeking to meet CMS’s “convenient access” requirement. This will significantly increase Omnicare’s bargaining leverage because Omnicare’s threats to terminate the Part D sponsor if it refuses to agree to Omnicare’s contractual demands will represent an unacceptable risk. Without the combined firm in its network, a Part D Plan would be unlikely to meet CMS’s access requirement. And no Part D sponsor would rationally put its entire Part D business at risk in negotiations with the combined entity over reimbursements for the small percentage of its Part D beneficiaries who reside in SNFs.

8. Omnicare’s use of termination threats to get price increases from Part D sponsors will likely escalate post-Acquisition as the combined firm flexes its increased bargaining leverage to extract even higher prices and better terms. The cost of these price increases ultimately will, in the end, largely be borne by the federal government, which subsidizes the overwhelming majority (74.5%) of each Part D Plan’s costs; as well as many Part D beneficiaries, who will be forced to pay higher premiums, deductibles, and co-pays to receive Part D benefits.

9. Even if the combined firm is not ultimately deemed necessary to meet CMS’s “convenient access” requirement, the acquisition of PharMerica’s significant additional SNF relationships will further increase Omnicare’s already substantial bargaining leverage over Part D sponsors. Omnicare and

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PharMerica are also each other's closest competitors for a significant number of SNFs, providing additional leverage for Omnicare in negotiations with Part D sponsors post-Acquisition.

**II.****THE RESPONDENT**

10. Respondent Omnicare is incorporated in Delaware and is headquartered at 1600 RiverCenter II, 100 East RiverCenter Boulevard, Covington, Kentucky 41011. Omnicare owns and operates approximately 204 LTC Pharmacy facilities located in 44 states, which serve approximately licensed SNF beds through its exclusive contracts with SNF operators. In 2010, Omnicare generated total revenues of approximately \$6.1 billion.

**III.****THE TARGET OF THE ACQUISITION**

11. Omnicare plans to acquire PharMerica, which is incorporated in Delaware and is headquartered at 1901 Campus Place, Louisville, Kentucky 40299. PharMerica owns and operates approximately 97 pharmacy facilities in 43 states, and controls approximately licensed SNF beds. In 2010, PharMerica had total annual revenues of approximately \$1.8 billion.

**IV.****JURISDICTION**

12. Omnicare and each of its relevant operating subsidiaries, are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

13. PharMerica and each of its relevant operating subsidiaries, are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and Section 1 of the Clayton Act, 15 U.S.C. § 12.

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14. The Acquisition constitutes an acquisition subject to Section 7 of the Clayton Act, 15 U.S.C. § 18.

**V.****THE ACQUISITION**

15. Through its hostile cash tender offer announced publicly on September 7, 2011, and currently set to expire on February 17, 2012, Omnicare proposes to acquire all outstanding shares of PharMerica to obtain ownership and control of the company. The value of the proposed Acquisition is approximately \$760 million.

**VI.****OVERVIEW OF PART D BENEFITS PROVIDED TO SNF RESIDENTS**

16. Medicare Part D has been in effect since January 1, 2006. Roughly 1.1 billion prescriptions per year are processed under Part D on behalf of the approximately 29 million beneficiaries enrolled in Part D Plans. The majority of patients receiving care at SNFs at any given time in the United States are enrolled in and receive benefits from a Part D Plan.

17. SNF residents may be covered by Medicare Part A or Part D when they first enter the facility. Medicare Part A is a federal program that subsidizes inpatient hospital costs for Medicare beneficiaries, as well their initial stay at a SNF upon release from the hospital (up to the first 100 days). Because the average SNF resident stays well beyond the initial Medicare Part A period, and because some residents are already receiving Part D benefits at the time they enter the SNF, a minority of SNF residents at any given time receive Part A benefits. CMS provides a per diem payment to SNFs to cover Part A residents' cost of care, including prescription medications. SNFs are then responsible for the actual cost of their care. Part A SNF residents almost always receive Part D benefits after their Part A benefits expire.

18. Five actors are involved in providing Medicare Part D benefits to SNF residents:

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- a. Medicare Part D beneficiaries – select the SNF where they will reside and receive care, and the Part D Plan that covers their medication costs. Beneficiaries do not select the LTC Pharmacies that provide their medications while they reside in a SNF.
- b. SNFs – care for Part D beneficiaries and other patients residing in their facilities. SNFs typically select a single LTC Pharmacy to provide the prescription medications for all of the SNF’s residents, including Part D beneficiaries. SNFs do not pay for LTC Pharmacy services covered by Part D; that responsibility falls to the Part D sponsors. Indeed, SNFs are generally not even aware of the rates negotiated by Part D sponsors and the LTC Pharmacies. SNFs do not contract with Part D sponsors for drug coverage.
- c. LTC Pharmacies (e.g., Omnicare and PharMerica) – dispense and deliver medication for the SNFs’ residents, typically on an exclusive basis. LTC Pharmacies contract with (and receive reimbursement payments from) Part D sponsors for providing pharmacy services to the sponsors’ beneficiaries residing at those SNFs with which the LTC Pharmacy has a contract.
- d. Part D sponsors – offer Medicare beneficiaries, including those residing in SNFs, Part D prescription drug plans. Sponsors contract with and pay LTC Pharmacies to provide medications to their beneficiaries residing in SNFs serviced by the LTC Pharmacy.
- e. CMS – approves and contracts with private sponsors that provide Part D Plans to Medicare beneficiaries. CMS subsidizes the majority (approximately 74.5%) of each Part D Plan’s costs.

19. CMS regulations require each Part D sponsor to provide “convenient access” to LTC Pharmacies for plan beneficiaries residing at SNFs. If a sponsor does not meet its “convenient

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access” obligation, CMS may prohibit the sponsor from offering Part D Plans in all or part of the country.

**VII.****THE RELEVANT PRODUCT MARKET**

20. The relevant product market in which to analyze the competitive effects of the Acquisition is the sale of LTC Pharmacy services to Part D sponsors for their SNF resident beneficiaries.

21. An appropriate relevant product or service market is found by determining whether a hypothetical monopolist of LTC Pharmacy products and services could profitably raise prices by a small but significant amount. Due to CMS regulations and the needs of Part D Plan beneficiaries residing in SNFs, no other services are reasonably interchangeable with those provided by LTC Pharmacies. Part D Plan beneficiaries residing in SNFs are typically immobile, cognitively impaired, or severely ill, and require medication to be ordered, delivered and administered to them at regular intervals. CMS regulations require Part D sponsors to establish LTC Pharmacy networks to meet the special pharmaceutical needs of their SNF resident beneficiaries. Accordingly, Part D sponsors could not substitute retail or mail order pharmacy services, or any other type of service, for LTC Pharmacy services.

**VIII.****THE RELEVANT GEOGRAPHIC MARKET**

22. The relevant geographic market in which to analyze the effects of the Acquisition is the United States.

23. An appropriate geographic market is determined by examining the geographic boundaries within which a hypothetical monopolist for the services at issue could profitably raise prices by a small but significant amount.

24. Part D Plans provide benefits to their beneficiaries throughout the country. Part D sponsors typically contract with

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LTC Pharmacies to provide pharmacy services from all of their locations in the United States. A hypothetical monopolist controlling all of the LTC Pharmacies in the country could profitably increase prices to Part D sponsors for LTC Pharmacy services by at least a small but significant amount.

25. Omnicare's and PharMerica's own documents and statements to investors assess market share on a national level and focus on providing LTC Pharmacy services to Part D sponsors nationally. CMS, Part D sponsors, and PBMs (contracting on behalf of Part D sponsors), confirm that Part D sponsors purchase LTC Pharmacy services nationally.

**IX.****MARKET STRUCTURE AND THE ACQUISITION'S  
PRESUMPTIVE ILLEGALITY**

26. Part D sponsors satisfy CMS's "convenient access" requirement by contracting with LTC Pharmacies that contract with SNFs. Each SNF bed is served by only one LTC Pharmacy, since each SNF typically enters into an exclusive contract with one LTC Pharmacy. The number and share of SNF beds that a LTC Pharmacy has under contract reflects that LTC Pharmacy's importance to a sponsor's Part D Plan network and ability to satisfy CMS's "convenient access" requirement. Therefore, shares in the relevant market are best measured by the number of licensed SNF beds a LTC Pharmacy services. In its business documents and in statements to investors, Omnicare routinely uses the number of SNF beds to measure its market share.

27. The Acquisition reduces the number of national LTC Pharmacies in the United States from two to one, leaving only small, regional and local pharmacies to compete with Omnicare post-Acquisition. Omnicare's post-Acquisition market share would be approximately 57%, as measured by licensed SNF beds. Under relevant case law and the Merger Guidelines, the Acquisition is presumptively unlawful.

28. The Merger Guidelines measure market concentration using the Herfindahl-Hirschman Index ("HHI"). Under that test, a merger or acquisition is presumed likely to create or enhance

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market power (and presumed illegal) when the post-merger HHI exceeds 2,500 points and the merger or acquisition increases the HHI by more than 200 points. The market concentration levels here exceed these thresholds by a wide margin. The post-Acquisition HHI level would be at least 3,253, with an increase of 1,404 points. The HHI figures are summarized in the following table.

<b>LTC Pharmacy</b>	<b>Pre-Acquisition Market Share</b>	<b>Post-Acquisition Market Share</b>
Omnicare	%	57%
PharMerica	%	--
Next Largest LTC Pharmacy	2%	2%
All others combined	41%	41%
<b>Pre-Acquisition HHI</b>		at least 1,849
<b>Post-Acquisition HHI</b>		at least 3,253
<b>HHI Increase</b>		1,404

**X.****ANTICOMPETITIVE EFFECTS**

29. Omnicare currently possesses considerable bargaining leverage over Part D sponsors because it controls a high percentage of the SNF beds in this country. Omnicare uses that leverage to obtain better prices and other more favorable contract terms than other LTC Pharmacies.

30. Omnicare has substantial leverage in negotiations with sponsors because even now there is doubt among Part D sponsors that they could meet CMS's "convenient access" requirement without Omnicare in their networks. Since Part D went into effect in 2006, CMS has not had occasion to reach a conclusion as to whether or not a participating Part D Plan must include Omnicare in its network. But Omnicare has exploited Part D sponsors'

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uncertainty about the need to have Omnicare in their networks to extract higher prices and better terms because sponsors doubt that they could offer their plans at all without reaching an agreement with Omnicare. If a Part D sponsor fails to obtain CMS approval to offer a Part D Plan, it would affect more than just the sponsor's beneficiaries residing in SNFs – the affected Part D sponsor would be barred from participating in Medicare Part D, which would mean losing an entire line of business, and for many sponsors, losing millions of beneficiaries and millions of dollars in revenues.

31. Before Omnicare's CEO, John Figueroa opened negotiations with one of the largest Part D sponsors, he asked his chief negotiator:

chief negotiator responded:

His

■ ■ ■ ■ ■ |  
■  
■

32. Omnicare also derives negotiating leverage from the fact that, if Omnicare and a Part D sponsor fail to reach an agreement, the Part D sponsor would likely lose most, if not all, of its beneficiaries residing in Omnicare-served SNFs. If Omnicare refuses to participate in a Part D sponsor's network, affected SNFs would likely assist the sponsor's beneficiaries to switch to a covered Part D Plan rather than switching LTC Pharmacies. CMS regulations are designed to provide SNF residents with tremendous flexibility in selecting a Part D Plan, and CMS specifically contemplates that SNF residents will select a Part D Plan that includes the SNF's LTC Pharmacy in its network. The SNFs' other options would be to either bring in a second LTC Pharmacy to serve the out-of-network Part D Plan's beneficiaries, or switch LTC Pharmacies altogether. Neither of these options are likely because they would: upset the exclusive relationship

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that exists between the SNF and its LTC Pharmacy; increase the risk of medication errors; and create other administrative, regulatory, and coordination of care problems.

33. In a number of recent negotiations, Omnicare has threatened to terminate its contracts with Part D sponsors to obtain higher prices and better terms. Part D sponsors have capitulated to Omnicare's demands to avoid the substantial risk of not having Omnicare in their networks.

34. Omnicare's own documents and statements demonstrate that Omnicare currently has unique bargaining leverage because of its share of SNF beds. For example, in a recent public statement to financial analysts and investors, John Figueroa, Omnicare's CEO, stated:

[Omnicare] basically control[s] 50% of the patient, you know, population in the nursing home agencies. So it is pretty difficult for a patient who walks into a nursing home that is contracted with Omnicare to pick a new pharmacy. I mean they can't do it. The easier thing for them to do is actually change their [Part D Plan]. . . . So with that type of leverage and market share, you know, we're in a different and unique position when we're negotiating our contracts with [Part D Plans].

Omnicare's description of the negotiating dynamics are consistent with the tactics it employs in its negotiations with the Part D sponsors and their outcomes.

35. The CEO's view is not an isolated one within the company. In documents prepared for investor meetings, Omnicare executives wrote that,

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36. Omnicare acknowledges that, as the largest LTC Pharmacy in the country, Part D sponsors would find it difficult to meet their beneficiaries' needs without Omnicare in their networks, and that this fact gives Omnicare significant bargaining leverage. For example, in a document prepared for an earnings call, Omnicare wrote that,

Just weeks before launching its hostile tender offer, Omnicare explained to potential lenders:

37. As the country's second-largest LTC Pharmacy, PharMerica also has leverage in negotiations with Part D sponsors, though substantially less than that of Omnicare. PharMerica has fewer SNF beds under contract than Omnicare does, therefore it is less likely that CMS would determine that a Part D Plan would not meet the "convenient access" requirement without PharMerica in its network. As a result, PharMerica generally receives lower prices and other less favorable terms than Omnicare.

38. Post-Acquisition, the combined firm would almost certainly become a "must have" for every Part D sponsor. At a minimum, it would be much less likely that any Part D Plan could meet CMS's "convenient access" requirement without the combined firm in its network. As the Chief Medical Officer of the Center for Medicare at CMS, testified:

While some ambiguity may exist as to whether a Sponsor could drop either PharMerica or Omnicare from its LTC pharmacy network, that ambiguity would be eliminated by the companies' proposed consolidation. Post-consolidation it would be virtually impossible for a Sponsor to establish convenient access without the combined firm in its network due to the sheer number of LTC pharmacies that Omnicare would own.

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39. Post-Acquisition, Omnicare would use its substantially greater bargaining leverage as a “must have” to increase prices for Part D sponsors to levels significantly above those that sponsors currently pay Omnicare or PharMerica. Indeed, PharMerica’s CEO testified that

40. Even if Part D sponsors could exclude the combined firm from their LTC Pharmacy networks and meet CMS’s “convenient access” requirement, Omnicare would possess a substantially greater number of exclusive SNF relationships post-Acquisition. A number of those SNFs, especially larger chains, consider Omnicare and PharMerica to be their two best choices for LTC Pharmacy services. The Acquisition, therefore, decreases the already low likelihood that SNFs would switch LTC pharmacies if Omnicare were to withdraw from a Part D sponsor’s network. As a result, the Acquisition will further entrench Omnicare’s bargaining leverage in negotiations with Part D sponsors and give it the ability and incentive to extract higher prices and other more favorable terms.

41. If Part D sponsors have higher LTC Pharmacy costs as a result of the Acquisition, these increased costs will likely be passed on to CMS and in the end, largely borne by U.S. taxpayers, as the federal government subsidizes the majority of Part D’s costs. Medicare Part D beneficiaries likely also will pay higher costs since Part D sponsors will have to cover some or all of the remainder of the cost increases with higher premiums, co-pays, and deductibles.

42. According to CMS, “Omnicare’s proposed acquisition of PharMerica appears likely to result in higher reimbursement rates (or to slow the likely decline in reimbursement rates) and thereby to increase the cost to CMS (and therefore the U.S. government and U.S. taxpayers) as well as any individuals who pay out-of-pocket costs in connection with such services.” CMS’s testimony is confirmed by the testimony of a number of the largest Part D sponsors.

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**XI.****ENTRY CONDITIONS**

43. Neither entry by new LTC Pharmacies, nor expansion by the remaining small, local and regional LTC Pharmacies, will deter or counteract the Acquisition's likely harm – higher prices paid by Part D sponsors (and others) as a result of the combined firm's increased bargaining leverage.

44. Typically, entry sufficient to counteract the anticompetitive effects of an acquisition is likely where higher post-acquisition prices induce firms to quickly enter the relevant market, providing additional supply and competition which ultimately drive prices back down. That competitive mechanism is absent here. The higher prices charged by the combined entity to Part D sponsors post-Acquisition are not likely to provide timely market opportunities for other LTC Pharmacies to win SNF business because any post-Acquisition price increases to Part D sponsors will likely not impact SNFs. If no opportunity is created to win additional SNF business, no new or fringe LTC Pharmacy is likely to be able to undermine the leverage against Part D sponsors that Omnicare will gain by acquiring PharMerica. Indeed, to the extent that the combined entity chooses to offer slightly better terms to SNFs for their Medicare Part A business after it raises its prices to Part D sponsors, Omnicare will be able to further entrench its share of SNF beds, and hence, its leverage against the Part D sponsors.

45. Only the combined firm will benefit from the expected price increase to Part D sponsors. New LTC Pharmacy entrants (and fringe players) will not benefit from the higher Part D rates because they will not have the bargaining leverage necessary to obtain those rates from Plan D sponsors. For this reason too, the post-Acquisition elevated Part D prices will not encourage entry into the LTC Pharmacy market, and will not reduce the combined firm's bargaining leverage.

46. The remaining small, local and regional LTC Pharmacies are not likely to grow significantly after the Acquisition. Even if they were to do so, they would need to grow to more than twenty times their current size to even approach Omnicare's share post-

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Acquisition, and even then, they would not be able to undermine Omnicare's increased bargaining leverage unless their twenty-fold growth came primarily at Omnicare's expense. Such growth (or entry on such a scale) is highly unlikely to occur in a timely manner sufficient to undermine Omnicare's leverage with Part D sponsors.

**XII.****EFFICIENCIES**

47. Respondent Omnicare will be unable to establish the existence of significant, cognizable, and merger-specific efficiencies sufficient to counteract the anticompetitive effects of the Acquisition.

**XIII.****VIOLATIONS**

48. The allegations of Paragraphs 1 through 47 above are incorporated by reference as though fully set forth herein.

49. The Acquisition, if consummated may substantially lessen competition in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and would be an unfair method of competition in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**NOTICE**

Notice is hereby given to the Respondent that the twenty-seventh day of June, 2012, at 10:00 a.m. is hereby fixed as the time, and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

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You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14th) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the answer is filed by the Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the answer is filed by the Respondent). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondent's answer,

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to make certain initial disclosures without awaiting a discovery request.

**NOTICE OF CONTEMPLATED RELIEF**

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 7 of the Clayton Act, as amended, or Section 5 of the FTC Act, as amended, the Commission may order such relief against Respondent as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant market, with the ability to offer such products and services as Omnicare and PharMerica were offering and planning to offer prior to the Acquisition.
2. A prohibition against any transaction between Omnicare and PharMerica that combines their businesses in the relevant market, except as may be approved by the Commission.
3. A requirement that, for a period of time, Omnicare and PharMerica provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant market with any other company operating in the relevant market.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the Acquisition or to restore PharMerica as a viable, independent competitor in the relevant market.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its

## Final Order

official seal to be hereto affixed, at Washington, D.C., this twenty-seventh day of January, 2012.

By the Commission, Commissioner Rosch dissenting.

**ORDER DISMISSING COMPLAINT**

On January 27, 2012, the Federal Trade Commission issued the Administrative Complaint in this matter, having reason to believe that Respondent Omnicare, Inc.'s cash tender offer to acquire PharMerica Corporation, if consummated, would violate Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Complaint Counsel and Respondent have now filed a Joint Motion to Dismiss Complaint, which states that Respondent is abandoning the proposed acquisition of PharMerica, and has withdrawn its Hart-Scott-Rodino Notification and Report Form filed for the proposed transaction.<sup>1</sup>

The Commission has determined to dismiss the Administrative Complaint without prejudice, as the most important elements of the relief set out in the Notice of Contemplated Relief in the Administrative Complaint have been accomplished without the need for further administrative litigation.<sup>2</sup> In particular, Respondent has announced that it is abandoning the proposed acquisition of PharMerica, and has withdrawn its Hart-Scott-Rodino Notification and Report Form

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<sup>1</sup> See Joint Motion To Dismiss Complaint (February 21, 2012), at <http://www.ftc.gov/os/adjpro/d9352/120221omnicaremtn.pdf>.

<sup>2</sup> See, e.g., *In the Matter of Thoratec Corporation and HeartWare International, Inc.*, Docket No. 9339, Order Dismissing Complaint (August 11, 2009), at <http://www.ftc.gov/os/adjpro/d9339/090811thoatecorder.pdf>; *In the Matter of CSL Limited and Cerberus-Plasma Holdings, LLC*, Docket No. 9337, Order Dismissing Complaint (June 22, 2009), at <http://www.ftc.gov/os/adjpro/d9337/090622commorderdismisscomplaint.pdf>.

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filed for the proposed transaction. As a consequence, the Respondent would not be able to effect the proposed transaction without filing a new Hart-Scott-Rodino Notification and Report Form.

For the foregoing reasons, the Commission has determined that the public interest warrants dismissal of the Administrative Complaint in this matter. The Commission has determined to do so without prejudice, however, because it is not reaching a decision on the merits. Accordingly,

**IT IS ORDERED THAT** the Administrative Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

## Complaint

## IN THE MATTER OF

**AMERIGAS PROPANE, L.P.,  
AMERIGAS PROPANE, INC.,  
ENERGY TRANSFER PARTNERS, L.P.,  
AND  
ENERGY TRANSFER PARTNERS, GP, L.P.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4346; File No. 121 0022  
Complaint, January 10, 2012 – Decision, February 24, 2012*

This consent order addresses the \$2.9 billion acquisition by AmeriGas Propane, L.P. of four entities owned by ETP, Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partner, L.P., and Titan Energy GP, L.L.C. The complaint alleges that the acquisition, as originally proposed, would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by substantially lessening competition in the market for preparing, filling, distributing and selling propane exchange cylinders in the United States and in certain regional areas within the United States. The consent order requires the Respondents to comply with all the terms of Amendment 2, including all terms pertaining to the provision of transition services by AmeriGas to Heritage Propane Express, LLC until such time as Heritage Propane Express, LLC is sold to another entity, or, barring a sale, for a period of one year. The Order also requires that, for a period of two years, ETP cannot sell the Heritage Propane Express assets without prior written approval of the Commission.

*Participants*

For the *Commission*: Tom Dahdouh, Susan Huber and Erika Wodinsky.

For the *Respondents*: Alan D. Rutenberg and Jay Varon, *Foley & Lardner LLP*; William D. Vigdor, *Vinson & Elkins*.

**COMPLAINT**

Pursuant to the Clayton Act and Federal Trade Commission Act (“FTC Act”), and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent AmeriGas Propane, L.P. (“AmeriGas”), intends to

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acquire the assets of Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partners, L.P., and Titan Energy GP, L.L.C., from Respondent Energy Transfer Partners, L.P. (“ETP”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows.

**I. RESPONDENTS**

1. Respondent AmeriGas is a limited partnership, organized, existing, and doing business, under, and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 460 North Gulph Road, King of Prussia, Pennsylvania 19406. Respondent AmeriGas is engaged in the marketing and sale of propane and propane supply related services, including the distribution and supply of bulk propane to residential, commercial, and agricultural customers, and the preparing, filling, distributing, marketing, and sale of 20 lb. portable cylinders prefilled with propane, typically used by consumers for barbeque grills or other purposes (hereinafter referred to as “propane exchange cylinders”).

2. Respondent AmeriGas Propane, Inc. is a corporation, organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its office and principal place of business located at 460 North Gulph Road, King of Prussia, Pennsylvania 19406. Respondent AmeriGas Propane, Inc., is the general partner of Respondent AmeriGas, and is a wholly-owned subsidiary of UGI Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania.

3. Respondent ETP is a limited partnership, organized, existing, and doing business under and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 3738 Oak Lawn Avenue, Dallas, Texas 72519. Respondent ETP is engaged in, among other things, the marketing

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and sale of propane and propane supply related services, including the distribution and supply of bulk propane to residential, commercial, and agricultural customers, and the preparing, filling, distributing, marketing, and sale of propane exchange cylinders.

4. Respondent Energy Transfer Partners GP, L.P. (“ETP GP”) is a limited partnership, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 8801 South Yale Ave., Suite 310, Tulsa, OK 74137. Respondent ETP GP is the general partner of Respondent ETP.

5. The office and principal place of business of the four entities to be acquired, Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partners, L.P., and Titan Energy GP, L.L.C., is 8801 South Yale Avenue, Suite 310, Tulsa, Oklahoma 74137. These four entities are subsidiaries of ETP.

6. Heritage Operating, L.P. has done business as Heritage Propane Express. ETP has engaged in the preparing, filling, distribution, marketing, and sale of propane exchange cylinders primarily or exclusively through this Heritage Propane Express division.

7. Respondents AmeriGas, AmeriGas Propane, Inc., ETP, and ETP GP are, and at all times relevant herein, have been engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are partnerships or corporations whose businesses are in or affect commerce, as “commerce” is defined in Section 4 of the FTC Act, as amended, 15 U.S.C. § 44.

## **II. THE PROPOSED ACQUISITION**

8. Pursuant to a Contribution and Redemption Agreement dated October 15, 2011, AmeriGas proposed to acquire all of the noncorporate assets of Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partners, L.P., and Titan Energy GP, L.L.C.

9. In November 2011, Commission staff advised Respondents of potential competitive issues and concerns in connection with AmeriGas’s proposed acquisition of certain

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propane assets of Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partners, L.P., and Titan Energy GP, L.L.C., used in connection with the preparation, filling, distributing, marketing and sale of propane exchange cylinders. These assets included, but were not limited to production facilities, depots, district offices, employees, cylinders, delivery trucks, cages used by retail locations to display and dispense exchange cylinders, customer contracts, trademarks, computer and information technology systems, and contracts providing for access to the supply of bulk propane necessary to fill propane exchange cylinders (hereinafter referred to as “exchange cylinder assets”).

10. After being advised by Commission staff of potential competitive concerns regarding the exchange cylinder assets, Respondents informed Commission staff of their willingness to enter into an amendment to the Contribution and Redemption Agreement, referred to in Paragraph 8 above, to exclude the exchange cylinder assets from the proposed acquisition.

11. Amendment 2 to the Contribution and Redemption Agreement (“Amendment 2”) excludes the exchange cylinder assets from the assets that Respondent AmeriGas will acquire from Respondents ETP and ETP GP. In addition, it requires that Respondents ETP and ETP GP will continue to own and operate the exchange cylinder assets through Heritage Propane Express, LLC, a Delaware limited liability corporation and wholly-owned subsidiary of ETP. Amendment 2 also requires AmeriGas to temporarily provide to Heritage Propane Express, LLC certain specified transition services currently provided by the businesses that AmeriGas is acquiring so that the exchange cylinder assets of Heritage Propane Express, LLC can continue to be used in the preparing, filling, distributing, marketing and sale of propane exchange cylinders.

### III. THE RELEVANT MARKETS

12. For purposes of this Complaint, the relevant line of commerce in which to analyze the effects of this acquisition is the preparing, filling, distributing, marketing and sale of propane exchange cylinders for large multi-state retail chains.

### Complaint

13. For purposes of this Complaint, the relevant geographic areas in which to analyze the effects of the acquisition are the United States and smaller regional areas.

#### **IV. THE STRUCTURE OF THE MARKET**

14. Consumers and commercial users of propane exchange cylinders typically utilize these cylinders for barbeque grills, patio heaters, and uses requiring the availability of propane in relatively small, portable tanks. Propane exchange cylinders offer consumers a way to obtain prefilled tanks. Many consumers prefer the convenience of obtaining prefilled cylinders rather than transporting the cylinders to commercial propane filling stations and refilling those cylinders. Many retailers also prefer the convenience and safety of selling properly prefilled exchange cylinders rather than maintaining large tanks of propane on retail premises, training employees to fill cylinders, and arranging for certifications usually required in connection with the inspection and filling of propane cylinders. In the past decade, the use of propane exchange cylinders has grown steadily, while refilling cylinders has declined. As a consequence, refilling cylinder services do not act as a competitive constraint on the price of propane cylinder exchange.

15. Prefilled cylinders for cylinder exchange purposes are generally delivered on a regular basis to cages located outside large national or regional retail establishments, as well as grocery, convenience, home improvement and hardware stores. These retail establishments then sell the prefilled cylinders to consumers. In most situations, consumers can choose whether to either purchase a cylinder that is prefilled with propane outright, or to exchange a used, empty exchange cylinder for another exchange cylinder that is prefilled with propane.

16. Many large multi-state retail chains require that their propane exchange cylinder suppliers have the scale and geographic scope of coverage to handle significant portions of their business. These chains also require that their propane exchange cylinder suppliers offer “just in time” deliveries to ensure that cages are continuously stocked with prefilled cylinders, particularly during peak holiday periods and weekends.

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17. The market for propane exchange cylinders suppliers that can service large multi-state retail chains is highly concentrated. There are three large propane exchange cylinder competitors in the United States. Ferrellgas Partners, L.P.'s "Blue Rhino" division is the largest supplier of propane exchange cylinders. AmeriGas is currently the second largest supplier of propane exchange cylinders in some or all of the relevant geographic areas through its AmeriGas Cylinder Exchange or "ACE" division.

18. ETP, through its Heritage Propane Express division, is the third largest supplier of propane exchange cylinders in some or all of the relevant geographic areas, providing propane exchange cylinders in 37 states. Heritage Propane Express is a maverick in the market for the distribution and sale of propane exchange cylinders by competing aggressively with Blue Rhino and ACE in terms of price and other terms and conditions. In some or all of the relevant geographic areas, Heritage Propane Express is the only viable alternative to Blue Rhino and ACE for a significant set of large multi-state retail chains.

19. If consummated, AmeriGas's initial proposed acquisition of ETP's propane assets, including the Heritage Propane Express division, pursuant to the original Contribution and Redemption Agreement, would reduce the number of cylinder exchange companies that can service multi-state chain retailers in all or a substantial part of the relevant geographic markets from three to two. It would also eliminate Heritage Propane Express, a low-priced competitor that has brought greater competition to the propane exchange cylinder marketplace for multi-state chain retailers. The current proposed acquisition pursuant to the terms set forth in Amendment 2 does not result in an increase in market concentration because it does not involve AmeriGas acquiring the Heritage Propane Express assets from ETP.

**V. ENTRY CONDITIONS**

20. Entry into the relevant market would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry into cylinder exchange involves two issues: the general cost of entry and the cost of entering at a sufficiently large scale to service large regional or national retailers. Timely entry at a

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scale that would be sufficient to provide services to a large regional or national customer is unlikely.

**VI. EFFECTS OF THE PROPOSED ACQUISITION**

21. Heritage Propane Express competes head-to-head with AmeriGas's ACE division in the market for the preparing, filling, distributing, marketing, and sale of propane exchange cylinders. The effects of the acquisition of the Heritage Propane Express assets by Respondent AmeriGas pursuant to the Contribution and Redemption Agreement, if consummated as originally proposed, may be to substantially lessen competition and to tend to create a monopoly in the relevant market in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways:

- a. by eliminating actual, direct and substantial competition between ACE and Heritage Propane Express in the market for propane exchange cylinders;
- b. by increasing the likelihood of, or facilitating, collusion or coordinated interaction between Blue Rhino and ACE in the relevant market by removing Heritage Propane Express, a maverick, from the marketplace;
- c. by increasing the likelihood that the merged entity will exercise market power unilaterally in the market for the provision of exchange cylinders to multi-state retail chains that sell these products to consumers; and
- d. by increasing the likelihood that consumers will be forced to pay higher prices for propane exchange cylinders due to the decrease in competition or the exercise of market power.

**VII. VIOLATIONS CHARGED**

22. AmeriGas's agreement to acquire Heritage Propane Express, as originally proposed in the Contribution and Redemption Agreement described in Paragraph 8, violates Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and if

## Decision and Order

consummated, constitutes a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this tenth day of January, 2012, issues its Complaint against said Respondents.

By the Commission.

**DECISION AND ORDER**  
**[Redacted Public Version]**

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent AmeriGas Propane, L.P. of certain assets of Respondent Energy Transfer Partners L.P. and Energy Transfer Partners GP, L.P., hereinafter referred to as Respondents, and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

## Decision and Order

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent AmeriGas Propane, L.P. is a limited partnership, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 460 North Gulph Road, King of Prussia, PA 19406.
2. Respondent AmeriGas Propane, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its office and principal place of business at 460 North Gulph Road, King of Prussia, PA 19406. AmeriGas Propane, Inc. is general partner of AmeriGas Propane, L.P and a wholly-owned subsidiary of UGI Corporation. UGI Corporation is a publically-traded corporation, organized, existing and doing business under and by virtue of the laws of the Commonwealth of Pennsylvania, with its office and principal place of business at 460 North Gulph Road, King of Prussia, PA 19406.
3. Respondent Energy Transfer Partners, L.P. is a publicly traded limited partnership, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 3738 Oak Lawn Avenue, Dallas, TX 75219.
4. Respondent Energy Transfer Partners GP, L.P. is a limited partnership, organized, existing and doing

## Decision and Order

business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 8801 South Yale Ave., Suite 310, Tulsa, OK 74137. Energy Transfer Partners GP, L.P. is the general partner of Energy Transfer Partners, L.P.

5. The Commission has jurisdiction over the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “AmeriGas” means AmeriGas Propane, L.P. and/or AmeriGas Propane, Inc. the directors, partners, officers, employees, agents, representatives, successors, and assigns of each; and their joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by AmeriGas Propane, L.P. or AmeriGas Propane, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each, and includes UGI Corporation, the parent of AmeriGas Propane, Inc.
- B. “ETP” means Energy Transfer Partners, L.P. and/or Energy Transfer Partners GP, L.P., the directors, partners, officers, employees, agents, representatives, successors, and assigns of each; and their joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Energy Transfer Partners, L.P. or Energy Transfer Partners GP, L.P., including but not limited to Heritage ETC and Heritage Propane Express, LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.

## Decision and Order

- D. “Acquisition” means the acquisition by AmeriGas of certain propane assets from ETP pursuant to the Contribution Agreement.
- E. “Amendment No. 2” means Amendment No. 2 to the Contribution Agreement, attached hereto as Confidential Appendix A, including the Cylinder Exchange Transition Services Agreement and all other annexes, schedules, exhibits, and amendments to the Amendment.
- F. “Buyer” means any person who, pursuant to the terms of this Order, acquires HPX from ETP.
- G. “Closing” means the consummation of the Acquisition under the Contribution Agreement.
- H. “Contribution Agreement” means the Contribution and Redemption Agreement, dated as of October 15, 2011, as amended, among Energy Transfer Partners, L.P., Energy Transfer Partners GP, L.P., Heritage ETC, L.P., and AmeriGas Partners, L.P., including Amendment No. 2.
- I. “Cylinder Exchange Business” means the business of preparing, distributing, marketing and selling 20-pound portable cylinders pre-filled with propane and collecting used 20-pound portable cylinders for refilling or disposal, within the territory of the United States. As used in this definition, 20-pound portable grill cylinders refer to cylinders that are designed to meet Department of Transportation specifications and are primarily used by consumers in barbeque grills.
- J. “Heritage Propane Express” or “HPX” means Heritage Propane Express, LLC, a limited liability company, organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business at 8801 South Yale Ave., Suite 310, Tulsa, OK 74137. Heritage Propane Express, LLC, is a wholly-owned indirect subsidiary of ETP. As used in this Order, “Heritage

## Decision and Order

Propane Express” and “HPX” shall refer to all rights and assets related to or used in any Cylinder Exchange Business in the possession or control of ETP after Closing, including all rights of ETP pursuant to Amendment No. 2.

**II.****IT IS FURTHER ORDERED** that:

- A. At or before Closing, Respondents shall amend the Contribution Agreement to include Amendment No. 2.
- B. Upon Closing, Amendment No. 2 shall be incorporated by reference into this Order and made a part hereof. Respondents shall comply with the terms of Amendment No. 2 and a breach by Respondents of any term of Amendment No. 2 shall constitute a violation of this Order. Further, Respondents shall not modify or amend Amendment No. 2 without the prior written approval of the Commission as provided in section 2.41(f) of the Commission’s Rules of Practice, 16 C.F.R. § 2.41(f). To the extent any term in Amendment No. 2 conflicts with the term in this Order such that Respondents cannot fully comply with both, Respondents shall comply with this Order.
- C. For a period lasting until two (2) years after Closing, Respondent ETP shall not sell, transfer or otherwise convey, directly or indirectly, any interest in HPX to any Person, in connection with the Acquisition or otherwise, without the prior approval of the Commission.
- D. For a period lasting ten (10) years after Closing, or until Respondent ETP no longer has an interest in a Cylinder Exchange Business, whichever comes first, Respondent ETP shall not acquire, directly or indirectly, any Cylinder Exchange Business, whether in connection with the Acquisition or otherwise, without providing prior written notification to the Commission before consummating any such

## Decision and Order

transaction; *provided, however,* that prior written notification shall not be required for the acquisition of any business with annual net sales in the United States derived from the Cylinder Exchange Business under \$22 million. For the avoidance of doubt, revenue from any sales, operations, or line of business other than a Cylinder Exchange Business shall not be included in determining if the revenue figure in this Paragraph is met.

*Further,* the prior written notification required by this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the Notification), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission, Notification need not be made to the United States Department of Justice, and Notification is required only of Respondent ETP and not of any other party to the transaction, unless otherwise expressly required by this Order. Respondent ETP shall provide the Notification to the Secretary of the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent ETP shall not consummate the transaction until thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Commission's Bureau of Competition; provided, however that Respondent ETP shall not be required to provide prior notification pursuant to this paragraph of a transaction for which notification is required to be made, and has

## Decision and Order

been made pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

- E. For a period lasting until ten (10) years after Closing, Respondent AmeriGas shall not acquire, directly or indirectly, any Cylinder Exchange Business, whether in connection with the Acquisition or otherwise, without providing prior written notification to the Commission before consummating any such transaction; *provided, however*, that prior written notification shall not be required for the acquisition of any business with annual net sales in the United States derived from the Cylinder Exchange Business under \$22 million. For the avoidance of doubt, revenue from any sales, operations, or line of business other than a Cylinder Exchange Business shall not be included in determining if the revenue figure in this Paragraph is met.

*Further*, the prior written notification required by this Paragraph shall be given on the Notification and Report Form set forth in the Appendix to Part 803 of Title 16 of the Code of Federal Regulations as amended (hereinafter referred to as the Notification), and shall be prepared and transmitted in accordance with the requirements of that part, except that no filing fee will be required for any such Notification, Notification shall be filed with the Secretary of the Commission, Notification need not be made to the United States Department of Justice, and Notification is required only of Respondent AmeriGas and not of any other party to the transaction, unless otherwise expressly required by this Order. Respondent AmeriGas shall provide the Notification to the Secretary of the Commission at least thirty (30) days prior to consummating any such transaction (hereinafter referred to as the "first waiting period"). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent AmeriGas shall not consummate the transaction until

## Decision and Order

thirty (30) days after submitting such additional information or documentary material. Early termination of the waiting periods in this Paragraph may be requested and, where appropriate, granted by letter from the Commission's Bureau of Competition; provided, however that Respondent AmeriGas shall not be required to provide prior notification pursuant to this paragraph of a transaction for which notification is required to be made, and has been made pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

- F. For a period lasting until up to one (1) year after Closing, Respondent AmeriGas shall, at the request of ETP or the Buyer, provide the services required in Amendment No. 2 ("Transition Services") in a manner sufficient to permit ETP or the Buyer to operate HPX in the same manner in all material respects equivalent to the manner in which ETP operated its Cylinder Exchange Business prior to Closing. Further, if ETP sells HPX to a Buyer within a year of Closing, AmeriGas shall, at the request of the Buyer, provide such Buyer with Transition Services for a period of up to six months, which period may, at the option of the Buyer be extended for up to an additional six months (this sentence is intended to enable a Buyer to receive Transition Services for up to twelve (12) months).
- G. For a period lasting until two (2) years after Closing, or Respondent ETP retains no interest in a Cylinder Exchange Business, whichever comes first; Respondent ETP shall (i) operate HPX in a manner that maintains its full economic viability and marketability and minimizes the risk of any loss of competitive potential, and prevents the destruction, removal, wasting, deterioration or impairment of any assets of HPX; and (ii) upon the sale of HPX, transfer the HPX assets in a manner that retains their full economic viability and provide such services and assistance to the Buyer as are reasonably necessary to enable the Buyer to operate HPX in a manner at least

## Decision and Order

equivalent to the manner in which it was operated by ETP.

- H. The purpose of this Decision and Order is to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint, and to assure that HPX remains viable, independent and competitive.

**III.****IT IS FURTHER ORDERED** that

- A. Respondent AmeriGas shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
1. Thirty (30) days after the Order becomes final;
  2. Six (6) months after the Order becomes final and every six months thereafter so long as Respondent AmeriGas is obligated to provide Transition Services pursuant to the Order; and
  3. Annually for ten (10) years after the Order becomes final.
- B. Respondent ETP shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order:
1. Thirty (30) days after the Order becomes final;
  2. Six months (6) after the Order becomes final and every six months thereafter for two (2) years; and
  3. Annually, for ten (10) years after the Order becomes final.

*Provided, however,* that ETP shall not be required to provide reports under this Paragraph if it no longer

## Decision and Order

owns, directly or indirectly, any interest in a Cylinder Exchange Business.

- C. For purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to a Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:
1. access, during business office hours of Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
  2. to interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

**IV.**

**IT IS FURTHER ORDERED** that

- A. Respondents shall notify the Commission at least thirty (30) days prior to:
1. any proposed dissolution of such Respondents;
  2. any proposed acquisition, merger or consolidation of Respondents; or

## Analysis to Aid Public Comment

3. any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

**V.**

**IT IS FURTHER ORDERED** that this Order shall terminate on January 10, 2022.

By the Commission.

**CONFIDENTIAL APPENDIX A****Amendment No. 2 to the Contribution Agreement**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT****I. Overview**

The Federal Trade Commission has accepted an Agreement Containing Consent Order (“Proposed Order”) with AmeriGas Propane, L.P. (“AmeriGas”), AmeriGas Propane, Inc., Energy Transfer Partners, L.P. (“ETP”), and Energy Transfer Partners GP, L.P. (“ETP GP”), which is designed to guard against possible anticompetitive effects that would likely result from the transaction as originally proposed.

## Analysis to Aid Public Comment

On October 15, 2011, AmeriGas entered into an agreement with ETP and ETP GP in which AmeriGas proposed to acquire ETP's Heritage Propane business through the approximately \$2.9 billion acquisition of four entities owned by ETP, Heritage Operating, L.P., Heritage GP, LLC, Titan Energy Partner, L.P., and Titan Energy GP, L.L.C. ETP's Heritage Propane business includes Heritage Propane Express, an entity that is engaged in the business of preparing, filling, distributing and selling portable cylinders prefilled with propane commonly used for barbecue grills (referred to herein as "propane exchange cylinders"). The AmeriGas Cylinder Exchange or "ACE" division is also engaged in the business of preparing, filling, distributing and selling exchange cylinders, and is the second largest provider of propane exchange cylinders in the United States. In response to competitive concerns raised by Commission staff regarding AmeriGas's purchase of the Heritage Propane Express Business, the parties subsequently proposed a modified transaction that excludes those assets. The Order, as accepted by the Commission, settles charges that the acquisition, as originally proposed, may have substantially lessened competition in the market for preparing, filling, distributing and selling propane exchange cylinders in the United States and in certain regional areas within the United States.

**II. The Parties**

AmeriGas, a limited partnership, is the largest propane distribution company in the United States. Its ACE division supplies prefilled propane exchange cylinders to retailers who then sell those cylinders to consumers. AmeriGas is the second largest supplier and marketer of propane exchange cylinders.

ETP GP is a publicly traded partnership and the general partner of ETP, which is also a publicly traded partnership. ETP is engaged in the business of supplying propane exchange cylinders through its Heritage Propane Express division. Heritage Propane Express is the third largest supplier and marketer of propane exchange cylinders in the country with operations in 37 states.

## Analysis to Aid Public Comment

**III. The Products and the Structure of the Market**

Propane exchange cylinders, often referred to as 20 pound DOT cylinders,<sup>1</sup> are small, portable tanks that can be filled with propane, and that are used primarily for barbeque grills, patio heaters, and mosquito magnets. At one time, the only option for consumers who needed to purchase propane for these uses was to purchase empty cylinders and take them to locations where they could have the cylinders filled. Starting in the 1990's cylinder exchange became popular. This option allows consumers to purchase a prefilled cylinder which can then be exchanged for a clean prefilled cylinder when the fuel in the first cylinder has been used. The consumer exchanging an empty cylinder for a full one typically pays only for the propane. Exchange cylinders are available for purchase and exchange at various locations, including grocery stores, home improvement stores, hardware stores, big box stores, conveniences stores, and gas stations. Although consumers have the option of refilling these cylinders, many prefer the convenience of purchasing prefilled exchange cylinders that have been cleaned and safety tested by the supplier before they are sold. Many retailers also prefer the convenience and possible safety benefits of selling prefilled exchange cylinders rather than arranging to have large propane tanks on their premises and training employees to perform refilling services. For these reasons, the use of propane exchange cylinders has grown, and the refilling of cylinders has declined over the last ten years. As a consequence of these changes in demand, refilling cylinders does not provide a competitive constraint on the price of propane cylinder exchange services.

Companies that distribute and sell propane exchange cylinders typically provide the following services, either directly or indirectly: cylinder preparation (including cleaning, rust removal, repainting and valve repairs for the cylinders); refilling with a designated amount of propane; marketing and distribution

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<sup>1</sup> The metal cylinders can hold approximately 25 pounds of propane, but for safety reasons, can only be filled to 80% capacity, or approximately 20 pounds. In the marketplace at this point in time, most exchange cylinders are only filled with 15 to 17 or so pounds of propane. The reference in this Analysis is intended as a description of the size and type of cylinder, and is not a reference to actual fill levels.

## Analysis to Aid Public Comment

(including delivery and retrieval of cylinders, and placement and maintenance of cages that display and dispense exchange cylinders at retail locations); and sale of exchange cylinders.

#### **IV. The Complaint**

The Complaint alleges that the market for propane exchange cylinder services that can serve large multi-state chain retailers is highly concentrated. Large multi-state retail chains generally require that their propane exchange cylinder suppliers have the scale and geographic scope of coverage to handle significant portions of their business. These retailers also require that their propane exchange cylinder suppliers offer “just in time” deliveries to ensure that cages are continuously stocked with prefilled cylinders, particularly during peak holiday periods and weekends. Currently, there are only three suppliers that can provide propane exchange cylinder services to such retailers: Ferrellgas Partners, L.P.’s “Blue Rhino” division, the largest provider of propane exchange cylinder services on a national and regional basis; AmeriGas’s ACE, the second largest provider of propane exchange cylinder services; and ETP’s Heritage Propane Express, the third largest provider of these services. The Complaint alleges that AmeriGas’s acquisition of the Heritage Propane Exchange assets, as originally proposed, would have reduced the number of companies that can supply these services to multi-state retail chains from three to two.

The Complaint further alleges that Heritage Propane Express played the role of a disruptive “maverick,” offering lower prices and better terms and conditions than the other two large players. In addition, the Complaint alleges that entry into the market for supply of propane exchange cylinder services to large multi-state chain retailers is not likely to be timely or sufficient to defeat a price increase due to the large scale of entry needed to service large national or regional retailers requiring reliable distribution services in many locations.

The Complaint alleges that the effect of the acquisition, as originally proposed, may be to substantially lessen competition by, *inter alia*, increasing the likelihood of collusion or coordinated interaction among the remaining two large

## Analysis to Aid Public Comment

competitors by removing Heritage Propane Express, a disruptive force in the marketplace.

**V. The Modified Transaction**

AmeriGas, AmeriGas Propane, Inc., ETP and ETP GP have now entered into an amendment to their original agreement. Pursuant to this amendment (“Amendment 2”), AmeriGas will not acquire the Heritage Propane Express assets. Rather, they will continue to be operated by ETP through a new subsidiary, Heritage Propane Express, LLC, until such time as ETP decides to sell those assets. However, because Heritage Propane Express, LLC will no longer have access to certain back office and propane supply services that will be transferred to AmeriGas, AmeriGas is required to make such services available to Heritage Propane Express, LLC at cost for a specified period of time. This provision will allow Heritage Propane Express, LLC to continue to function as a viable entity. Amendment 2 contains a number of other provisions addressing the provision of transition services that are likely to be needed. Because Amendment 2 contains competitively sensitive information, the details of the transition services are not publicly available.

**VI. The Order**

The Order remedies the Commission’s competitive concerns raised by the original transaction, as proposed.

The Order incorporates Amendment 2, described above, into the Order and requires the Respondents to comply with all the terms of that document, including all terms pertaining to the provision of transition services by AmeriGas to Heritage Propane Express, LLC until such time as Heritage Propane Express, LLC is sold to another entity, or, barring a sale, for a period of one year. The specified transition services include access to propane supply under specified terms.

Section II.C of the Order requires that, for a period of two years, ETP cannot sell the Heritage Propane Express assets without prior written approval of the Commission. This ensures that the Commission will have an opportunity to review a future sale of these assets, particularly if the assets would not be

## Analysis to Aid Public Comment

reportable under the Hart-Scott-Rodino Antitrust Improvements Act. Section II.D requires ETP to provide prior notification to the Commission before acquiring any other cylinder exchange businesses for the next 10 years. Section II.E similarly requires AmeriGas to provide prior notification to the Commission before acquiring any other cylinder exchange businesses for the next 10 years. Both II.D and II.E provide that prior notification is not necessary for transactions that fall under a certain threshold in terms of the annual sales of propane exchange cylinders by any company that they propose to acquire.

Section II.F addresses the availability of the transition services outlined in Amendment 2. It requires that AmeriGas make these transition and supply services available to ETP for up to one year, so that Heritage Propane Express, LLC can be operated as a viable entity. If that company is sold within one year, Section II.F requires that AmeriGas provide transition and propane supply services to Heritage Propane Express's buyer for a period of six months, with an option to extend the arrangement for another six months. These provisions are designed to ensure that the Heritage Propane Express assets will continue to be viable as a stand-alone propane exchange cylinder business and that any new purchaser will have the necessary services and supply for a short transition period. Section II.G requires ETP to operate the Heritage Propane Express assets in a manner that maintains their economic viability for a period of two years or until ETP no longer holds an interest in the assets.

The remaining Order provisions are standard reporting requirements to allow the Commission to determine on-going compliance with the provisions of the Order.

## Analysis to Aid Public Comment

**VII. Opportunity for Public Comment<sup>2</sup>**

The Final Order has been placed on the public record for 30 days to receive comments from interested parties. Comments received during this period will become part of the public record. After 30 days, the Commission will review the comments received and determine whether to take further action. The purpose of this analysis is to facilitate comment on the Consent Agreement and Order. This analysis does not constitute an official interpretation of the Consent Agreement or Order, nor does it modify its terms in any way. The Consent Agreement does not constitute an admission by AmeriGas, ETP or ETP GP that they have violated the law or that the facts as alleged in the Complaint, other than the jurisdictional facts, are true.

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<sup>2</sup>The Commission normally will issue an order for public comment but not issue a final order until it considers all comments received during the comment period. Here, however, consistent with Commission Rule 2.34(c), 16 C.F.R. § 2.34(c), the Commission has issued the Final Order in advance of the comment period. The Commission took this step to avoid any unnecessary and potentially costly delay to the larger underlying transaction involving the sale of ETP's bulk propane business, which is not the subject of the Order, and is a highly seasonal business; that is, the market for bulk propane and related services is greatest during the winter and early spring. After the public comment period, the Commission will have the option to initiate a proceeding to reopen and modify the Decision and Order or commence a new administrative proceeding if the public comments lead it to believe that such action is appropriate.

## Complaint

## IN THE MATTER OF

**SIGMA CORPORATION**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4347; File No. 101 0080**Complaint, February 27, 2012 – Decision, February 27, 2012*

This consent order addresses Sigma Corporation's business methods, which made it easier to coordinate price levels through an entity known as the Ductile Iron Fittings Research Association. The complaint alleges that Sigma violated Section 5 of the Federal Trade Commission Act by inviting McWane and Star to collude with Sigma to increase DIPF prices in early 2009. The consent order prohibits Sigma from participating in or maintaining any combination or conspiracy between any competitors to fix, raise or stabilize the prices at which DIPF are sold in the United States, or to allocate or divide markets, customers, or business opportunities.

*Participants*

For the *Commission*: Christopher G. Renner.

For the *Respondent*: Douglas Jasinski, White & Case LLP.

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondent Sigma Corporation ("Sigma") has violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

**NATURE OF THE CASE**

1. This action concerns Sigma's unfair methods of competition relating to the marketing and sale of ductile iron pipe fittings ("DIPF").

## Complaint

2. Beginning in January 2008 and continuing through January 2009, Sigma, along with its competitors McWane, Inc. (“McWane”) and Star Pipe Products, Ltd. (“Star”), conspired to raise and stabilize the prices at which DIPF are sold in the United States. Sigma, McWane and Star (collectively, the “Sellers”) exchanged sales data in order to facilitate this price coordination.

3. The passage of the American Recovery and Reinvestment Act (“ARRA”) in February 2009 significantly altered the competitive dynamics of the DIPF industry, and upset the terms of coordination among the Sellers. In the ARRA, the United States Congress allocated more than 6 billion dollars to water infrastructure projects, conditioned on the use of domestically produced materials, including DIPF, in those projects (the “Buy American” requirement).

4. At the time the ARRA was passed, McWane was the sole supplier of a full line of domestically produced DIPF in the most commonly used size ranges. Federal stimulus of the domestic DIPF market potentially left McWane in a position to reap a monopoly profit.

5. In response to the passage of the ARRA and its Buy American provision, Sigma, Star and others attempted to enter the domestic DIPF market in competition with McWane.

6. Instead of competing with one another in the domestic DIPF market, Sigma and McWane conspired to monopolize that market by (i) entering into a distribution agreement that eliminated Sigma as an actual potential entrant into the domestic DIPF market, and (ii) excluding actual and potential competitors, including Star, through the adoption and enforcement of exclusive dealing policies.

7. Sigma’s conduct has restrained competition and led to higher prices for both imported and domestically produced DIPF.

**THE RESPONDENT**

8. Respondent Sigma is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its principal place of business located at 700

### Complaint

Goldman Drive, Cream Ridge, New Jersey 08154. Sigma imports, markets and sells products for the waterworks industry, including DIPF.

9. At all times relevant herein, Sigma has been, and is now, a corporation as “corporation” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

10. Sigma’s acts and practices, including the acts and practices alleged herein, are in or affect commerce in the United States, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

### **THE DIPF INDUSTRY**

11. DIPF are a component of pipeline systems transporting drinking and waste water under pressurized conditions in municipal distribution systems and treatment plants. DIPF are used to join pipes, valves and hydrants in straight lines, and to change, divide or direct the flow of water. The end users of DIPF are typically municipal and regional water authorities.

12. Independent wholesale distributors, known as “waterworks distributors,” are the primary channel of distribution of DIPF to end users. Waterworks distributors specialize in distributing products for water infrastructure projects, and generally handle the full spectrum of waterworks products, including pipes, DIPF, valves and hydrants. Waterworks distributors employ sales personnel dedicated to servicing the needs of end users, and are generally able to satisfy the needs of end users for rapid service by stocking inventory in relatively close proximity to project sites.

13. Direct sales of DIPF to end users, or to the utility contractors that often serve as the agent of the end user in purchasing and installing DIPF, are uncommon. End users and DIPF suppliers alike prefer to work through waterworks distributors with locations near project sites. As a result, DIPF suppliers need to distribute DIPF through local waterworks distributors in each region of the country in order to compete effectively in that region.

## Complaint

14. Both imported and domestically produced DIPF are commercially available. All of the Sellers sell imported DIPF. Before Star's entry into domestic production in 2009, McWane was the sole domestic producer of a full line of small and medium-sized DIPF.

15. The end user of DIPF specifies whether on a particular project it will accept both imported and domestically produced DIPF, or only domestically produced DIPF. This specification is often mandated by municipal code, or by state or federal law.

16. Domestically produced DIPF sold for use in projects specified as domestic only are sold at higher prices than imported or domestically produced DIPF sold for use in projects not specified as domestic only.

**THE RELEVANT MARKETS**

17. The relevant product market in which to evaluate Sigma's conduct is the marketing and sale of DIPF, and narrower relevant markets as contained therein (collectively, the "relevant DIPF markets"), including:

- a. DIPF for projects not specified as domestic only;
- b. DIPF for projects specified as domestic only; and
- c. DIPF of certain size ranges (*e.g.*, 24" in diameter and smaller).

18. In particular, the marketing and sale of domestically produced small and medium-sized (3-24" in diameter) DIPF for use in projects specified as domestic only constitutes a separate relevant product market (the "relevant domestic DIPF market").

19. There are no widely used substitutes for DIPF, and no other product significantly constrains the prices of DIPF.

20. Before and after the passage of the ARRA, some end users purchasing DIPF for use in projects specified as domestic only were unable to substitute imported DIPF, or any other product, for domestically produced DIPF. The passage of the ARRA and its

## Complaint

Buy American requirement temporarily expanded the relevant domestic DIPF market.

21. The relevant geographic market is the United States. To compete effectively within the United States, DIPF suppliers need distribution assets and relationships within the United States. DIPF suppliers located outside the United States that lack such assets and relationships are unable to constrain the prices of DIPF suppliers that have such assets and relationships.

22. The relevant DIPF markets have several features that facilitate price coordination among DIPF suppliers. The relevant DIPF markets are highly concentrated. In 2008, the Sellers collectively made more than 90 percent of sales within the relevant DIPF markets. Other features of the relevant DIPF markets that facilitate price coordination include product homogeneity, barriers to timely entry of new DIPF suppliers, inelastic demand at competitive prices, and uniform published prices.

**THE SELLERS RESTRAINED PRICE COMPETITION IN  
THE RELEVANT DIPF MARKETS**

23. Beginning in January 2008 and continuing through January 2009, the Sellers conspired to raise and stabilize the prices at which DIPF were sold in the United States.

24. Due to rising input costs, all of the Sellers desired price increases in 2008. However, McWane was concerned that Sigma and Star would not adhere to announced price increases, which would result in lost sales for McWane.

25. In January 2008, McWane formulated a plan to trade its support for higher prices in exchange for specific changes to the business methods of Sigma and Star that would reduce the risk that local sales personnel for these competitors would sell DIPF at prices lower than published levels.

26. McWane communicated the terms of its plan to Sigma and Star. Sigma and Star manifested their understanding and acceptance of McWane's offer by publicly taking steps to limit

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their discounting from published price levels in order to induce McWane to support higher price levels.

27. McWane then led a price increase, and Sigma and Star followed.

28. In June 2008, McWane formulated a plan to trade its support for higher prices in exchange for information from Sigma and Star documenting the volume of their monthly sales of DIPF. This exchange of information was to be achieved under the auspices of an entity styled as the Ductile Iron Fittings Research Association (“DIFRA”).

29. McWane communicated the terms of its plan to Sigma and Star through a public letter sent by McWane to waterworks distributors, the common customers of the Sellers. A section of that letter was meaningless to distributors, but was intended to inform Sigma and Star of the terms of McWane’s offer.

30. Sigma and Star manifested their understanding and acceptance of McWane’s offer by initiating their participation in the DIFRA information exchange in order to induce McWane to support higher price levels.

31. McWane then led a price increase, and Sigma and Star followed.

**DIFRA FACILITATED PRICE COORDINATION AMONG  
THE SELLERS**

32. The DIFRA information exchange operated as follows. The Sellers submitted a report of their previous month’s sales to an accounting firm. Shipments were reported in tons shipped, subdivided by diameter size range (*e.g.*, 2-12”) and by joint type. Data submissions were aggregated and distributed to the Sellers. Data submitted to the accounting firm was typically no older than 45 days, and the summary reports returned to the Sellers contained data typically no more than 2 months old.

33. During its operation between June 2008 and January 2009, the DIFRA information exchange enabled each of the Sellers to determine and to monitor its own market share and, indirectly, the

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output levels of its rivals. In this way, the DIFRA information exchange facilitated price coordination among the Sellers on the pricing of DIPF.

**SIGMA INVITED McWANE AND STAR TO COLLUDE  
WITH SIGMA**

34. Sigma and Star stopped participating in the DIFRA information exchange in January 2009.

35. In April 2009, McWane announced a new price list for DIPF. McWane's new published prices for medium and large diameter DIPF, the size ranges dominated by Sigma and Star, were lower than prevailing prices.

36. Sigma perceived McWane's new price list as a punishment of Sigma and Star for failing to adhere to published price levels and for withdrawing from the DIFRA information exchange.

37. Sigma initially resisted McWane's new price list, and proposed, in public and private communications with McWane and Star, an alternative arrangement to alleviate McWane's concerns about secret discounting. One term of Sigma's proposal was an offer to resume participation in the DIFRA information exchange. Another term of Sigma's proposal was that McWane would rescind its announced price list and continue the use of the old price list in exchange for the commitment of Sigma and Star to adhere to published price levels for DIPF.

38. McWane and Star rejected Sigma's invitation to collude.

**McWANE AND SIGMA CONSPIRED TO MONOPOLIZE  
THE RELEVANT DOMESTIC DIPF MARKET**

39. At the time of the enactment of the ARRA in February 2009 and thereafter, McWane possessed monopoly power in the relevant domestic DIPF market.

40. At the time of the enactment of the ARRA, McWane was the only manufacturer of a full line of DIPF in the relevant domestic DIPF market and controlled nearly 100 percent of the

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relevant domestic DIPF market. Despite Star's entry into the relevant domestic DIPF market in late 2009, McWane continues to make more than 90 percent of sales in the relevant domestic DIPF market.

41. McWane's monopoly power in the relevant domestic DIPF market is protected by substantial barriers to effective entry and expansion, including the unfair methods of competition of McWane and Sigma, as alleged in Paragraphs 44 through 60 below.

42. For suppliers of the relevant DIPF that have existing relationships and goodwill with waterworks distributors and established reputations for quality and service in the provision of the relevant DIPF, McWane's unfair and exclusionary methods of competition are the primary barriers to effective entry and expansion in the relevant domestic DIPF market.

43. Federal stimulus of the relevant domestic DIPF market gave Sigma, Star and other suppliers of imported DIPF an incentive to enter the relevant domestic DIPF market.

**McWane Eliminated Sigma as an Actual Potential Entrant**

44. After the enactment of the ARRA, Sigma took steps to evaluate entry into domestic production of DIPF, including but not limited to (i) formulating a complete or nearly complete operational plan, (ii) arranging for an infusion of equity capital to fund domestic production, (iii) obtaining the approval of its Board of Directors for its entry plans, and (iv) casting prototype product.

45. McWane perceived that Sigma was preparing to enter the relevant domestic DIPF market. McWane sought to eliminate the risk of competition from Sigma by inducing Sigma to become a distributor of McWane's domestic DIPF rather than a competitor in the relevant domestic DIPF market.

46. McWane and Sigma executed a Master Distribution Agreement dated September 17, 2009 ("MDA"). The principal terms of the MDA were as follows:

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- a. McWane would sell domestic DIPF to Sigma at a 20 percent discount off of McWane's published prices;
- b. McWane would be Sigma's exclusive source for the relevant domestic DIPF;
- c. Sigma would resell McWane's domestic DIPF at or very near McWane's published prices for domestic DIPF; and
- d. Sigma would resell McWane's domestic DIPF to waterworks distributors only on the condition that the distributor agreed to purchase domestic DIPF exclusively from McWane or Sigma.

47. An unwritten term of the MDA was that McWane would also sell its domestic DIPF at or very near its published prices.

48. In the absence of a sufficiently profitable arrangement with McWane, Sigma would likely have entered the relevant domestic DIPF market in competition with McWane.

49. Under the MDA, McWane controlled the price at which Sigma could sell domestic DIPF and the customers to whom Sigma could sell domestic DIPF. Sigma's participation in the relevant domestic DIPF market under the MDA was not equivalent to, and for consumers not a substitute for, Sigma's competitive entry into the relevant domestic DIPF market.

50. Sigma's independent, competitive entry into the relevant domestic DIPF market would likely have benefitted consumers by constraining McWane's prices for the relevant domestic DIPF.

51. Through the MDA, McWane transferred a share of its sales and monopoly profits in the domestic DIPF market to Sigma in exchange for Sigma's commitment to abandon its plans to enter the relevant domestic DIPF market as an independent competitor.

52. Both McWane and Sigma entered into the MDA with the specific intent to maintain and share in McWane's monopoly profits in the relevant domestic DIPF market by eliminating competition among themselves and excluding their rivals.

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**McWane Excluded Star Through Exclusive Dealing**

53. Star announced its entry into the relevant domestic DIPF market in June 2009. McWane knew that, initially, Star would have a shorter product line and a smaller inventory than McWane. Star would therefore have difficulty convincing a waterworks distributor to purchase all of its domestic DIPF from Star.

54. McWane responded to Star's entry into the relevant domestic DIPF market by adopting restrictive and exclusive distribution policies (collectively, "McWane's exclusive dealing policies").

- a. McWane threatened waterworks distributors with delayed or diminished access to McWane's domestic DIPF, and the loss of accrued rebates on the purchase of McWane's domestic DIPF, if those distributors purchased domestic DIPF from Star.
- b. As part of its MDA with McWane, Sigma agreed to implement a similar distribution policy, as alleged in Paragraph 46, above.
- c. McWane threatened some waterworks distributors with the loss of rebates in other product categories, such as ductile iron pipe, waterworks valves, and hydrants, if those distributors purchased domestic DIPF from Star.
- d. Beginning in 2011, McWane changed its rebate structure for domestic DIPF to require waterworks distributors to make certain minimum, and high, shares of their total domestic DIPF purchases from McWane in order to qualify for these rebates.

55. The purpose and effect of McWane's exclusive dealing policies has been and is to compel the majority of waterworks distributors to deal with McWane and Sigma on an exclusive or nearly exclusive basis for their domestic DIPF business.

- a. Due to Star's perceived or actual status as an untested supplier of domestic DIPF with a shorter product line

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and smaller inventory than McWane, many distributors interested in purchasing domestic DIPF from Star were unwilling to switch all of their domestic DIPF business to Star.

- b. Instead, many distributors wished to purchase domestic DIPF from both McWane/Sigma and Star, and thereby to garner the benefits of price and service competition.
- c. McWane's exclusive dealing policies increased the risk of purchasing domestic DIPF from Star.
- d. Distributors otherwise interested in purchasing domestic DIPF from Star were and are unwilling to do so under the terms of McWane's exclusive dealing policies, and have remained exclusive or nearly exclusive with McWane and Sigma, contrary to their preference.

56. McWane's exclusive dealing policies have foreclosed Star from a substantial volume of sales opportunities with waterworks distributors.

57. By foreclosing Star from a substantial volume of sales opportunities with waterworks distributors, McWane's exclusive dealing policies tend to minimize and delay Star's ability to benefit consumers by constraining the prices of domestically produced DIPF charged by McWane and Sigma.

58. McWane's exclusive dealing policies have also raised barriers to entry into the relevant domestic DIPF market by other potential entrants. This conduct has contributed to McWane's monopolization of the relevant domestic DIPF market.

**COMPETITIVE EFFECTS**

59. The acts and practices of Sigma, as alleged herein, have the purpose, capacity, tendency, and effect of (i) maintaining and stabilizing prices of DIPF in the relevant DIPF markets, (ii) eliminating potential competition from Sigma in the relevant domestic DIPF market, (iii) impairing the competitive

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effectiveness of Star in the relevant domestic DIPF market, and (iv) raising barriers to entry for potential rivals in the relevant domestic DIPF market. The conduct of Sigma is reasonably capable of making a significant contribution to the enhancement or maintenance of McWane's monopoly power in the relevant domestic DIPF market.

60. There are no legitimate procompetitive efficiencies that justify the conduct of Sigma as alleged herein, or that outweigh its anticompetitive effects.

**FIRST VIOLATION  
ALLEGED RESTRAINT OF TRADE**

61. As alleged herein, Sigma conspired with its competitors to restrain price competition. These concerted actions unreasonably restrain trade and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**SECOND VIOLATION  
ALLEGED RESTRAINT OF TRADE**

62. As alleged herein, Sigma conspired with its competitors to exchange competitively sensitive sales information. These concerted actions unreasonably restrain trade and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**THIRD VIOLATION  
ALLEGED INVITATION TO COLLUDE**

63. As alleged herein, Sigma invited competitors to collude with Sigma. These actions constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

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**FOURTH VIOLATION  
ALLEGED RESTRAINT OF TRADE**

64. As alleged herein, McWane and Sigma entered into the MDA. The agreement unreasonably restrains trade and constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**FIFTH VIOLATION  
ALLEGED CONSPIRACY TO MONOPOLIZE**

65. As alleged herein, McWane and Sigma entered into the MDA with the specific intent to monopolize the relevant domestic DIPF market, and took overt acts to exclude their rivals in furtherance of their conspiracy, constituting an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this twenty-seventh day of February, 2012, issues its complaint against Sigma.

By the Commission.

**DECISION AND ORDER**

The Federal Trade Commission (“Commission”) having initiated an investigation of certain acts and practices of Sigma Corporation (“Sigma”), hereinafter sometimes referred to as “Respondent,” and Respondent having been furnished thereafter with a copy of a draft Complaint that counsel for the Commission proposed to present to the Commission for its consideration and

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which, if issued, would charge Respondent with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waives and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated said Act, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment filed thereafter by an interested person pursuant to Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings and issues the following Order:

1. Respondent Sigma Corporation is a corporation organized and existing under the laws of the State of New Jersey, with its principal address at 700 Goldman Drive, Cream Ridge, New Jersey 08550.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

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**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “Commission” means the Federal Trade Commission.
- B. “Respondent” means Sigma Corporation, its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- C. “Communicate” means to transfer or disseminate any information, regardless of the means by which it is accomplished, including without limitation orally, by letter, e-mail, notice, or memorandum. This definition applies to all tenses and forms of the word “communicate,” including, but not limited to, “communicating,” “communicated” and “communication.”
- D. “Competitively Sensitive Information” means any information regarding the cost, price, output, or customers of or for DIPF marketed by Respondent or any Competitor, regardless of whether the information is prospective, current or historical, or aggregated or disaggregated.

*Provided, however,* that “Competitively Sensitive Information” shall not include:

1. information that is a list of prices or other pricing terms that has been widely Communicated by Respondent to its customers through a letter, electronic mailing, sales catalog, Web site, or other widely accessible method of posting;

## Decision and Order

2. information that relates to the terms on which Respondent will buy DIPF from, or sell DIPF to, the Person to whom the Competitively Sensitive Information is Communicated;
  3. information that relates to transactions that occurred at least three (3) years prior to the date of the Communication of such information; or
  4. information that must be disclosed pursuant to the Federal Securities Laws.
- E. “Competitor” means any Person that, for the purpose of sale or resale within the United States: (1) manufactures DIPF; (2) causes DIPF to be manufactured; or (3) imports DIPF.
- F. “Designated Manager” means a Regional Manager or the OEM Manager for sales of DIPF in and into the United States, and any employee performing any job function of a Regional Manager or the OEM Manager with responsibility for sales of DIPF in or into the United States.
- G. “Ductile Iron Pipe Fittings” or “DIPF” means any iron casting produced in conformity with the C153/A21 or C110/A21 standards promulgated by the American Water Works Association, including all revisions and amendments to those standards and any successor standards incorporating the C153/A21 or C110/A21 standards by reference.
- H. “Federal Securities Laws” means the securities laws as that term is defined in § 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. § 78c(a)(47), and any regulation or order of the Securities and Exchange Commission issued under such laws.
- I. “Industry Statistics” means statistics derived from Input Data and Communicated by the Third Party Manager.

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- J. “Input Data” means the Competitively Sensitive Information Communicated by Competitors to the Third Party Manager.
- K. “Information Exchange” means the entity Managed by A Third Party Manager that: (1) Communicates Industry Statistics and (2) includes Respondent and at least one other Competitor.
- L. “Insider” means a consultant, officer, director, employee, agent, or attorney of Respondent. *Provided, however*, that no other Competitor shall be considered to be an “Insider.”
- M. “Managed by A Third Party Manager” means that a Third Party Manager is solely and exclusively responsible for all activities relating to Communicating, organizing, compiling, aggregating, processing, and analyzing any Competitively Sensitive Information.
- N. “Participate” in an entity or an arrangement means (1) to be a partner, joint venturer, shareholder, owner, member, or employee of such entity or arrangement, or (2) to provide services, agree to provide services, or offer to provide services through such entity or arrangement. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”
- O. “Person” means any natural person or artificial person, including, but not limited to, any corporation, unincorporated entity, or government. For the purpose of this Order, any corporation includes the subsidiaries, divisions, groups, and affiliates controlled by it.
- P. “Third Party Manager” means a Person that (1) is not a Competitor, and (2) is responsible for all activities relating to Communicating, organizing, compiling, aggregating, processing, and analyzing any

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Competitively Sensitive Information Communicated or to be Communicated between or among Respondent and any other Competitor.

**II.**

**IT IS FURTHER ORDERED** that in connection with the business of manufacturing, marketing or selling DIPF in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device:

- A. Entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors:
1. To raise, fix, maintain, or stabilize prices or price levels, or engage in any other pricing action; or
  2. To allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

*Provided, however,* that nothing in Paragraph II.A of this Order prohibits Respondent from entering into an agreement with another Competitor regarding the price of DIPF, if and only if that agreement relates exclusively to the terms under which Respondent will buy DIPF from, or sell DIPF to, that other Competitor.

- B. Communicating to any Person who is not an Insider, that Respondent is ready or willing:
1. To raise, fix, maintain, or stabilize price or price levels conditional upon any other Competitor also raising, fixing, maintaining, or stabilizing price or price levels; or

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2. To forbear from competing for any customer, contract, transaction, or business opportunity conditional upon any other Competitor also forbearing from competing for any customer, contract, transaction, or business opportunity.
- C. Entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors to Communicate or exchange Competitively Sensitive Information.
- D. Communicating Competitively Sensitive Information to any other Competitor.
- E. Attempting to engage in any of the activities prohibited by Paragraphs II.A, II.B, II.C, or II.D.

*Provided, however,* that it shall not of itself constitute a violation of Paragraph II.B, II.C, OR II.D of this Order for Respondent to Communicate:

1. Competitively Sensitive Information to a Competitor where such Communication is reasonably related to a lawful joint venture, license, or potential acquisition, and is reasonably necessary to achieve the procompetitive benefits of such a relationship;
2. To any Person reasonably believed to be an actual or prospective purchaser of DIPF, the price and terms of a sale of DIPF; or
3. That Respondent is ready and willing to adjust the terms of a sale of DIPF in response to a Competitor's offer.

*Provided further, that* it shall not of itself constitute a violation of Paragraphs II.B, II.C, II.D or II.E of this Order for Respondent to Communicate with or Participate in an Information Exchange that is limited

## Decision and Order

exclusively to the Communication of Input Data or Industry Statistics when:

1. Any Input Data relates solely to transactions that are at least six (6) months old;
2. Any Industry Statistic relates solely to transactions that are at least six (6) months old;
3. Industry Statistics are Communicated no more than one time during any six (6) month period;
4. Any Industry Statistic represents an aggregation or average of Input Data for transactions covering a period of at least six (6) months;
5. Any Industry Statistic represents an aggregation or average of Input Data received from no fewer than five (5) Competitors;
6. Relating to price, output, or total unit cost, no individual Competitor's Input Data to any Industry Statistic represents more than twenty-five (25) percent of the total reported sales (whether measured on a dollar or unit basis) of the DIPF product from which the Industry Statistic is derived;
7. Relating to price, output, or total unit cost, the sum of no three Competitors' Input Data to any Industry Statistic represents more than sixty (60) percent of the total reported sales (whether measured on a dollar or unit basis) of the DIPF product from which the Industry Statistic is derived;
8. Any Industry Statistic is sufficiently aggregated or anonymous such that no Competitor that receives that Industry Statistic can, directly or indirectly, identify the Input Data submitted by any other particular Competitor;

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9. Respondent does not Communicate with any other Competitor relating to the Information Exchange, other than those Communications (i) occurring at official meetings of the Information Exchange; (ii) relating to topics identified on a written agenda prepared in advance of such meetings; and (iii) occurring in the presence of antitrust counsel;
10. Respondent retains, for submission to a duly authorized representative of the Commission upon reasonable notice, a copy of all Input Data Communicated to the Third Party Manager and all Industry Statistics Communicated by the Third Party Manager to Respondent; and
11. All Industry Statistics are, at the same time they are Communicated to any Competitor, made publicly available.

**III.**

**IT IS FURTHER ORDERED** that Respondent shall:

- A. Within sixty (60) days from the date this Order becomes final distribute by first-class mail, return receipt requested, or by electronic mail with return confirmation, a copy of this Order with the Complaint, to each of its officers, directors, and Designated Managers; and
- B. For five (5) years from the date this Order becomes final, distribute by first-class mail, return receipt requested, or by electronic mail with return confirmation, a copy of this Order with the Complaint, within sixty (60) days, to each Person who becomes its officer, director, or Designated Manager and who did not previously receive a copy of this Order and Complaint.
- C. Require each Person to whom a copy of this Order is furnished pursuant to Paragraphs III.A and III.B of this Order to sign and submit to Respondent within sixty

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(60) days of the receipt thereof a statement that: (1) represents that the undersigned has read and understands the Order; and (2) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject Respondent to penalties for violation of the Order.

**IV.**

**IT IS FURTHER ORDERED** that Respondent shall file verified written reports within ninety (90) days from the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include, among other information that may be necessary:

- A. A description of any Information Exchange, including a description of (i) the identity of any Competitors participating in such exchange; (ii) the Competitively Sensitive Information being exchanged; (iii) the identity of the Third Party Manager and a description of how the Competitively Sensitive Information has been and is expected to be Managed by the Third Party Manager; and (iv) the identity of each employee of the Respondent who received information, directly or indirectly, from the Third Party Manager;
- B. Copies of the signed return receipts or electronic mail with return confirmations required by Paragraphs III.A, III.B, and III.C of this Order;
- C. One copy of each Communication during the relevant reporting period that relates to changes in Respondent's published list price or multiplier discounts for sales of DIPF made in or into the United States when that Communication is to two (2) or more customers and those changes are simultaneously applicable to two (2) or more customers; and

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- D. A detailed description of the manner and form in which Respondent has complied and is complying with this Order.

**V.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission:

- A. Of any change in its principal address within twenty (20) days of such change in address; and
- B. At least thirty (30) days prior to any proposed: (1) dissolution of Respondent; (2) acquisition, merger, or consolidation of Respondent; or (3) any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**VI.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondent, and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession, or under the control, of Respondent relating to compliance with this Order, which copying services shall be provided by Respondent at its expense; and
- B. Upon fifteen (15) days notice, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

## Concurring and Dissenting Statement

**VII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on February 27, 2032.

By the Commission.

**STATEMENT OF COMMISSIONER J. THOMAS  
ROSCH, CONCURRING IN PART AND DISSENTING  
IN PART IN THE MATTER OF MCWANE, INC. AND  
STAR PIPE PRODUCTS, LTD., AND IN THE MATTER  
OF SIGMA CORPORATION**

The Commission has voted separately (1) to issue a Part 3 Administrative Complaint against Respondents McWane, Inc. (“McWane”) and Star Pipe Products, Ltd. (“Star”), and (2) to accept for public comment a Consent Agreement settling similar allegations in a draft Part 2 Complaint against Respondent Sigma Corporation (“Sigma”). While I have voted in favor of both actions, I respectfully object to the inclusion—in both the Part 3 Administrative Complaint and in the draft Part 2 Complaint—of claims against McWane and Sigma, to the extent that such claims are based on allegations of exclusive dealing, as explained in Part I below. I also respectfully object to naming Star, a competitor of McWane and Sigma, as a Respondent in the Part 3 Administrative Complaint, which alleges, *inter alia*, that Star engaged in a horizontal conspiracy to fix the prices of ductile iron pipe fittings (DIPFs) sold in the United States, and in a related, information exchange, as described in Part II below.

**I.**

For reasons similar to those that I articulated in a recent dissent in another matter, *Pool Corp.*, FTC File No. 101-0115, <http://www.ftc.gov/os/caselist/1010115/111121poolcorpstatementrosch.pdf>, I do not think that the Part 3 Administrative Complaint against McWane and the draft Part 2 Complaint against Sigma

## Concurring and Dissenting Statement

adequately allege exclusive dealing as a matter of law. In particular, there is case law in both the Eighth and Ninth Circuits blessing the conduct that the complaints charge as exclusive dealing.

**II.**

I also object to the allegations in the Part 3 Administrative Complaint and in the draft Part 2 Complaint that name Star as a co-conspirator in the alleged horizontal price-fixing of DIPF sold in the United States and the related, alleged DIFRA information exchange.<sup>1</sup> I do not consider naming Star, along with McWane and Sigma, as a co-conspirator to be in the public interest. There are at least three reasons why this is so. First, although there may be reason to believe Star conspired with McWane and Sigma in this oligopolistic industry, Star seems much less culpable than the others. More specifically, I believe that we must be mindful of the consequences of public law enforcement in assessing whether the public interest favors joining Star as a co-conspirator.<sup>2</sup> Second, I am concerned that a trier of fact may find it hard to believe that Star could be both a victim of McWane's alleged "threats" to deal exclusively with distributors, and at more or less the same time (the "exclusive dealing" program began in September 2009), a co-conspirator with McWane in a price-fixing conspiracy (June 2008 to February 2009). (This concern further explains why I do not have reason to believe that the exclusive dealing theory is a viable one.) Third, I am concerned that Star's alleged participation in the price-fixing conspiracy and information exchange relies, in part, on treating communications to distributors as actionable signaling on prices or price levels.<sup>3</sup> *See,*

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1 *See* McWane/Star Part 3 Administrative Compl. ¶¶ 29–38, 64–65; Sigma draft Part 2 Compl. ¶¶ 23–33.

2 *See* Credit Suisse Secs. (USA) LLC v. Billing, 551 U.S. 264, 281–84 (2007) (questioning the social benefits of private antitrust lawsuits filed in numerous courts when the enforcement-related need is relatively small); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557–60 (2007) (expressing concern with the burdens and costs of antitrust discovery, and the attendant *in terrorem* effect, associated with private antitrust lawsuits).

3 McWane/Star Part 3 Administrative Compl. ¶ 34b; Sigma draft Part 2 Compl. ¶ 29.

## Analysis to Aid Public Comment

*e.g., Williamson Oil Co., Inc. v. Philip Morris USA*, 346 F.3d 1287, 1305–07 (11th Cir. 2003).

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a proposed consent order (“Agreement”) from Sigma Corporation (“Sigma”). The Agreement seeks to resolve charges that Sigma violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, by engaging in a variety of collusive and exclusionary acts and practices in the market for ductile iron pipe fittings (“DIPF”).

The Commission anticipates that the competitive issues described in the complaint will be resolved by accepting the proposed order, subject to final approval, contained in the Agreement. The Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and any comments received, and will decide whether it should withdraw from the Agreement or make final the proposed order contained in the Agreement.

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment concerning the proposed order. It is not intended to constitute an official interpretation of the Agreement and proposed order or in any way to modify its terms.

The proposed order is for settlement purposes only and does not constitute an admission by Sigma that it violated the law or that the facts alleged in the complaint, other than jurisdictional facts, are true.

## Analysis to Aid Public Comment

**I. The Complaint**

The following allegations are taken from the complaint and publicly available information.

**A. Background**

DIPF are used in municipal water distribution systems to change pipe diameter or pipeline direction. DIPF suppliers distribute these products through wholesale distributors, known as waterworks distributors, which specialize in distributing products for water infrastructure projects. The end users of DIPF are typically municipal and regional water authorities.

Both imported and domestically produced DIPF are commercially available. Sigma and its largest competitors in the DIPF market, McWane, Inc. (“McWane”) and Star Pipe Products Ltd. (“Star”), all sell imported DIPF. McWane was the only domestic producer of a full line of small and medium-sized DIPF until Star’s entry into domestic production in 2009.

There are no widely available substitutes for DIPF. Some projects require that only domestically produced DIPF be used. Domestically produced DIPF sold for use in these projects typically command higher prices than comparable imported DIPF.

DIPF prices are based off of published list prices and discounts, with customers negotiating additional discounts off of those list prices and discounts on a transaction-by-transaction basis. DIPF suppliers also offer volume rebates.

**B. Challenged Conduct**

Between January 2008 and January 2009, Sigma allegedly conspired with McWane and Star to increase the prices at which imported DIPF were sold in the United States. In furtherance of the conspiracy, and at the request of McWane, Sigma changed its business methods to make it easier to coordinate price levels, first by limiting the discretion of regional sales personnel to offer price discounts, and later by exchanging information documenting the volume of its monthly sales, along with McWane and Star,

## Analysis to Aid Public Comment

through an entity known as the Ductile Iron Fittings Research Association (“DIFRA”).

After the collapse of the DIFRA information exchange in early 2009, Sigma attempted to revive the conspiracy by convincing McWane and Star to raise their prices and to resume the exchange of sales data through DIFRA. McWane and Star rejected Sigma’s invitation to collude.

The collapse of DIFRA coincided with the enactment of The American Recovery and Reinvestment Act of 2009 (“ARRA”) in February 2009. In the ARRA, the United States Congress allocated more than \$6 billion to water infrastructure projects, but included a provision requiring the use of domestically produced materials in those projects (the “Buy American” requirement). At the time the ARRA was passed, McWane was the sole supplier of a full line of domestic DIPF in the most commonly used size ranges, and possessed monopoly power in that market.

In response to the passage of the ARRA and its Buy American provision, Sigma, Star and others attempted to enter the domestically produced DIPF market in competition with McWane. Rather than compete with one another in the domestic DIPF market, Sigma and McWane executed a Master Distributor Agreement (“MDA”), whereby Sigma was appointed as a distributor of McWane’s domestically produced DIPF. Through the MDA, Sigma accepted compensation from McWane in exchange for abandoning its planned entry into the domestic DIPF market. Sigma also agreed to adopt exclusive dealing policies similar to those adopted by McWane, in furtherance of a conspiracy with McWane to exclude Star and to monopolize the domestic DIPF market.

The complaint alleges that Sigma had no legitimate business justification for this course of conduct, and that Sigma’s collusive and exclusionary conduct has caused higher prices for both imported and domestically produced DIPF.

## **II. Legal Analysis**

We analyze first the various agreements allegedly reached by Sigma with its competitors to limit competition relating to

## Analysis to Aid Public Comment

imported DIPF, and then address Sigma's participation, along with McWane, in the alleged monopolization of the domestic DIPF market.

### A. Sigma's Involvement in the 2008 Price Fixing Conspiracy

The January and June 2008 price restraints among Sigma, McWane and Star alleged in the complaint are the sort of naked restraints on competition that are *per se* unlawful.<sup>1</sup> The June 2008 agreement, which was allegedly reached after a public invitation to collude by McWane, illustrates how price fixing agreements may be reached in public. Here, McWane's invitation to collude was conveyed in a letter sent to waterworks distributors, the common customers of McWane, Sigma and Star. McWane's letter contained a section that was meaningless to waterworks distributors, but was intended to inform Sigma and Star of the terms on which McWane desired to fix prices.<sup>2</sup>

The DIFRA information exchange was also illegal. The complaint alleges that the DIFRA information exchange played a critical role in the 2008 price fixing conspiracy, first as the *quid pro quo* for a price increase by McWane in June 2008, and then by enabling Sigma, McWane and Star to monitor each others' adherence to the collusive arrangement through the second half of 2008.<sup>3</sup>

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1 FEDERAL TRADE COMMISSION & UNITED STATES DEPARTMENT OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATION AMONG COMPETITORS ("Competitor Collaboration Guidelines") § 1.2 (2000); *In re North Texas Specialty Physicians*, 140 F.T.C. 715, 729 (2005) ("We do not believe that the *per se* condemnation of naked restraints has been affected by anything said either in *California Dental* or *Polygram*").

2 Because McWane's communication informed its rivals of the terms of price coordination desired by McWane without containing any information for customers, this communication had no legitimate business justification. *See In re Petroleum Products Antitrust Litig.*, 906 F.2d 432, 448 (9th Cir. 1990) (public communications may form the basis of an agreement on price levels when "the public dissemination of such information served little purpose other than to facilitate interdependent or collusive price coordination").

3 The Commission articulated a safe harbor for exchanges of price and cost information in Statement 6 of the 1996 Health Care Guidelines. *See* DEP'T OF

## Analysis to Aid Public Comment

**B. Sigma's 2009 Invitation to Collude**

The complaint includes allegations of a stand-alone Section 5 violation, namely that Sigma invited McWane and Star to collude with Sigma to increase DIPF prices in early 2009.<sup>4</sup> The term “invitation to collude” describes an improper communication from a firm to an actual or potential competitor that the firm is ready and willing to coordinate on price or output. Such invitations to collude impose a significant risk of anticompetitive harm to consumers, and as such, violate Section 5 of the FTC Act absent a legitimate business justification.

**C. Sigma's Involvement in a 2009 Conspiracy with McWane to Eliminate Competition in the Domestic DIPF Market**

The complaint alleges that, after the passage of the ARRA, Sigma prepared to enter the domestic DIPF market in competition

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JUSTICE & FEDERAL TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, STATEMENT 6: ENFORCEMENT POLICY ON PROVIDER PARTICIPATION IN EXCHANGES OF PRICE AND COST INFORMATION (1996). The DIFRA information exchange failed to qualify for the safety zone of the Health Care Guidelines for several reasons. Although the DIFRA information exchange was managed by a third party, the information exchanged was insufficiently historical, the participants in the exchange too few, and their individual market shares too large to qualify for the permissive treatment contemplated by the Health Care Guidelines. While failing to qualify for the safety zone of the Health Care Guidelines is not in itself a violation of Section 5, firms that wish to minimize the risk of antitrust scrutiny should consider structuring their collaborations in accordance with the criteria of the safety zone.

4 *In re U-Haul International, Inc.*, F.T.C. File No. 081-0157, 2010 FTC LEXIS 61, \*6 (July 14, 2010); *In re Valassis Communications, Inc.*, F.T.C. File No. 051-008, 2006 FTC LEXIS 25, \*4-7 (April 19, 2006); *In re MacDermid, Inc.*, F.T.C. File No. 991-0167, 1999 FTC LEXIS 191, \*10 (Feb. 4, 2000); *In re Stone Container Corp.*, 125 F.T.C. 853 (1998); *In re Precision Moulding Co.*, 122 F.T.C. 104 (1996); *In re YKK (USA) Inc.*, 116 F.T.C. 628 (1993); *In re A.E. Clevite, Inc.*, 116 F.T.C. 389 (1993); *In re Quality Trailer Products Corp.*, 115 F.T.C. 944 (1992). In addition, an invitation to collude may violate Section 2 of the Sherman Act as an act of attempted monopolization, and may also violate federal wire and mail fraud statutes. *See United States v. American Airlines*, 743 F.2d 1114 (5th Cir. 1984); *United States v. Ames Sintering Co.*, 927 F.2d 232 (6th Cir. 1990).

## Analysis to Aid Public Comment

with McWane. However, McWane wanted to avoid this competition, so McWane and Sigma agreed that Sigma would participate in the domestic DIPF market only as a distributor of McWane's product. Through this arrangement, McWane shared a portion of its monopoly profits in the domestic DIPF market with Sigma in exchange for Sigma's commitment to abandon its plans to enter that market in competition with McWane. Such agreements are presumptively unlawful.<sup>5</sup>

#### **D. McWane and Sigma Conspired to Monopolize the Domestic DIPF Market**

The elements of a conspiracy to monopolize are: (1) the existence of a combination or conspiracy; (2) an overt act in furtherance of the conspiracy; and (3) a specific intent to monopolize.<sup>6</sup> Here, the complaint alleges that through their MDA arrangement, McWane and Sigma agreed to limit competition between themselves in the domestic DIPF market, and to exclude their rivals in that market, including Star, by the adoption of duplicate exclusive dealing policies, and did so with the common and specific intent to maintain and share monopoly profits in the domestic DIPF market.

### **III. The Proposed Order**

The proposed order is designed to remedy the unlawful conduct charged against Sigma in the complaint and to prevent the recurrence of such conduct.

Paragraph II.A of the proposed order prohibits Sigma from participating in or maintaining any combination or conspiracy between any competitors to fix, raise or stabilize the prices at which DIPF are sold in the United States, or to allocate or divide markets, customers, or business opportunities.

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<sup>5</sup> E.g., *Palmer v. BRG of Georgia, Inc.*, 498 U.S. 46, 49-50 (1990); *United States v. Masonite Corp.*, 316 U.S. 265, 281 (1942); *In re SKF Industries, Inc.*, 94 F.T.C. 6, 97-104 (1979).

<sup>6</sup> See *Volvo N. Am. Corp. v. Men's Int'l Prof'l Tennis Council*, 857 F.2d 55, 74 (2d Cir. 1988).

## Analysis to Aid Public Comment

Paragraph II.B of the proposed order prohibits Sigma from soliciting or inviting any competitor to participate in any of the actions prohibited in Paragraphs II.A.

Paragraph II.C of the proposed order prohibits Sigma from participating in or facilitating any agreement between competitors to exchange “Competitively Sensitive Information” (“CSI”), defined as certain types of information related to the cost, price, output or customers of or for DIPF. Paragraph II.D of the proposed order prohibits Sigma from unilaterally disclosing CSI to a competitor, except as part of the negotiation of a joint venture, license or acquisition, or in certain other specified circumstances. Paragraph II.E of the proposed order prohibits Sigma from attempting to engage in any of the activities prohibited by Paragraphs II.A, II.B, II.C, or II.D.

The prohibitions on Sigma’s communication of CSI with competitors contained in Paragraphs II.C and II.D of the proposed order are subject to a proviso that permits Sigma to communicate CSI to its competitors under certain circumstances. Under the proposed order, Sigma may participate in an information exchange with its competitors in the DIPF market provided that the information exchange is structured in such a way as to minimize the risk that it will facilitate collusion among the Sigma and its competitors. Specifically, the proposed order requires any exchange of CSI to occur no more than twice yearly, and to involve the exchange of aggregated information more than six months old. In addition, the aggregated information that is exchanged must be made publicly available, which increases the likelihood that an information exchange involving Sigma will simultaneously benefit consumers. The proposed order also prohibits Sigma’s participation in an exchange of CSI involving price, cost or total unit cost of or for DIPF when the individual or collective market shares of the competitors seeking to participate in an information exchange exceed specified thresholds. The rationale for this provision is that in a highly concentrated market the risk that the information exchange may facilitate collusion is high. Due to the highly concentrated state of the DIPF market as currently structured, an information exchange involving Sigma and relating to price, output or total unit cost of or for DIPF is unlikely to reoccur in the foreseeable future.

Analysis to Aid Public Comment

The proposed order has a term of 20 years.

## Complaint

## IN THE MATTER OF

**PROMEDICA HEALTH SYSTEM, INC.**COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED  
VIOLATIONS OF SECTION 7 OF THE CLAYTON ACT

*Docket No. 9346; File No. 101 0167*  
*Complaint, January 6, 2011 – Decision, March 22, 2012*

This case addresses the acquisition by ProMedica Health System, Inc. of St. Luke's Hospital. The complaint alleges that the acquisition violated Section 7 of the Clayton Act by reducing competition substantially in the markets for general acute-care inpatient hospital services for commercially insured patients and obstetric services in Lucas County, Ohio. Chief Administrative Law Judge D. Michael Chappell ("ALJ") issued an Initial Decision, 152 F.T.C. 708, holding that ProMedica's acquisition of St. Luke's Hospital eliminated competition between the two firms in the market for general acute care inpatient hospital services and reduced the number of competing hospitals in the Lucas County market from four to three. *Id.* at 980. The ALJ held that the acquisition increased ProMedica's bargaining power with commercial health plans, thereby leading to higher reimbursement rates. The ALJ further concluded that those higher rates likely would be passed on to the commercial health plans' customers, including employers and employees, to the detriment of consumers. *Id.* The ALJ ordered ProMedica to divest St. Luke's Hospital to a Commission-approved buyer within 180 days. *Id.* at 994. The order further required ProMedica to take steps to maintain the viability of St. Luke's Hospital until it is divested and to provide transitional services to the approved acquirer. *Id.* at 1005. The Order of the Commission adopts the Findings of Fact and Conclusions of Law, to the extent not inconsistent with the findings of fact and conclusions contained in the Commission's Opinion.

*Participants*

For the *Commission*: Alexis Gilman, Kevin Hahm, Krisztian Katona, Jeanne Liu, Sara Razi, Stephanie Reynolds, Kaj Rozga, Nick Widnell, Stelios Xenakis, and Michelle Yost.

For the *Respondent*: David Marx, Jr. and Stephen Wu, McDermott Will & Emery.

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by the Act, the Federal Trade Commission, having reason to believe that

## Complaint

Respondent ProMedica Health System, Inc. (“ProMedica”) consummated a joinder agreement (the “Acquisition”) in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

## I.

**NATURE OF THE CASE**

1. ProMedica’s acquisition (the “Acquisition”) of St. Luke’s Hospital (“SLH” or “St. Luke’s”) threatens to substantially lessen competition for critical healthcare services in Lucas County, Ohio. This diminished competition will stifle beneficial quality improvements and will result in significant increases in healthcare costs to local residents, many of whom are already struggling to keep up with rising medical expenses.

2. ProMedica effectively acquired and took control of its nearby competitor St. Luke’s upon consummation of a joinder agreement on August 31, 2010. Ordinary course documents reveal that a principal motivation for the Acquisition was to gain enhanced bargaining leverage with health plans and the ability to raise prices for services. Indeed, SLH’s internal strategic plans unambiguously reveal that the Acquisition could allow ProMedica to

documents observe that an  
Elsewhere, SLH’s  
and could

3. Rate increases would generate higher profits for the Respondent, but – as SLH’s internal business plans acknowledge – would impose significant burdens on local employers and employees, either directly or through higher health insurance premiums, co-pays, and other out-of-pocket healthcare expenses. These cost increases have real health-related consequences, as they inevitably force some employers to reduce or eliminate health-insurance coverage for their employees, force some families to drop their health insurance altogether, and cause others

## Complaint

to delay or forgo checkups and other medical care that they can no longer afford.

4. The Acquisition reduces the number of competitors in Lucas County for general acute-care inpatient hospital services from four to three and, for inpatient obstetrical services, from three to two. After the Acquisition, ProMedica –

– has just two competitors in Lucas County for general acute-care hospital services: Mercy Health Partners (“Mercy”) and University of Toledo Medical Center (“UTMC”). Because UTMC does not offer obstetrical services, there is even less competition for those services; the Acquisition has resulted in a duopoly, with ProMedica facing only Mercy as a competitor.

5. Post-Acquisition, ProMedica now controls nearly 60% of the general acute-care inpatient hospital services market in Lucas County and over 80% of the market for obstetrical services, as measured by patient days. These extraordinarily high market shares and concentration levels render the Acquisition presumptively unlawful *in both relevant markets* – general acute-care services and obstetrics – under the relevant case law and the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (“Merger Guidelines”). This strong presumption of illegality is independently confirmed and supported by an array of qualitative and quantitative evidence from sources including health plans, local employers, third-party hospitals, and the merged parties themselves.

6. The price and non-price competition eliminated by the Acquisition will not be replaced by other hospitals in the next several years, if ever. Significant barriers to entry and expansion, including regulatory requirements and funding needs, prevent new hospitals from entering the market and prevent existing hospitals from substantially expanding existing services. The cost of opening a new obstetrics department in an existing hospital is also prohibitive. Finally, the Respondent’s purported efficiencies are also insufficient to offset the significant anticompetitive harm likely to result from the Acquisition.

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**II.****RESPONDENT**

7. ProMedica is a not-for-profit healthcare system incorporated under and by virtue of the laws of Ohio. ProMedica is headquartered at 1801 Richard Road, Toledo, Ohio, 43607. ProMedica's healthcare system serves northwestern and west-central Ohio and southeastern Michigan.

8. Excluding St. Luke's, ProMedica operates three general acute-care hospitals in Lucas County, Ohio: The Toledo Hospital ("TTH"); Flower Hospital ("Flower"); and Bay Park Community Hospital ("Bay Park"). ProMedica also owns Paramount Health Care ("Paramount"), a for-profit corporation that operates one of the largest commercial health plans in Lucas County, and Toledo Children's Hospital. ProMedica is by far the largest employer of physicians in Lucas County. In 2009, ProMedica's revenues totaled approximately \$1.6 billion.

9. As of August 31, 2010, ProMedica effectively acquired and took control of St. Luke's, a formerly independent, not-for-profit acute-care community hospital located at 5901 Monclova Road, Maumee, Ohio, 43537. St. Luke's was broadly recognized as a high-quality, low-cost hospital, which generated revenues of approximately \$156 million in 2009.

**III.****JURISDICTION**

10. ProMedica, through its relevant operating subsidiaries, is, and at all relevant times has been, engaged in commerce or in activities affecting commerce, within the meaning of the Clayton Act. The Acquisition constitutes an acquisition under Section 7 of the Clayton Act.

**IV.****THE ACQUISITION**

11. By virtue of the joinder agreement consummated on August 31, 2010, ProMedica currently is the sole corporate

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member of St. Luke's and its affiliated entities, with control and ultimate authority over all significant business decisions at St. Luke's. ProMedica also acquired ownership, including all stock interest, in certain SLH for-profit entities. Thus, ProMedica now controls SLH's strategic planning, operating and capital budgets, large unbudgeted expenditures, and significant borrowing and contracting. Importantly, ProMedica also will negotiate SLH's contracts with commercial health plans.

## V.

**THE RELEVANT SERVICE MARKETS**

## A.

**General Acute-Care Inpatient Services Market**

12. The Acquisition threatens substantial harm to competition in two relevant service markets. The first is general acute-care inpatient hospital services sold to commercial health plans, which encompasses a broad cluster of basic medical and surgical diagnostic and treatment services that include an overnight hospital stay, such as emergency services, internal medicine, and minor surgeries. It is appropriate to evaluate the Acquisition's likely effects across this entire cluster of services, rather than analyzing each service independently, because the group of services is offered by the same competitors under similar competitive conditions.

13. The general acute-care inpatient services market excludes outpatient services because health plans and patients could not substitute outpatient services for inpatient care in response to a price increase. Similarly, more sophisticated and specialized tertiary and quaternary services, such as major surgeries and organ transplants, also are properly excluded from the relevant market because they are not substitutes for general acute-care inpatient services.

## Complaint

**B.****Inpatient Obstetrical Services**

14. The Acquisition also threatens substantial competitive harm in the market for inpatient obstetrical services. This market encompasses hospital services provided for labor and delivery of newborns. No other hospital services are reasonably interchangeable with inpatient obstetrical services, making this an appropriate relevant market within which to analyze the likely effects of the Acquisition.

15. Within the broader relevant market for general acute-care services, it is appropriate to define a narrower relevant service where it more fully accounts for unique competitive conditions. Here, these unique competitive conditions include that there are fewer hospitals offering inpatient obstetrical services in Lucas County: neither UTMC, one of the two remaining competitors in the market for general acute-care inpatient services, nor Mercy's St. Anne Hospital provide obstetrical services.

**VI.****THE RELEVANT GEOGRAPHIC MARKET**

16. The relevant geographic market in which to analyze the effects of the Acquisition for each relevant service market is Lucas County, Ohio.

17. The appropriate geographic market is determined by examining the geographic boundaries within which a hypothetical monopolist for the services at issue could profitably raise prices by a small but significant amount.

18. Due to residents' clear preference for local hospital care, health plans must have a strong representation of Lucas County hospitals in their provider networks in order to satisfy employers and their employees. Health plans could not steer members to hospitals outside of Lucas County in response to rate increases at the Lucas County hospitals. Thus, a hypothetical monopolist that controlled *all* of the hospitals, or all obstetrical services, in Lucas County could profitably increase rates by at least a small but

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significant amount. Hospitals outside of Lucas County do not meaningfully compete with Lucas County hospitals.

19. According to the merged hospitals' own ordinary-course documents, ProMedica and St. Luke's do not regard non-Lucas County hospitals as significant competitors. Instead, ProMedica and St. Luke's have focused their competitive efforts on – and have repeatedly computed market shares based on – hospitals in and around Toledo. Patient discharge data demonstrates that less than three percent of Lucas County residents leave the county for general acute-care or obstetrical services.

**VII.****MARKET STRUCTURE AND THE ACQUISITION'S  
PRESUMPTIVE ILLEGALITY**

20. The Acquisition reduces the number of general acute-care competitors in Lucas County from four to three, leaving ProMedica facing only two competitors, Mercy and UPMC. Because UPMC does not provide obstetrical services, the Acquisition reduces the competitors for obstetrical services from three to two, resulting in a duopoly of ProMedica and Mercy.

21. Under relevant case law and the Merger Guidelines, the Acquisition is presumptively unlawful in both relevant service markets. ProMedica's post-Acquisition market share in the general acute-care inpatient services market approaches 60%, as measured by patient days. In the market for inpatient obstetrical services, the post-Acquisition market share exceeds 80%. These extraordinarily high market shares easily surpass levels that have been found presumptively unlawful by the Supreme Court.

22. The Merger Guidelines measure market concentration using the Herfindahl-Hirschman Index ("HHI"). Under that test, a merger or acquisition is presumed likely to create or enhance market power (and presumed illegal) when the post-merger HHI exceeds 2500 points and the merger or acquisition increases the HHI by more than 200 points. The market concentration levels here exceed these thresholds by a wide margin. The post-Acquisition HHI is 4391 in the general acute-care inpatient services market, with an increase of 1078 points. HHI levels are

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even higher in the obstetrical services market, with a post-Acquisition HHI of 6854 and an Acquisition-related increase of 1323. The HHI figures for each relevant service market are summarized in the following tables.

<b>GENERAL ACUTE-CARE INPATIENT SERVICES</b>		
<b>Hospital/System</b>	<b>Pre-Acquisition Market Share</b>	<b>Post-Acquisition Market Share</b>
ProMedica	46.8%	58.3%
Mercy	28.7%	28.7%
St. Luke's	11.5%	--
UTMC	13.0%	13.0%
<b>Pre-Acquisition HHI</b>		3312.5
<b>Post-Acquisition HHI</b>		4390.7
<b>HHI Increase</b>		1078.2

<b>OBSTETRICAL SERVICES</b>		
<b>Hospital/System</b>	<b>Pre-Acquisition Market Share</b>	<b>Post-Acquisition Market Share</b>
ProMedica	71.2%	80.5%
Mercy	19.5%	19.5%
St. Luke's	9.3%	--
<b>Pre-Acquisition HHI</b>		5531.2
<b>Post-Acquisition HHI</b>		6853.7
<b>HHI Increase</b>		1322.5

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**VIII.****ANTICOMPETITIVE EFFECTS****A.****Increased Bargaining Leverage for ProMedica**

23. By eliminating significant, beneficial competition between Respondent ProMedica and St. Luke's, the Acquisition vests ProMedica with an increased ability and incentive to demand supra-competitive reimbursement rates from commercial health plans and their membership.

24. Before the Acquisition, ProMedica and St. Luke's were close competitors in the markets for general acute-care inpatient services and inpatient obstetrical services, in terms of geographic proximity and similarity of service offerings. Indeed, SLH's CEO testified that ProMedica had been SLH's

for inpatient hospital services and obstetrical services in its main service area. For its part, ProMedica was so focused on St. Luke's as a key competitor before the Acquisition that it

ProMedica's documents also expressly

25. Prior to the Acquisition, St. Luke's had significantly less bargaining leverage than ProMedica, a far more dominant provider system in Lucas County. As a result, St. Luke's negotiated substantially lower rates with health plans than ProMedica did. ProMedica and St. Luke's will now be able to use their enhanced to raise SLH's rates to levels at least equal to the other ProMedica hospitals in Lucas County. Indeed, SLH's motivation for entering into the Acquisition was

An increase in St. Luke's rates merely to the levels of the other ProMedica hospitals could force employers and

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employees to pay from more for inpatient services obtained there.

26. With the addition of St. Luke's to its hospital system, ProMedica has become a "must-have" system for health plans seeking to do business in Lucas County, because health plans are no longer able to offer a commercially viable provider network without including ProMedica's hospitals. Health plans no longer have the ability to drop ProMedica from their networks, or even credibly threaten to do so, as before. In fact, in at least the past decade, no health plan has offered a network in Lucas County consisting of only the Mercy hospitals and UTMC, as they would have to do without agreeing to ProMedica's rates today. Thus, health plans in the area now must either reach agreement with ProMedica, likely at substantially higher rates, offer a commercially unattractive hospital network to their members, or even be forced to exit the Lucas County market altogether.

27. This significant change in the negotiating dynamic gives ProMedica much-enhanced bargaining clout in contract negotiations and the ability to extract higher rates for inpatient services at St. Luke's and at its other Lucas County hospitals. ProMedica is widely recognized as having the highest rates in Lucas County and for making aggressive rate increase demands, relative to other hospitals, and particularly St. Luke's. In fact, ProMedica's CEO acknowledged to other senior executives in 2010 that health plans viewed ProMedica as Health plans predict

Indeed, this ability to demand higher rates was a principal motivation behind the Acquisition.

28. ProMedica's ownership of the for-profit commercial health plan Paramount may further increase its ability and incentive to increase rates. If other health plans must pay higher rates to access ProMedica's hospitals or, worse yet, must exit Lucas County altogether, ProMedica would benefit because Paramount would capture some of the business of its disadvantaged, or departed, health-plan competitors. As a result, ProMedica's ownership of Paramount may render a post-Acquisition price increase even more profitable – and therefore more likely.

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29. Price increases resulting from the Acquisition will be passed on to local employers and their employees. In Lucas County, nearly 70% of commercial health-plan membership is self-insured. Self-insured employers rely on health plans only to negotiate rates and provide administrative support; the employers themselves pay the full cost of their employees' healthcare claims. As a result, self-insured employers immediately and directly bear the full burden of higher rates. Fully-insured employers also are inevitably harmed by higher rates, because health plans pass on at least a portion of hospital rate increases to these customers.

30. Employers, in turn, must pass on their increased healthcare costs to their employees, in whole or in part. Employees will bear these costs in the form of higher premiums, higher co-pays, reduced coverage or restricted services. Some Lucas County residents will forgo or delay necessary healthcare services because of the higher costs.

**B.****The Loss of Quality Competition**

31. The Acquisition also will reduce the quality and breadth of services available in Lucas County.

32. Competition between ProMedica and St. Luke's has spurred both parties to increase quality of care, offer additional services, and has fostered other, non-financial benefits for the residents of Lucas County. These important elements of competition will be lost after the Acquisition.

33. Before the transaction, St. Luke's offered the highest quality healthcare service in Lucas County, and did so at the lowest cost. St. Luke's is consistently recognized by third-party quality-rating organizations as being in the top 10% of hospitals nationally, based on outcomes, cost, and patient satisfaction. The Acquisition of St. Luke's by ProMedica – a higher-cost, lower-quality competitor – will diminish the quality of care at St. Luke's. Indeed, SLH's CEO and Board

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**IX.****ENTRY BARRIERS**

34. Neither hospital entry nor expansion by the two remaining hospitals will deter or counteract the Acquisition's likely harm to competition in the relevant service markets.

35. New hospital entry or significant expansion in Lucas County would not be timely. Construction of a new general acute-care hospital would take more than two years from the initial planning stages to opening doors to patients. Significant expansion of services such as obstetrics takes years as well, and requires time-consuming recruitment of additional professional staff.

36. Entry and expansion also are unlikely due to very high construction costs, operating costs, and financial risk, along with significant hospital bed-overcapacity in the Toledo area. Constructing a new obstetrics department in an existing hospital would cost well over \$1 million, with operating costs of tens of millions of dollars a year. Notably,

—  
even if prevailing rates for general acute-care and obstetrical services increase significantly — and SLH's strategic documents confirm that

**X.****EFFICIENCIES**

37. Extraordinary merger-specific efficiencies are necessary to justify the Acquisition in light of its vast potential to harm competition. Such efficiencies are lacking here.

38. Respondent's efficiency claims — described by one ProMedica executive as deriving from a mere — are too speculative to be cognizable. Moreover, the fact that SLH is the lowest cost hospital in the area and, by all accounts, a "lean" operation, suggests any claimed operational cost savings should be viewed with skepticism. Even if the claimed efficiencies were

## Complaint

substantiated and achievable, they are not merger-specific, as St. Luke's could have affiliated with suitable and interested alternative partners – such as UTMC – far less restrictive of competition.

**XI.****VIOLATIONS****COUNT I - ILLEGAL ACQUISITION**

39. The allegations of Paragraphs 1 through 38 above are incorporated by reference as though fully set forth.

40. The Acquisition may substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

**NOTICE**

Notice is hereby given to the Respondent that the thirty-first day of May, 2011, at 10:00 a.m. is hereby fixed as the time, and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580, as the place when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14<sup>th</sup>) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

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If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the answer is filed by the Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the answer is filed by the Respondent). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondent's answer, to make certain initial disclosures without awaiting a discovery request.

### **NOTICE OF CONTEMPLATED RELIEF**

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondent as is supported by the record and is necessary and appropriate, including, but not limited to:

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1. Divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as ProMedica and St. Luke's were offering and planning to offer prior to the Acquisition.
2. A prohibition against any transaction between ProMedica and St. Luke's that combines their businesses in the relevant markets, except as may be approved by the Commission.
3. A requirement that, for a period of time, ProMedica and St. Luke's provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to ensure the creation of one or more viable, competitive independent entities to compete against ProMedica and St. Luke's in the relevant markets.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this sixth day of January, 2011.

By the Commission.

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## Opinion of the Commission

By Commissioner Julie Brill

### I. INTRODUCTION<sup>1</sup>

This case involves the consummated joinder (“the Joinder”) of two hospital providers in Toledo, Ohio: ProMedica Health System, Inc. (“ProMedica”), a large multi-hospital system that operates three hospitals in the Toledo area; and St. Luke’s Hospital (“St. Luke’s”), formerly an independent community hospital located in Maumee, a suburb in the southwest sector of the Toledo area. In addition to ProMedica and St. Luke’s, there are only two other hospital providers in Toledo: Mercy Health Partners (“Mercy”), which is also a multi-hospital system with three hospitals in the Toledo area; and the University of Toledo Medical Center (“UTMC”), a state-supported teaching hospital. The Joinder therefore reduced the number of competing hospital providers from four to three in Lucas County, Ohio, which encompasses the Toledo area. It also reduced the number of hospital providers offering obstetrical (“OB”) services from three to two – a merger to duopoly in that market.

The Commission challenged the Joinder out of concern that it would significantly harm patients, employers, and employees in the Toledo area by eliminating significant, beneficial competition between ProMedica and St. Luke’s through the creation of a combined hospital system with an increased ability to obtain

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<sup>1</sup> This opinion uses the following abbreviations:

ID – INITIAL DECISION OF THE ADMINISTRATIVE LAW JUDGE  
 IDF – Numbered Findings of Fact in the ALJ’s Initial Decision  
 JX – Joint Exhibits  
 PX – Complaint Counsel’s Exhibit  
 RX – Respondent’s Exhibit  
 Tr. – Transcript of Trial before the ALJ.  
 RAppB – Respondent’s Appeal Brief  
 RAnsB – Respondent’s Answering Brief to Complaint Counsel’s Appeal  
 RRB – Respondent’s Reply Brief in Support of its Appeal  
 CCAppB – Complaint Counsel’s Appeal Brief  
 CCAnsB – Complaint Counsel’s Answering Brief  
 CCRB – Complaint Counsel’s Reply Brief  
 JSLF – Joint Stipulation of Law and Fact (JX00002A)

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supra-competitive reimbursement rates from commercial health plans, and, ultimately, from their members. We conclude that anticompetitive effects are indeed likely, resulting in higher health care costs for patients, employers, and employees in the Toledo area. The record compiled during a full administrative trial lasting more than thirty days confirms that eliminating a substantial competitor from two highly concentrated markets will substantially lessen competition. That record includes testimony and documents from the merging parties acknowledging ProMedica's pre-Joinder market dominance and demonstrating that increased bargaining leverage resulting in higher reimbursement rates was an objective and expected result of the Joinder; testimony from numerous health plans that the Joinder will enable ProMedica to extract higher rates; and economic and statistical analyses showing that significant price increases are likely.

Following the administrative hearing, Chief Administrative Law Judge D. Michael Chappell issued an Initial Decision in which he held that the Joinder is likely to substantially lessen competition in the market for the sale of general acute-care ("GAC") inpatient hospital services to commercial health plans in Lucas County, Ohio, in violation of Section 7 of the Clayton Act. He entered an order requiring ProMedica to divest St. Luke's. We affirm the ALJ's conclusion on liability, although we define GAC inpatient hospital services somewhat differently. We also conclude that the Joinder is likely to substantially lessen competition in a separate relevant market consisting of inpatient OB services sold to commercial health plans. Having found liability, we enter an order requiring ProMedica to divest St. Luke's to an approved buyer in accordance with established Commission procedures.

## **II. PROCEDURAL HISTORY**

### **A. Investigation, Pleadings, and Preliminary Injunction**

On May 25, 2010, ProMedica and St. Luke's entered into a Joinder Agreement, under which St. Luke's became part of

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ProMedica Health System.<sup>2</sup> In return, ProMedica agreed, *inter alia*, to pay St. Luke's parent a \$5 million commitment fee at closing; to provide St. Luke's Hospital with at least \$30 million in capital funding, payable in three \$10 million annual installments due by the anniversary dates of the transaction's closing; and to permit St. Luke's to contract with and become an in-network hospital in Paramount Healthcare, ProMedica's commercial health plan, which previously had been closed to St. Luke's.<sup>3</sup>

FTC staff opened an investigation of the transaction in July 2010. On August 18, 2010, ProMedica entered into a limited Hold Separate Agreement that allowed the deal to close but restricted ProMedica from making certain changes to St. Luke's. See PX0069; IDF 12. Among other things, the Hold Separate Agreement prevents ProMedica from terminating St. Luke's contracts with health plans; eliminating, transferring or consolidating clinical services at St. Luke's; or terminating any St. Luke's employees without cause. The Hold Separate Agreement also allows health plans the option to extend their St. Luke's contracts past the termination date rather than to negotiate new contracts with ProMedica. IDF 13. The Joinder Agreement was consummated on August 31, 2010. Answer ¶ 2.

On January 6, 2011, the Commission issued an administrative Complaint against ProMedica. The Complaint alleged that the Joinder threatens to substantially lessen competition for health care services in Lucas County, Ohio. Complaint ¶¶ 1, 2. Two relevant service markets were alleged: (1) GAC inpatient hospital services sold to commercial health plans; and (2) inpatient OB services. *Id.* ¶¶ 12-15. The alleged relevant geographic market is Lucas County, Ohio. *Id.* ¶¶ 16-19. In its Answer to the Complaint, Respondent admitted that GAC inpatient hospital

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<sup>2</sup> See PX0058. ProMedica became the sole corporate member or shareholder of St. Luke's Hospital and its affiliated entities. *Id.* at 009-012. Consequently, for antitrust analysis of the transaction, post-Joinder ProMedica controls St. Luke's.

<sup>3</sup> *Id.* at 021-023. As of the close of the administrative record on August 23, 2011, ProMedica had paid the \$5 million to the St. Luke's Foundation and had made the first \$10 million capital contribution to St. Luke's Hospital. IDF 980-83; Hanley, Tr. 4679.

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services sold to commercial health plans constitutes a valid service market, but denied that OB services is a separate relevant market. Answer ¶¶ 12-15. Although the Answer denied that Lucas County, Ohio, is the relevant geographic market, Respondent subsequently admitted it. *See, e.g.*, Resp. to Compl. Counsel's Req. for Admiss. ¶ 7; Guerin-Calvert, Tr. 7683. Respondent denied all other material allegations of the Complaint.

The FTC and the State of Ohio also brought suit in the U.S. District Court for the Northern District of Ohio, seeking a temporary restraining order and preliminary injunction, because the Hold Separate Agreement was scheduled to expire. On March 29, 2011, Judge Katz, concluding that the FTC had satisfied its burden of proof, entered a preliminary injunction holding the parties to the terms of their Hold Separate Agreement pending the outcome of the administrative proceedings. *FTC v. ProMedica Health Sys., Inc.*, No. 3:11 CV 47, 2011 WL 1219281 (N.D. Ohio March 29, 2011).

**B. Initial Decision**

On December 5, 2011, Judge Chappell issued an Initial Decision in which he concluded that the Joinder was likely to substantially lessen competition in violation of Section 7 of the Clayton Act. ID 6, 35, 137-43. He delineated a product market consisting of the sale of GAC inpatient hospital services to commercial health plans, referred to as managed care organizations ("MCOs"). Unlike the Complaint, however, the ALJ included in the GAC inpatient hospital services market tertiary services, which are generally not offered by St. Luke's. *See* ID 140; JSLF ¶ 6. He also rejected Complaint Counsel's contention that OB services constituted a separate relevant market. ID 6, 36, 143-44. The ALJ concluded that Lucas County, Ohio, was the relevant geographic market. ID 6, 37-38, 145.

Within the relevant GAC inpatient hospital services market, Judge Chappell found that the Joinder would significantly increase ProMedica's market share and market concentration, reducing the number of competing hospital providers from four to three and causing concentration levels to substantially exceed the thresholds in the 2010 **HORIZONTAL MERGER GUIDELINES**

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**(U.S. DEPT. OF JUSTICE & FED. TRADE COMM’N, HORIZONTAL MERGER GUIDELINES** (Aug. 19, 2010), *available at* <http://www.ftc.gov/os/2010/08/100819hmg.pdf> (“2010 HORIZONTAL MERGER GUIDELINES”). ID 6, 40-43, 147-52. He concluded that by eliminating St. Luke’s and ProMedica as separate options for MCOs, the Joinder would significantly enhance ProMedica’s bargaining leverage in negotiations and would enable ProMedica to obtain higher reimbursement rates, which likely would be passed along to the customers of the MCOs, including employers and consumers. ID 6, 65-79, 162-74.

The ALJ found Respondent’s defenses unpersuasive. First, he concluded that the evidence did not support Respondent’s claims that excess hospital bed capacity in Toledo, repositioning by competitors, and steering patients away from high-priced hospitals by doctors, employers, or health plans would constrain post-Joinder price increases. ID 7, 80-86, 176-79. Second, he found that the procompetitive benefits and efficiencies Respondent asserted were not merger-specific, did not represent significant economies that would benefit competition, or were insufficient to outweigh the Joinder’s likely anticompetitive effects. ID 7, 114-31, 192-204. Third, with respect to Respondent’s claim that St. Luke’s was financially weak and a limited competitor, the ALJ found that “St. Luke’s clearly was struggling financially prior to the Joinder and faced significant financial challenges to remaining independent in the future.” ID 190. At the same time, the ALJ determined that prior to the Joinder “St. Luke’s [had] succeeded in significantly raising its patient volume and market share,” and “was still competing in the market.” ID 189. On balance, he ruled, Respondent’s weakened competitor justification should be rejected. ID 189; *see* ID 91-112, 180-90.

Having found liability, the ALJ ordered divestiture of St. Luke’s to a Commission-approved buyer. ID 204-11. He rejected Respondent’s proposal to allow the Joinder to stand under terms requiring separate and independent negotiating teams for the pre-joinder ProMedica hospitals (the “legacy hospitals”) and St. Luke’s. Judge Chappell determined that extensive integration of St. Luke’s into the ProMedica hospital system had not yet occurred and that unwinding the Joinder would be unlikely to

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involve substantial costs. He held that Respondent had failed to demonstrate that this case presents unusual circumstances sufficient to overcome the presumption that divestiture is the appropriate remedy. ID 7.

**III. STANDARD OF REVIEW**

Pursuant to 16 C.F.R. § 3.54, the Commission reviews the ALJ's findings of fact and conclusions of law *de novo*, considering "such parts of the record as are cited or as may be necessary to resolve the issues presented." The Commission may "exercise all powers which it could have exercised if it had made the initial decision."<sup>4</sup> *Id.* We adopt the ALJ's findings of fact to the extent that those findings are not inconsistent with this opinion.<sup>5</sup>

**IV. FACTUAL BACKGROUND****A. The Third-Party Insurance System**

In most markets, vendors set or negotiate a price that is paid in full by their customers. However, the market for hospital services is more complex. Hospitals and their patients rarely negotiate directly over the price of hospital services, and few patients directly pay their hospital costs. Instead, the costs of hospital services are typically paid by various third-party payor insurers, both public and private.

The primary public insurance programs are the federal Medicare program which covers hospital costs for the elderly, and the federal/state Medicaid program which covers the costs of low-income patients. IDF 40-42. Reimbursement rates for patients covered under these programs are set by the government, are not

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4 The *de novo* standard of review is required by the Administrative Procedure Act, 5 U.S.C. § 557(b), and the FTC Act, 15 U.S.C. § 45(b), (c), and applies to both findings of fact and inferences drawn from those facts. See *Realcomp II, Ltd.*, No. 9320, 2009 WL 6936319 at \*16 n.11 (FTC 2009), *aff'd*, *Realcomp II, Ltd. v. FTC*, 635 F.3d 815 (6th Cir. 2011).

5 Respondent's appeal does not dispute the ALJ's findings and conclusions on the lack of procompetitive benefits and efficiencies from the Joinder; therefore, our Opinion does not address the issue other than to adopt the ALJ's findings.

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subject to negotiation by the hospitals, and are generally lower than hospitals' costs of providing care. IDF 43, 292.

Most other patients are covered under various types of commercial health insurance plans, including PPOs and HMOs.<sup>6</sup> The insurers that offer such plans (MCOs) create provider networks and offer their plans to employers, which in turn offer them to their employees as part of their compensation packages. IDF 45, 251. Hospital charges incurred by the employee are then paid by the MCO, subject in some cases to copayments or deductibles depending on the specific terms of the plan.

In Lucas County, approximately 65 percent of the patients are covered under the government programs, and 29 percent are privately insured. The remaining 6 percent are self-pay or charity patients. IDF 39, 52.

## **B. The Competitive Dynamics of MCO Contracting**

### **1. The MCOs**

MCOs contract with hospitals, physicians, and other health care providers in a given geographic area to create provider networks that the MCOs then market to employers. The MCOs compete against one another to be included on the menu of health insurance products that employers offer to their employees, and then, after they are included as an option, they compete to attract the employee/members. IDF 234, 238.

MCOs seek to offer marketable plans to employers in terms of cost, geographical coverage, quality, and breadth of services,

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<sup>6</sup> IDF 44. In a traditional health maintenance organization (“HMO”), a patient can receive care only from a designated set of providers and must be referred by a primary care physician who acts as a “gatekeeper” to specialists. IDF 118-21. In a preferred provider organization (“PPO”), a patient can go to providers outside the network, but pays more if he or she does so. IDF 122-23. Some insurers also offer what are known as point-of-sale (“POS”) plans, which are less restrictive than HMOs but more restrictive than PPOs, as well as traditional indemnity plans, where there are no restrictions on where patients can receive care, and the insurer pays whatever the hospital or other provider bills. IDF 125,127. While some insurers offer a choice of products, others offer only a more limited menu. *See, e.g.*, IDF 130, 148, 166.

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while at the same time staying competitive by, among other things, obtaining favorable rates from hospitals and other providers. IDF 278. They seek to offer within the network a complete complement of GAC inpatient services, from relatively simple primary and secondary services through more advanced services, including tertiary services. IDF 274. One important factor an MCO considers in creating its network is how broad to make it. On the one hand, narrower hospital networks, *i.e.*, networks that exclude certain hospitals in the market, drive more patient volume to the in-network hospitals. This, in turn, increases the network's value to those in-network hospitals and generally allows the MCO to obtain lower rates from those hospitals. IDF 269. On the other hand, the MCO's customers (employers, directly, and their employees, indirectly) generally favor broad networks that do not restrict their choice of providers. IDF 276. Thus, MCOs have to balance their customers' preference for broad networks against potentially higher rates. IDF 276-77.

## 2. The Hospitals

Hospitals compete with one another for inclusion in MCOs' provider networks because a hospital's commercially-insured patient volume is significantly affected by the provider networks in which it participates. IDF 240-41. In contract negotiations with MCOs, hospital providers seek to maximize the reimbursement they will receive from the MCOs for treating the MCOs' enrollees. The rates the provider will be able to achieve in negotiations are affected by its bargaining leverage, which, in turn, is dependent on its hospitals' relative attractiveness to employers and their employees: the more valued a provider's hospitals, the more important it is to the MCO's ability to market its network to employers, and the more bargaining leverage the hospital provider has in its negotiations with the MCO. IDF 295.

In negotiating reimbursement rates with commercial insurers, hospitals seek to cover their total patient care costs and an operating margin sufficient to fund needed capital expenditures and expansion, and to maintain a strong balance sheet. IDF 290. Because Medicare/Medicaid reimbursements do not cover actual patient care costs, hospitals try to make up the shortfall with rates charged to MCOs. IDF 292. Accordingly, it is critical for a

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hospital to be able to attract a sufficient volume of commercially-insured patients, and that, in turn, is affected by the MCO networks in which the hospital is a participating provider.

### **3. Employers and Employees**

Most commercially-insured patients obtain health insurance through their employers. IDF 250. The employers do not negotiate directly with the hospitals on behalf of their employees, but rather rely on the MCOs to do so. IDF 248-49. While some employers have exclusive relationships with only one MCO, others offer their employees a variety of insurance options. IDF 252-53.

In selecting which MCOs to offer their employees, employers consider factors such as cost, the breadth of the network in terms of geographical coverage, the types of services offered, and the choice of providers. All else being equal, employers favor broad networks. Some are willing to pay more for broader network coverage, while others may consider the lower cost associated with narrower networks to be more important. IDF 256-57. Generally, employers seek to satisfy the health-care coverage preferences of their employees, while keeping costs low. IDF 260.

### **4. The Bargaining Process for Reimbursement Rates**

Reimbursement rates for hospital services are determined through the bargaining process between MCOs and hospitals. IDF 509. Although negotiations between hospitals and MCOs cover a variety of contractual terms (IDF 512), reimbursement rates and the contractual terms that affect rates are particularly important. IDF 513.

Both the parties and the MCOs acknowledged that higher hospital reimbursement rates are passed on to employers and often to their employees. IDF 596, 599, 655-63. Thus, the MCOs would not themselves absorb the higher rates; the higher rates would be passed on to the community-at-large.

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### C. Types of Hospital Services

Hospitals typically provide both inpatient services (those services requiring admission to the hospital for 24 hours or more) and outpatient services (which do not require an overnight stay). IDF 19. Within the category of inpatient services, different hospitals may provide different types of services along a continuum of care, ranging from primary services, which treat common conditions of mild to moderate severity, to quaternary services, such as organ transplants, which are the most complex and require the most specialized equipment and expertise. IDF 20-23, 25. Tertiary services include services such as neurological intensive care that are more complex than secondary services such as orthopedic surgery, but less complex than quaternary services. IDF 22-23. Hospitals that provide tertiary services also typically provide primary and secondary services, IDF 24, but many hospitals that provide primary and secondary services do not provide more complex tertiary services.<sup>7</sup> Thus, MCOs, in structuring their networks to attract employers and their employees, strive to enter into contracts with one or more hospitals that will give their covered enrollees access to various levels of care.

### D. The Merging Parties

#### 1. ProMedica

ProMedica is a non-profit, integrated health care system headquartered in Toledo, Ohio. IDF 1. It operates 11 hospitals in Ohio and southeast Michigan. IDF 3. It also owns and operates Paramount Health Care, which is one of the largest MCOs in Lucas County, Ohio. IDF 163. In 2009, ProMedica generated revenues of approximately \$1.6 billion. Answer ¶ 8.

Prior to the Joinder, ProMedica operated three general acute-care hospitals in Lucas County.<sup>8</sup> The largest is The Toledo

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<sup>7</sup> The dividing line between various levels of services is not, however, precisely defined. IDF 26.

<sup>8</sup> ProMedica also operates a specialty hospital, Children's Hospital, located on The Toledo Hospital's campus. IDF 53.

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Hospital (“TTH”), which is located in downtown Toledo, and has between 700 and 800 licensed beds, 550 of which are staffed. IDF 55. It offers all basic acute care services, ranging from general medical-surgical to orthopedics and OB services, as well as tertiary care services. IDF 56-57. It is also one of only two Lucas County hospitals that offers more complex Level III OB services. IDF 58. TTH is the single largest general acute-care hospital in Lucas County.

In addition to TTH, ProMedica operates two smaller community hospitals in Lucas County. Flower Hospital is located in Sylvania, Ohio, in the northwest Toledo area, and has about 300 licensed beds, 250 of which are staffed. IDF 61, 65. Bay Park Hospital is located in Oregon, Ohio, in the eastern Toledo area, and has about 86 licensed beds. IDF 70-71. Both Bay Park and Flower offer OB services, but neither offers any tertiary services. IDF 63-64, 68-69.

ProMedica regards itself as the dominant hospital system in Lucas County, and that assessment is shared by others. PX00270 at 025; PX00319 at 001; PX00221 at 002. It is also among the most expensive hospital systems in Ohio, IDF 525; at the same time, however, some of its quality scores are “subpar.” PX00153 at 001.

## **2. St. Luke’s Hospital**

Before the Joinder, St. Luke’s was an independent not-for-profit community hospital. St. Luke’s was a wholly owned subsidiary of OhioCare Health System, Inc., along with several other subsidiaries, including St. Luke’s Hospital Foundation, Care Enterprises, Inc., Physician Advantage MSO, and OhioCare Physicians, LLC. IDF 10.

St. Luke’s is located in Maumee, Ohio, a suburban area in southwest Lucas County. IDF 72. St. Luke’s provides a broad range of outpatient and inpatient services, including Level 1 OB services, and limited oncology, neurosurgery and pediatric services. IDF 73, 75. St. Luke’s was reputed to be a low-cost, high-quality provider. *See, e.g.*, Pugliese, Tr. 1443-48, 1521-22; McGinty, Tr. 1190-92, 1205-06. It has about 178 staffed beds. IDF 77.

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**E. Other Hospitals in Lucas County**

In addition to the ProMedica hospitals and St. Luke's, there are four other hospitals in Lucas County. Three are owned and operated by the same hospital system, Mercy, which, in turn, is part of the Catholic Health Partners health care system headquartered in Cincinnati, Ohio. IDF 79; Shook, Tr. 887-90. The remaining hospital is UTMC, which is part of the University of Toledo and an instrumentality of the State of Ohio. IDF 103.

**1. The Mercy System Hospitals**

The Mercy system hospitals in Lucas County are Mercy St. Vincent, Mercy St. Anne, and Mercy St. Charles. IDF 81. St. Vincent is a large tertiary hospital with 568 registered beds, 445 of which are staffed. IDF 82-83. In addition to basic acute care services, it also offers a variety of tertiary services, including a large cardiology center, and is the only Lucas County hospital other than TTH that offers Level III inpatient OB services. IDF 82, 84. St. Vincent is located in downtown Toledo. IDF 87.

Both St. Anne and St. Charles are smaller general medical-surgical hospitals. IDF 92, 99. St. Anne has 128 registered beds, 96 of which are staffed (IDF 93); St. Charles is somewhat larger with 350 registered beds, but fewer than 150 are staffed (IDF 101). Neither hospital offers any tertiary services. IDF 92, 100. St. Anne discontinued providing OB services in 2008 because of insufficient demand, IDF 94-95; St. Charles does offer OB services, including Level II services. IDF 99. St. Anne is located in west Toledo; St. Charles is located in Oregon, Ohio, just east of Toledo. IDF 92, 98.

**2. UTMC**

UTMC is a research and teaching hospital, located south of downtown Toledo. IDF 103; PX00900. It has about 300 registered beds, of which about 225 are staffed. IDF 111. It focuses primarily on providing tertiary and quaternary services as part of its teaching mission, IDF 109, and is the only hospital in Lucas County to provide quaternary services. IDF 108. It offers no inpatient OB services and has no plans to do so. IDF 110.

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**F. MCOs in Lucas County**

Several MCOs market health insurance products to employers in Lucas County. The largest is Medical Mutual of Ohio (“MMO”), which offers a variety of PPO, HMO, and POS plans to Lucas County employers. IDF 130, 132. It covers about 100,000 lives in Lucas County. IDF 132. Its network includes all the Lucas County hospitals: Mercy, UTMC, and St. Luke’s all have been in the MMO network for more than ten years; ProMedica has participated since 2008. IDF 135-39.

Anthem Blue Cross Blue Shield (“Anthem”) is another large MCO operating in Lucas County, with about 30,000 commercially-insured members. IDF 147. In Lucas County, Anthem offers only a PPO network, which currently includes all the Lucas County hospitals. IDF 149, 156. ProMedica has participated in the Anthem network for at least 20 years; Mercy has participated since 2008; and UTMC has participated since 2003 or 2004. IDF 156-59. St. Luke’s participated in Anthem’s network prior to 2005, but was terminated effective January 31, 2005. IDF 160-61. It resumed participation in July 2009. IDF 162.

Paramount Healthcare (“Paramount”) is also one of the largest MCOs operating in Lucas County, with about 85,000 to 90,000 covered lives in commercially insured products. IDF 163, 168. Paramount is a wholly-owned subsidiary of ProMedica and offers a closed or limited network of hospitals. IDF 172. Prior to the Joinder, Paramount’s network included only the ProMedica hospitals and UTMC; pursuant to the Joinder Agreement, it now includes St. Luke’s. IDF 177-79.

FrontPath Health Coalition (“FrontPath”) is a membership organization composed of various corporate and other sponsors. IDF 183. It is one of the top three or four MCOs in Lucas County, with approximately 80,000 covered lives. IDF 188. All the Lucas County hospitals participate in the FrontPath network. IDF 191.

MCOs with a smaller presence in Lucas County include Aetna, United Healthcare, and Humana, all of which are large companies offering health insurance products throughout the

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United States. IDF 197, 209, 226. Aetna offers HMO, PPO, and POS plans. IDF 212-13, 216. It has contracted with all the Lucas County hospitals since 2006; prior to that time, its network did not include UTMC. IDF 222-23. United offers primarily PPO plans in Lucas County and has approximately 15,000 commercially insured members. IDF 198, 200. All Lucas County hospitals currently participate in its network. IDF 204. Humana offers only a PPO in Lucas County and covers about 2,000 commercially-insured lives. IDF 228, 230. It too includes all Lucas County hospitals in its network.<sup>9</sup>

At the time of the Joinder, ProMedica was in-network with MMO, Anthem, FrontPath, United, Paramount, and Aetna. IDF 521. St. Luke's at that time was in-network with MMO, Anthem, FrontPath, United, and Aetna. IDF 528.

**G. St. Luke's Financial Condition**

In the years prior to the Joinder, St. Luke's was experiencing significant financial difficulties. IDF 371-85; 785-86, 792-95, 799. St. Luke's experienced operating losses from 2007 until the month prior to the Joinder in 2010, *see* IDF 786, and its operating performance was below that of other comparable hospitals. IDF 787-89, 795. Responding to its financial needs, St. Luke's began deferring some capital projects in order to conserve cash. IDF 808. It also instituted a hiring freeze, cut pay and benefits, and froze pay. IDF 800-03. St. Luke's cash reserves declined, IDF 862-66, and its bond rating was downgraded from A2 to Baa2. IDF 873, 875, 880, 883. Although its bond debt was relatively low, IDF 916-18, and it still had enough in cash and investments to pay off all its outstanding debt, IDF 862, 919, St. Luke's was struggling. IDF 899, 901, 914-15.

In February 2008 St. Luke's hired a new chief executive officer, Mr. Daniel Wakeman, who had previously engineered successful turnarounds of several other community hospitals. IDF 920. In June 2008 Mr. Wakeman developed a three-year strategic plan that contained certain goals for St. Luke's centered on five

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<sup>9</sup> IDF 233. In addition, Blue Cross/BlueShield of Michigan covers some patients of Lucas County hospitals. *See* PX02148 at 103.

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strategic “pillars”: “Growth, People, Quality, Service, and Finance/Corporate.” *Id.* By August 31, 2010, St. Luke’s had achieved its growth goals of increasing inpatient revenues by more than \$3.5 million a year on average, and outpatient revenues by more than \$5 million a year on average. IDF 924-25. It had also achieved its goal of obtaining more than a 40 percent market share in its core service area, IDF 928,<sup>10</sup> and its occupancy rate in the year prior to the Joinder increased by approximately percent. IDF 930. However, St. Luke’s overall cost coverage ratio remained below one, meaning that St. Luke’s was not generating sufficient reimbursements to cover its costs across all payors. IDF 944, 947. St. Luke’s management identified the primary source of St. Luke’s financial problem as “extremely low reimbursement rates from third party payors.” IDF 388, *quoting* PX01390 at 0002, ¶ 6, *in camera*.

St. Luke’s financial position improved in 2010. IDF 949. Its operating losses declined and its operating margins improved, as patient volumes increased and expenses declined. IDF 950-54, 957-58. By August 2010 – the month the Joinder was consummated – St. Luke’s was able to post a positive operating margin. IDF 948. In his monthly report for August 2010, CEO Wakeman reported that “[t]he high activity produced a positive operating margin of \$7,000 on \$36.7 million in gross revenue. It is not impressive, but it is better than a loss. This positive margin confirms that we can run in the black if activity stays high. After much work, we have built our volume up to a point where we can produce an operating margin and keep our variable expenses under control.” *Id.*, *quoting* PX00170 at 001.

#### H. St. Luke’s Decision to Affiliate with ProMedica

St. Luke’s management pursued a number of options to address its financial condition. These included instituting various cost-cutting measures, IDF 800-03; exploring the interest of several out-of-market hospitals in acquiring St. Luke’s, Wakeman, Tr. 2544-45; PX1016 at 024; entering discussions with ProMedica, Mercy, and UTMC about possible affiliation

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10 St. Luke’s “core service area” is the top eight zip codes from which St. Luke’s draws 60 percent of its patient volume. *See, e.g.*, PX01235 at 5.

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arrangements, IDF 404; and attempting to renegotiate MCO contracts to obtain more favorable reimbursement rates. IDF 541-45, 547-49.

In August 2009, Mr. Wakeman, in a document entitled “Options for St. Luke’s – St. Luke’s is now at a crossroads,” presented three options to the Board: (i) “Remain independent. Surgically remove all financially losing services/programs until accepted margin is realized”; (ii) “Push the payors to . . . raise SLH reimbursement rates to an acceptable margin”; or (iii) merge with one of the other in-market hospitals. IDF 390, 393-95; PX01018 at 008, 009, 014-017, *in camera*. With respect to the first option, management noted that it would entail cutting “bone and muscle,” not just fat, and would require that St. Luke’s “cut major services and programs (downsizing), not just rightsizing.” PX01018 at 008, *in camera*.

With respect to the second option, management noted that “St. Luke’s is being grossly underpaid.” IDF 391, *quoting* PX1018 at 003, *in camera*. It cautioned, however, that

PX1018 at  
009, *in camera*.

The final option involved a merger with Mercy, UTMC, or ProMedica. IDF 395. St. Luke’s management believed that affiliating with ProMedica had several potential advantages, including ProMedica’s strong managed care contracts, a “huge” cash inflow (directly and indirectly through inclusion in ProMedica’s MCO, Paramount), the likelihood of upgrades to the St. Luke’s campus, improved information technology systems, a good history of execution, and a greater likelihood of local control. IDF 396; PX1018 at 014, *in camera*.

The Board rejected the possibility of service cuts, and began to focus on the affiliation options. IDF 401; Black, Tr. 5703-04. In an October 30, 2009 update on affiliation options, St. Luke’s management detailed the advantages and disadvantages of affiliating with each of the in-market hospitals. IDF 402-05; PX01030, *in camera*. On December 15, 2009, senior management presented another affiliation update to the Board in

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which it detailed a variety of financial “pressing concerns” and again analyzed the pros and cons of affiliating with ProMedica, Mercy, or UTMC. IDF 409-14. The update acknowledged that any of the three options “could increase prices/cost to the community.” IDF 419-21. As to affiliating with ProMedica, the update identified the pros as: favorable insurance contracts (noting access to ProMedica’s MCO affiliate, Paramount); access to capital; investment in St. Luke’s campus; potential for local governance and control; solid physician strategy and infrastructure; and financial stabilization of the organization’s ability to serve and expand. IDF 421, *citing* PX01016 at 023, *in camera*. The cons were: “some quality measures are poor and history of poor relations with partners/affiliates.” *Id.*

On December 15, 2009, Mr. Wakeman recommended to the St. Luke’s Board of Directors that St. Luke’s pursue an affiliation with ProMedica; the Board approved his recommendation that same day.<sup>11</sup> On May 25, 2010, the parties signed a Joinder Agreement and on August 31, 2010, consummated the transaction subject to the Hold Separate Agreement.

### **I. St. Luke’s Pricing Objectives for the Joinder**

At the time of the Joinder, commercial reimbursement rates paid to St. Luke’s were significantly lower than those received by ProMedica and Mercy. IDF 530. In contrast, ProMedica’s commercial reimbursement rates at the time of the Joinder were the highest in Lucas County, IDF 524, and among the highest in Ohio. IDF 525.

St. Luke’s expected to be able to raise its rates after the Joinder. Indeed, one of the primary reasons it chose to affiliate

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<sup>11</sup> IDF 422-23. St. Luke’s cut off talks with Mercy and UTMC, which had remained interested in affiliating with St. Luke’s, when St. Luke’s decided to pursue an affiliation with ProMedica. Wakeman Tr. 2554-55, 2559. The Board decided not to pursue affiliation with Mercy based upon several issues, including concerns about lack of local governance. IDF 424. It decided not to pursue affiliation with UTMC principally because UTMC’s proposed board structure was not acceptable to St. Luke’s due to UTMC’s desire to maintain full veto power. The Board was also concerned about the potential incompatibility between UTMC’s state institution and union culture and St. Luke’s culture. IDF 425.

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with ProMedica was the expectation that St. Luke's would be able to significantly increase its reimbursement rates because of ProMedica's more favorable bargaining leverage with MCOs, which would be further enhanced with the deal. IDF 600-03. Highlighting this belief, a 2009 presentation regarding potential affiliation partners made to St. Luke's Board of Directors states: "An SLH affiliation with ProMedica has the greatest potential for higher hospital rates. A ProMedica-SLH partnership would have a lot of negotiating clout." IDF598; PX01030 at 020, *in camera*. The presentation conveyed management's belief that "ProMedica had a significant leverage on negotiations with some of the [health plans]" and that this leverage would allow St. Luke's to obtain higher reimbursement rates; it expressed concern that an affiliation with ProMedica could, in the short term, "harm the community by forcing higher hospital rates on them." IDF 598, *quoting* Wakeman, Tr. 2700, *in camera*.

**J. The Joinder Agreement**

Under the Joinder Agreement, ProMedica committed to "maintain[ing] St. Luke's using its current name and identity and at its current location for a minimum of ten (10) years . . . as a fully operational acute care hospital providing the following services: emergency room, ambulatory surgery, inpatient surgery, obstetrics, inpatient nursing and a CLIA certified laboratory." IDF 428, *quoting* PX00058 at 023, 045-046. ProMedica promised to pay \$5 million at closing and to provide an additional \$30 million in equal annual installments over a three-year period to fund various capital projects at St. Luke's, including converting semi-private rooms to private rooms, updating St. Luke's IT systems, constructing an outpatient lobby, renovating the heart center, moving administrative services, expanding surgical areas, and increasing the private postpartum and infant nursery. IDF 429-30, PX00058 at 021, 056. The Agreement also enabled St. Luke's to become a participating provider in the Paramount network, from which it previously had been excluded. IDF 432, PX00058 at 022-023. In return, ProMedica received the power to appoint two members of St. Luke's Board and to approve St. Luke's Board nominees, as well as certain important reserve powers, including the right to approve St. Luke's budgets and to appoint or remove St. Luke's management. IDF 434-35, PX00058 at 016-018.

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**V. LEGAL FRAMEWORK**

Section 7 of the Clayton Act prohibits the acquisition of assets “where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.” 15 U.S.C. § 18. Section 7 prohibits acquisitions that create a reasonable probability of anticompetitive effects. “Congress used the phrase ‘*may be* substantially to lessen competition’ to indicate that its concern was with probabilities, not certainties.” *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 713 (D.C. Cir. 2001), quoting *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962). “Thus, to establish a violation of Section 7, the FTC need not show that the challenged merger or acquisition *will* lessen competition, but only that the loss of competition is a ‘sufficiently probable and imminent’ result of the merger or acquisition.” *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 35 (D.D.C. 2009), quoting *United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 623 (1974).

Merger enforcement is therefore concerned with preventing the unlawful acquisition, maintenance, and exercise of market power. 2010 Horizontal Merger Guidelines § 1. Mergers that enhance market power can enable the merged firm to profitably alter its marketplace decisions to the detriment of consumers, for example, by raising prices, cutting output, or reducing product quality or variety. Mergers that enhance market power can also diminish incentives for innovation.

Courts have traditionally analyzed Section 7 claims under a burden-shifting framework. See, e.g., *Heinz*, 246 F.3d at 715; *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990). Under this framework, the government can establish a presumption of liability by defining a relevant product and geographic market and showing that the transaction will lead to undue concentration in the relevant market.<sup>12</sup> The typical measure for determining market concentration is the Herfindahl-

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<sup>12</sup> See *United States v. Philadelphia Nat’l Bank*, 374 U.S. 321, 363 (1963); *Baker Hughes*, 908 F.2d at 982-83.

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Hirschman Index (the “HHI”). *CCC Holdings*, 605 F.Supp. 2d at 37.

“Once the Government establishes its *prima facie* case, the respondent may rebut it by producing evidence to cast doubt on the accuracy of the Government’s evidence as predictive of future anticompetitive effects.” *Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 423 (5th Cir. 2008); *Baker Hughes*, 908 F.2d at 982-983. The stronger the government’s *prima facie* case, the greater the respondent’s burden of production on rebuttal. *Heinz*, 246 F.3d at 725; *Baker Hughes*, 908 F.2d at 991. Factors that may be considered include “ease of entry into the market, the trend of the market either toward or away from concentration, and the continuation of active price competition.” *Kaiser Alum. & Chem. Corp. v. FTC*, 652 F.2d 1324, 1341 (7th Cir. 1981). Rebuttal evidence may also include factors relating to competition in the relevant market or the competitive or financial weakness of the acquired company. *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 494-504 (1974); *Baker Hughes, Inc.*, 908 F. 2d at 985 (citing *Lektro-Vend v. Vendo Co.*, 660 F.2d 255, 276 (7th Cir. 1981); *United States v. Int’l Harvester Co.*, 564 F. 2d 769, 773-79 (7th Cir. 1977); *FTC v. Nat’l Tea Co.*, 603 F.2d 694, 699-700 (8th Cir. 1979)).

Finally, if the respondent successfully rebuts the *prima facie* case, the burden of production shifts back to the government and merges with the ultimate burden of persuasion, which remains with the government. *Chicago Bridge*, 534 F.3d at 423. A plaintiff can bolster a *prima facie* case based on market structure with evidence showing that anticompetitive effects are likely. *Heinz*, 246 F.3d at 717. Common sources of evidence include the merging parties, customers, other industry participants, and industry observers. 2010 Horizontal Merger Guidelines § 2.2.

This traditional burden-shifting framework is not the only appropriate manner in which to conduct a proper merger analysis. The courts have recognized that in practice, evidence is often considered together and the burdens are not strictly demarcated. *Chicago Bridge*, 534 F.3d at 424-25. Accordingly, the burden shifting is regarded as describing a flexible analytical framework rather than an airtight rule. *Id.* at 424. As we said in *Evanston Nw. Healthcare Corp.*, 2007 WL 2286195 at \*44 (FTC 2007),

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“[a]lthough the courts discuss merger analysis as a step-by-step process, the steps are, in reality, interrelated factors, each designed to enable the fact-finder to determine whether a transaction is likely to create or enhance existing market power.” Moreover, we have noted in prior cases and the courts have also recognized that a framework derived from defining a relevant market and showing undue concentration in that market “does not exhaust the possible ways to prove a § 7 violation on the merits.” *F.T.C. v. Whole Foods Market, Inc.*, 548 F.3d 1028, 1036 (D.C. Cir. 2008); *see also Polypore Int’l, Inc.*, 2010 WL 5132519 at \*14 (FTC Dec. 13, 2010); *Evanston*, 2007 WL 2286195 at \*73-76.<sup>13</sup>

The 2010 **HORIZONTAL MERGER GUIDELINES** further elaborate on this principle by explaining that merger analysis should not consist of uniform application of a single methodology. 2010 **HORIZONTAL MERGER GUIDELINES** § 1. Rather, the fact-specific nature of merger review necessarily entails a flexible analysis tailored to the nature of the market under examination, and there are a range of analytical tools that can be applied to the evidence to evaluate the competitive concerns from a transaction. *Id.* Definition of the relevant market is often a useful tool to begin the competitive analysis of a merger, but it need not always be the first step because evidence of competitive effects can often inform market definition. *Id.* § 4. Thus, in some merger cases, depending on the facts, it may make sense to begin the analysis with an examination of the competitive effects. *Id.*

In this case, based on the evidence before us, it is appropriate to begin the analysis utilizing the traditional burden-shifting framework.

## **VI. RELEVANT MARKETS**

We begin our review of the Joinder by identifying the relevant markets to determine whether the transaction will substantially lessen competition “within the area of effective competition.” *See*

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<sup>13</sup> In a consummated merger, post-acquisition evidence of actual anticompetitive harm may in some cases be sufficient to establish Section 7 liability, without separate proof of market definition. *Evanston*, 2007 WL 2286195 at \*81-84 (Comm’r Rosch, concurring).

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*United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (internal quotation omitted). “The ‘area of effective competition’ must be determined by reference to a product market (the ‘line of commerce’) and a geographic market (the ‘section of the country’),” *Brown Shoe*, 370 U.S. at 324, for purposes of Section 7 of the Clayton Act. See 15 U.S.C. § 18.

**A. Relevant Product Market**

The relevant product market can be defined by examining the reasonable interchangeability of use by consumers or the cross-elasticity of demand between the product itself and substitutes for it. *Brown Shoe*, 370 U.S. at 325. As one court explained, “[i]nterchangeability of use and cross-elasticity of demand look to [1] the availability of products that are similar in character or use to the product in question and [2] the degree to which buyers are willing to substitute those similar products for the product.” *FTC v. Swedish Match N. Am., Inc.*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000) (citing *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 393 (1956)).

The 2010 **HORIZONTAL MERGER GUIDELINES** use a related test to define the relevant product market. Under those Guidelines, the product market is defined by asking whether a hypothetical monopolist of the proposed product market could impose a small but significant and nontransitory increase in price and not lose an amount of its sales to alternative products that would make the price increase unprofitable. If so, then the proposed market constitutes a relevant product market. *Id.* § 4.1.1 (explaining that the hypothetical monopolist test identifies a set of reasonably interchangeable products because the resulting product market contains enough substitutes so that it could be subject to a post-merger exercise of market power). Many courts have applied the 2010 **HORIZONTAL MERGER GUIDELINES’** hypothetical monopolist test. See, e.g., *Whole Foods Market*, 548 F.3d at 1038; *Swedish Match*, 131 F. Supp. 2d at 160-66.

In this case, the parties agree that there is a relevant product market for GAC inpatient hospital services sold to commercial

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health plans.<sup>14</sup> Complaint ¶¶ 12-13; Answer ¶ 12 (ProMedica “admits that general acute-care inpatient hospital services sold to commercial health plans constitutes a valid service market”). Accordingly, Judge Chappell found that there is a relevant product market for GAC inpatient hospital services sold to commercial health plans. ID 145. The parties also agree that this relevant product market is properly described as a cluster market. ID 139-40. A cluster market for GAC inpatient hospital services has consistently been found to be the relevant product market in prior hospital merger cases. *See, e.g., FTC v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995); *FTC v. Univ. Health Inc.*, 938 F.2d 1206, 1210-12 (11th Cir. 1991); *United States v. Rockford Mem’l Corp.*, 898 F.2d 1278, 1284 (7th Cir. 1990); *Evanston*, 2007 WL 2286195 at \*40-41. In this proceeding, Judge Chappell concluded that the relevant market encompasses “all GAC inpatient hospital services – primary, secondary, and tertiary services – sold to commercial health plans.” ID 143-45.

Complaint Counsel appeal two issues regarding the precise boundaries of the GAC inpatient hospital services cluster market. First, they argue that tertiary services should be excluded from the GAC inpatient hospital services market. Second, they argue that there is a separate relevant product market for inpatient OB services. Respondent defends the ALJ’s product market. Resolution of these issues is important from the standpoint of analytical precision and guidance for future cases, but in this case it does not make a difference on the ultimate question of liability.<sup>15</sup> As discussed *infra* in Section VII, the market structure in this case generates a presumption of competitive harm

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14 The parties also agree that the relevant product market focuses on the sale of the services to commercial health plans rather than to government payors such as Medicare and Medicaid.

15 For this reason our analysis should not give rise to accusations of “gerrymandering” the relevant product market so as to make it more susceptible to a structural presumption of liability, as Commissioner Rosch suggests in his concurring statement.

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regardless of whether the ALJ's or Complaint Counsel's markets are accepted.<sup>16</sup>

### 1. Two Proposed Approaches to Cluster Market Methodology

The parties present two differing approaches for defining a cluster market. Complaint Counsel's approach aggregates smaller relevant markets that, for reasons of analytical convenience, can be assessed collectively because they all involve the same competitive conditions. Respondent's approach does not focus on the competitive conditions of the smaller relevant markets, but rather, focuses on the aggregation of hospital services that MCOs tend to purchase as a package in single negotiated transactions.

The first step in Complaint Counsel's cluster market approach is to identify the individual inpatient hospital services (*e.g.*, knee surgery, appendectomy) for which there is an overlap in services provided by ProMedica and St. Luke's. *See* CCRB 2. Each individual inpatient hospital service is potentially a self-standing, relevant product market under the 2010 **HORIZONTAL MERGER GUIDELINES** because the individual services are not clinical substitutes for one another. CCAppB 22.

Complaint Counsel then collect into a cluster all of the individual relevant service markets that have similar competitive conditions – here, a common group of hospital providers. This is done merely for the convenience of analysis: as long as the competitive conditions for each individual product are alike, only a single analysis of competitive effects is necessary. Complaint Counsel argue that this approach, “allows the analysis to be done efficiently, without creating inconsistent or distorted results, precisely because GAC inpatient hospital services are offered

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<sup>16</sup> Moreover, these issues affect only a small subset of the inpatient hospital services that are within the GAC inpatient hospital services market. Even if both OB services and tertiary services are excluded from the GAC inpatient market found by the ALJ, a substantial core group of GAC inpatient hospital services that the parties agree belong in a relevant product market remains and warrants analysis regarding possible anticompetitive effects arising from the Joinder.

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under similar market conditions, by the same market participants, and within the same geographic market.” CCApB 22.

Applying this approach, Complaint Counsel define a cluster market consisting of the group of GAC inpatient hospital services (i) for which there is an overlap between ProMedica and St. Luke’s *and* (ii) that are provided by all four Lucas County hospital competitors. Because St. Luke’s generally does not provide tertiary services,<sup>17</sup> there is no tertiary overlap with ProMedica, and Complaint Counsel do not place these services into the GAC inpatient services market. Complaint Counsel also argue that because patients are willing to travel greater distances for tertiary and quaternary services, the set of available hospitals may be broader than for primary and secondary services. For this reason too, tertiary services would not be aggregated into the cluster that corresponds to Toledo hospitals. Similarly, because UTMC does not provide OB services, the competitive conditions (*i.e.*, the number of competing suppliers) differ from those for GAC inpatient services. Consequently, Complaint Counsel exclude OB services from their GAC inpatient hospital services cluster market and, instead, analyze OB services separately.

In contrast, Respondent proposes an approach to defining the GAC inpatient hospital services market cluster based on the idea of transactional complements – the bundle of complementary inpatient hospital services for which MCOs demand access for their commercially insured patients and for which MCOs generally negotiate and contract as a package. RAnsB 3-4. According to Respondent, a cluster based on transactional complements covers the full range of inpatient hospital services available to commercially insured patients that MCOs negotiate for as a package. It includes both tertiary and OB services because both are demanded by MCOs when they contract with hospitals.

The ALJ adopted Respondent’s transactional complements approach. ID 140 (explaining that “MCOs demand, and contract for, a broad array of inpatient hospital services together . . . on

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<sup>17</sup> See JSLF ¶ 6 (“St. Luke’s currently performs few, if any, tertiary services and no quaternary services.”).

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behalf of the members they insure”). The ALJ included tertiary services because “MCOs contract for a broad array of primary, secondary, and tertiary inpatient services from hospitals together in a single negotiated transaction.” ID 142-43; IDF 304. He found that limiting “the market to only those services that both St. Luke’s and ProMedica actually provide is not what MCOs demand or contract to purchase.” ID at 143. The ALJ similarly determined that inpatient OB services are included in the GAC inpatient hospital services market. ID 144 (explaining that “to carve out individual hospital services would be contrary to the logic upon which the inpatient services ‘cluster market’ rests”).

## **2. Selecting the Appropriate Cluster Market Methodology – Facilitating the Analysis of Competitive Effects**

### **a. Complaint Counsel’s “Cluster for Analytical Convenience”**

The primary purpose of defining a relevant product market is to facilitate the analysis of competitive effects of a transaction. We do not undertake market definition as an exercise in and of itself. *See du Pont*, 353 U.S. at 593 (citing *Standard Oil Co. v. United States*, 337 U.S. 293, 299 (1949)) (“Determination of the relevant market is a necessary predicate to a finding of a violation of the Clayton Act because the threatened monopoly must be one which will substantially lessen competition ‘within the area of effective competition.’ Substantiality can be determined only in terms of the market affected.”); 2010 **HORIZONTAL MERGER GUIDELINES** §§ 4, 4.1.1 (noting “the overarching principle that the purpose of defining the market and measuring market shares is to illuminate the evaluation of competitive effects” and explaining that “[t]he measurement of market shares and market concentration is not an end in itself, but is useful to the extent it illuminates the merger’s likely competitive effects”).

With that purpose in mind, we find that cluster markets based on analytical convenience are useful and appropriate for evaluating competitive effects in this case. The identification of substitutes is at the core of product market definition. *See, e.g., Brown Shoe*, 370 U.S. at 325 (“[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use

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or the cross-elasticity of demand between the product itself and substitutes for it.”). Viewed from this perspective, the individual service lines provided by the hospitals lack substitutes and each could be treated as a relevant product market. Both parties’ expert witnesses agreed. *See* Guerin-Calvert, Tr. 7632-33 (Respondent’s expert explaining that as a general matter, the individual service lines within the cluster are not substitutes for each other; from a demand-side analysis they can be considered separate product markets; and one could evaluate competitive effects within each individual service line); Town, Tr. 3665 (Complaint Counsel’s expert explaining that individual services are not clinical substitutes for each other), 3667 (stating that “each of the services in the cluster [is its] own relevant product market”); *see also Rockford Mem’l*, 898 F.2d at 1284 (explaining that if you need a kidney transplant or have a heart attack, you will go to an acute-care hospital for inpatient treatment: “The fact that for other services you have a choice between inpatient care at such a hospital and outpatient care elsewhere places no check on the prices of the services we have listed, for their prices are not linked to the prices of services that are not substitutes or complements.”).

We also find that the collection of individual hospital service relevant product markets into a cluster for purposes of evaluating competitive effects enables us to analyze efficiently the Joinder’s effect in hundreds of relevant product markets.<sup>18</sup> JSLF ¶ 57 (“the cluster market is used ‘as a matter of analytical convenience [because] there is no need to define separate markets for a large number of individual hospital services . . . when market shares and entry conditions are similar for each,’” quoting *Emigra Group v. Fragomen*, 612 F. Supp. 2d 330, 353 (S.D.N.Y. 2009)); *see also* Commentary on the Horizontal Merger Guidelines (2006) at 8-9 (“when the analysis is identical across products or geographic areas that could each be defined as separate relevant markets using the smallest market principle, the Agencies may elect to

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18 Of course, it is possible that out of the hundreds of services that are aggregated into the cluster, there may be a few services for which one Lucas County hospital did not have a patient with that diagnosis in a particular year. Such isolated instances at this level of detail during the aggregation into a cluster market would not meaningfully alter the relevant product market in this case.

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employ a broader market definition that encompasses many products or geographic areas to avoid redundancy in presentation”). Collecting the service lines into a cluster based on whether they have similar market conditions enables an accurate assessment of competitive effects, which is our ultimate goal. As one commentator explains,

when the same firms sell the same set of products, which do not happen to be substitutes, in the same geographic areas with similar market shares, and when each individual product would constitute a product market under the [Merger] Guidelines, the antitrust analysis of each would be so similar in practice that no loss of analytic power comes from treating the products as a collection. . . . If there is no compelling reason to believe demand and supply substitutability opportunities, entry conditions, or market shares differ significantly across individual products, then the antitrust analysis will be similar for each good so they may conveniently be analyzed as a collection.

Jonathan B. Baker, *The Antitrust Analysis of Hospital Mergers and the Transformation of the Hospital Industry*, 51 L. & Contemp. Probs., Spring 1988, at 93, 138.

Respondent, nonetheless, maintains that Complaint Counsel’s approach to defining a cluster market introduces supply-side considerations into market definition, contrary to the instructions of the 2010 **HORIZONTAL MERGER GUIDELINES**. RAnsB 10-11 (citing 2010 **HORIZONTAL MERGER GUIDELINES** § 4 (“Market definition focuses solely on demand substitution factors”). According to Respondent, collecting services into clusters according to the number and identity of the competing hospitals relies improperly on a supply-side consideration. We disagree. Complaint Counsel’s methodology considers demand-side substitution because each individual service line (*e.g.*, knee replacement, appendectomy) is found to be a relevant product market based on demand-side substitution. The grouping or collection of those services into clusters for analytical convenience is part of the competitive effects analysis. *See* Town, Tr. 3595.

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This approach to defining a cluster market is generally consistent with prior cases that have found cluster markets. In *Philadelphia National Bank*, the Supreme Court found that “the cluster of products (various kinds of credit) and services (such as checking accounts and trust administration) denoted by the term ‘commercial banking’ composes” a relevant product market because the court determined that each of the products or services was effectively free from competition from other financial institutions. 374 U.S. at 356-57. In short, the competitive conditions faced by commercial banks was the same for each of the products or services in the cluster. Similarly, in *United States v. Grinnell Corp.*, 384 U.S. 563 (1966), the Court found a cluster of central station services in which the dominant firm with a 73 percent market share faced 38 competitors; whether the remaining 27 percent of the market in each service (*i.e.*, fire alarm, waterflow alarm) was provided by 24 or 38 competitors, the competitive conditions were the same. *Id.* at 572-73 n.6.

An approach that groups product markets with competitive overlaps when competitive conditions are similar is consistent with the GAC inpatient hospital service markets defined in prior hospital merger cases. Thus, courts and adjudicators regularly exclude outpatient services from the cluster markets because the competitors for those services differ from the competitors for inpatient services. *See, e.g., Evanston*, 2007 WL 2286195 at \*46-47; *Rockford Mem’l*, 898 F.2d at 1284; *FTC v. Butterworth Health Corp.* 946 F. Supp. 1285, 1290-91 (W.D. Mich. 1996). Also, in *Butterworth*, the court found a separate relevant product market for primary care inpatient hospital services in addition to the GAC inpatient hospital services cluster because the primary service lines were offered by a greater number of hospitals in competition with the merging hospitals.<sup>19</sup>

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<sup>19</sup> *Butterworth*, 946 F. Supp. at 1291 (discussing analysis of product market). *But see California v. Sutter Health Sys.* 130 F. Supp. 2d 1109, 1119-20 (N.D. Cal. 2001) (defining a cluster market that included all primary, secondary, and tertiary services when some services faced competition from niche hospitals in addition to full-range hospital competitors).

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**b. Respondent's "Transactional Complements" Cluster**

In contrast, Respondent's approach to defining the cluster market does not facilitate the effective analysis of competitive effects. The fact that MCOs negotiate primary, secondary, and tertiary services in a single transaction may suggest a contracting efficiency, but it does not account for why the resulting cluster allows for an accurate assessment of competitive effects.

Respondent's attempt to elaborate – stressing that MCOs demand the full range of inpatient hospital services – provides no persuasive reason for defining a corresponding cluster market, given the manner in which MCOs assemble the combination of hospitals in their networks. MCOs do not demand the full range of inpatient services from *each* hospital or from *each* hospital provider in their network.<sup>20</sup> Rather, MCOs ensure that the full range of inpatient services is available to insured members at *some* hospital within the network. IDF 274 (“MCOs require at least one hospital in the network that offers advanced services, including tertiary services, but the network need not include more than one such hospital”), 449. Thus, the rationale on which Respondent's cluster is based – the cluster is the full range of inpatient services that MCOs demand when they negotiate with hospitals – is contradicted by the observation of actual services demanded by MCOs from each hospital or hospital provider.<sup>21</sup>

Worse, we find that treating all of the services within the contract in a single analysis of competitive effects likely

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20 In Lucas County, MCOs contract with and include UTMC and Mercy St. Anne in their hospital networks despite the fact that those hospitals do not provide OB services. IDF 92, 110. Similarly, MCOs contract with and include St. Luke's and the ProMedica and Mercy community hospitals in the networks even though those hospitals do not provide most tertiary services. IDF 63, 68, 74, 92, 100.

21 Respondent notes that the contracts between hospitals and MCOs include prices for services that are not provided by the hospital. RAnsB 5. In light of MCOs' willingness to satisfy their networks' needs through a combination of hospital providers, we would not expect the listing of prices for unprovided services to be a meaningful determinant of the scope of the market relevant for assessing competitive effects on services that are provided.

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obfuscates the competitive consequences of the transaction. Indeed, a cluster that mixes services with different geographic markets, or that groups together services for which the merger leaves different numbers of remaining rivals or has a different competitive impact, could easily confuse the competitive analysis unless great care were taken to separately analyze different aspects of the transaction's competitive effects. *See* Thomas L. Greaney, *Chicago's Procrustean Bed: Applying Antitrust Law in Health Care*, 71 **ANTITRUST L. J.** 857, 882-84 (2004).

In particular, when the prices of individual services within the cluster may be the subject of negotiation, treating all services in a single competitive analysis does not account for the relevant economic factors – the availability of substitutes – that would affect those individual prices. *See Rockford Mem'l Corp.*, 898 F.2d at 1284 (explaining that the price of an individual hospital service depends on the availability of substitutes for that service, and the prices are not linked to the prices of services that are not substitutes or complements). The record demonstrates that MCO/hospital negotiations consider individual terms that fall within the resulting contract and permit modifications to those individual contractual terms. *See* IDF 317 (explaining that contracts between MCOs and hospitals may contain “carve-outs” that price one hospital service differently from other hospital services); Randolph, Tr. 6953-56, 6960, *in camera*; Pirc, Tr. 2287; Radzialowski, Tr. 753. When each negotiating party may exert its bargaining power based on the availability of substitutes for a particular service and the number of substitutes differs for particular services, a cluster market that fails to account for such differences does not properly facilitate the analysis of competitive effects.

Respondent's approach has not been followed in prior cases. Respondent claims that the cluster is the entire group of services that a customer demands. Yet, in *Philadelphia National Bank*, where the Court defined a “commercial banking” cluster that it understood to include services as diverse as checking accounts and trust administration, 374 U.S. at 356, individual customers would hardly be expected to frequently purchase the entire group of services in a single transaction. In *Grinnell*, the Court found that Grinnell held majority control over three principal protective

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service suppliers: Holmes, which provided only burglary services; AFA, which supplied only fire protection services; and ADT, which provided both. 384 U.S. at 566. Certainly, customers who bought from Holmes or AFA were not demanding and negotiating for the entire group of central station protective services in a single transaction.<sup>22</sup>

Respondent's proposed approach to defining the cluster has previously been rejected by the FTC. In *Evanston*, the Commission rejected the analogous claim that the relevant product market included hospital-based outpatient services "because MCOs purchase both inpatient and outpatient services from hospitals." *Evanston*, 2007 WL 2286195 at \*46-47. Indeed, earlier in that proceeding Administrative Law Judge Stephen J. McGuire explained:

Respondent argues that the relevant product market should be determined by using a demand-side analysis, which looks at the products sold by each merging firm, and that where a customer purchases several services together, it is those services taken as a whole that constitute the relevant product market. . . . [T]he Court of Appeals for the Seventh Circuit has explicitly rejected an approach that defined the relevant product market as *all* the services provided by the merging parties and demanded by customers. . . . The reasoning of the Seventh Circuit in *Rockford Memorial* applies with equal force here.

*Evanston Nw. Healthcare Corp.*, No. 9315, Initial Decision at 134 (Oct. 21, 2005), <http://www.ftc.gov/os/adjpro/d9315/051020initialdecision.pdf>, *aff'd*, 2007 WL 2286195 at 46-47 (FTC Aug. 6, 2007) (citing *Rockford Mem'l*, 898 F.2d at 1284).

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<sup>22</sup> Although the Court suggested that customers often purchased more than one item in the protective services cluster, its point was that the cluster could be justified based on economies of scope – a supply-side consideration very different from Respondent's demand-oriented transactional complements. See *Grinnell*, 384 U.S. at 573 (observing that customers utilized in combination different services provided from a single office).

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Similarly, in this case, Judge Chappell found that the single hospital contract was not a basis to include outpatient services in the relevant product market even though those services are part of the single negotiation between an MCO and a hospital. *Compare* IDF 307, 308 (explaining that outpatient services are not part of the relevant product market) *with* ID 172-73 (explaining that complex negotiations and single contracts between MCOs and hospitals cover outpatient as well as inpatient services); *see also*, *e.g.*, *Butterworth Health*, 946 F. Supp. at 1290-91.

Thus, based on the facts of this case and this industry, and, consistent with precedent, we reject Respondent's approach to defining a cluster market.<sup>23</sup>

### 3. Defining the Relevant Markets

We now address the specific issues raised by Complaint Counsel's appeal. First, we conclude that tertiary services are not part of the GAC inpatient hospital services market in this case. Importantly, in its Answer to the Complaint, Respondent admitted that tertiary services are excluded from the GAC inpatient market. Answer ¶ 13. A party is bound by the admissions in its answer. *Gibbs ex rel. estate of Gibbs v. Cigna Group*, 440 F.3d 571, 578 (2d Cir. 2006); *Mahtui v. Bohrell*, 219 F.2d 642, 643 (9th Cir. 1955). The admissions in an answer help to focus the issues in the litigation; Complaint Counsel, the ALJ, and the Commission should be able to rely on those admissions. We will not allow a Respondent to admit things in its Answer and, post-discovery, change its position.

Even if Respondent were not bound by its Answer, we would exclude tertiary services from the relevant GAC inpatient hospital services market in this case. St. Luke's generally does not provide tertiary services. *See* JSLF ¶ 6; ID 140. Absent an overlap or potential overlap involving a given service line, there is

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<sup>23</sup> We do not conclude that Respondent's approach could not be appropriate under different factual circumstances. After all, market definition is a fact-specific exercise. We conclude only that a cluster market based on the scope of what MCOs demand and negotiate in single transactions with hospitals does not produce a meaningful relevant product market in which to assess competitive effects in this case.

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no substantial lessening of competition, and, thus, no need to include the service in the relevant product market.<sup>24</sup> Moreover, inclusion of tertiary services could obscure the analysis of competitive effects. Because patients are likely willing to travel farther for more complex treatments, IDF 283, the geographic market for tertiary services could be larger than that for primary and secondary services. If so, the number of competitors that could constrain price increases for those tertiary services could be higher (although it would have little impact on prices for primary and secondary services), and an analysis limited to hospital providers in Lucas County might be inappropriate.<sup>25</sup> Under an analysis that takes care to group together only relevant service markets with similar competitive conditions, tertiary services should not be aggregated into the cluster for GAC inpatient hospital services.

Judge Chappell notes that prior hospital merger cases have been inconsistent regarding whether tertiary services are included in a GAC inpatient hospital services market. ID 141-42 (citing *Butterworth*, 946 F. Supp. at 1291 and *United States v. Long Island Jewish Med. Center*, 983 F. Supp. at 137, 140, as examples where tertiary services were excluded from the GAC inpatient hospital services market). This is not surprising because defining a relevant product market in any particular case is a fact-specific question. However, we disagree with the ALJ's description of the

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<sup>24</sup> See *CCC Holdings*, 605 F. Supp. 2d at 37 (“the relevant product market identifies the product and services with which the defendants’ products compete”); *Little Rock Cardiology Clinic v. Baptist Health*, 573 F. Supp. 2d 1125, 1140-41 (E.D. Ark. 2008) (finding that a firm cannot monopolize or create anticompetitive effects in a market where it does not participate); 2010 **HORIZONTAL MERGER GUIDELINES** § 4.1 (explaining that the antitrust Agencies begin market definition when a product of one merging firm competes with a product of the other merging firm); cf. *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 976 (N.D. Iowa 1995) (explaining that parties agreed that the relevant product market was acute care inpatient services, limited “to those services for which Mercy and Finley currently compete for patients”).

<sup>25</sup> Typically, a respondent seeks to expand the relevant product market to increase the number of competitors. Here, however, Respondent seeks to include tertiary services in the GAC inpatient market, but does not argue that there are additional competitors. Granting Complaint Counsel’s appeal on this issue does not affect the number of competitors.

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Commission's treatment of the market in *Evanston*. Although the complaint in *Evanston* excluded tertiary services from the alleged relevant product market, at trial counsel for both sides agreed that, based on the particular facts of that case, tertiary services should be part of the GAC inpatient hospital services market. See Compl. Counsel's Answering and Cross-Appeal Brief, *In the Matter of Evanston Northwestern Healthcare Corp.*, Docket No. 9315 at 37, available at: <http://www.ftc.gov/os/adjpro/d9315/060210ccattachmntpursuantrule.pdf>. Thus, the issue of whether to include tertiary services in the relevant product market was not raised on appeal. Not surprisingly, the Commission decision included tertiary services in the GAC inpatient hospital services market without any analysis of the issue and focused instead on the disagreement between the parties over whether outpatient services should be included in the GAC hospital services market. *Evanston*, 2007 FTC LEXIS 210, at \*146-151. The Commission is faced with a different situation here, and our decision to exclude tertiary services from the relevant GAC inpatient hospital services product market is based on the particular facts of this case.<sup>26</sup> Similarly, *FTC v. University Health Inc.*, 938 F.2d 1206 (11th Cir. 1991), is not inconsistent with our analysis. The Court of Appeals for the Eleventh Circuit expressly chose not to analyze whether the market was broader than the overlap services. It explained that determining the precise bounds of the relevant product market "would be of no moment for [its] purposes," and accepted the broader market merely "for ease of discussion." *Id.* at 1211 n.11.

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<sup>26</sup> Commissioner Rosch's Concurring Opinion relies on *Evanston* for his conclusion that we should include tertiary services in the GAC inpatient hospital services market. In our view, the reasons set forth above for excluding tertiary services from the relevant market in this case outweigh an argument premised on another case with its own facts, particularly where the decision contained no analysis of the issue. Commissioner Rosch also cites Professor Baker in footnote 1 of his Concurring Opinion when he explains that market definition may be supported simply by "convenienc[ce]." Yet Professor Baker is careful to explain that a cluster market may be used for "analytic convenience in situations where it will not be misleading." Baker, *supra*, at 137-38 (emphasis added). As Professor Baker explained, the cluster market is *not misleading* only when it collects services that have common market conditions, and in this case, that means excluding tertiary services from the relevant GAC inpatient hospital services market. *Id.*

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Second, we conclude that inpatient OB services are not in the GAC inpatient hospital services cluster market but rather constitute a separate relevant product market. As with many of the individual inpatient hospital services grouped together in the GAC cluster market, OB services warrant delineation as a relevant product market under standard principles of analysis. No other services are interchangeable with OB services. IDF 313; Resp. to Compl. Counsel's Req. for Admiss. at 6. An OB services market passes the 2010 **HORIZONTAL MERGER GUIDELINES** test: a hypothetical monopolist could profitably impose a small but significant and non-transitory increase in price. 2010 **HORIZONTAL MERGER GUIDELINES** § 4.1.1. Respondent's economic expert conceded as much. Guerin-Calvert, Tr. 7679-80 (acknowledging that prices "could materially change" if ProMedica achieved a monopoly over OB services). Moreover, examination of "practical indicia," which courts use to augment the interchangeability analysis, *see, e.g., Brown Shoe*, 370 U.S. at 325; *CCC Holdings*, 605 F. Supp. 2d at 38, indicates that OB services are a separate relevant product market. Obstetrics is recognized as a separate field of medicine with distinct providers of OB services. In addition, the merging hospitals track OB services market shares separately from GAC inpatient services. IDF 314; *see, e.g., PX01016* at 003, *in camera* (St. Luke's presentation regarding affiliation partners); *PX00009* at 022 (ProMedica Credit Presentation to Standard & Poor's).

Respondent argues that OB services cannot be a separate relevant product market because there is no evidence that hospitals price discriminate with regard to OB services. We disagree: there is no requirement that price discrimination be proved to find a separate relevant market. The OB services market satisfies the hypothetical monopolist test in its own right – there is no need to look within it for a subset of customers who could be harmed by price discrimination. Respondent's reliance on Section 4.1.4 of the 2010 **HORIZONTAL MERGER GUIDELINES** is misplaced. The 2010 **HORIZONTAL MERGER GUIDELINES** describe a circumstance where a firm targets a particular group of customers within a single product market, not a cluster market as we have here. As we previously explained, the cluster market is a collection of properly-defined relevant product

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markets – here, lines of services at Lucas County hospitals – that were aggregated only to facilitate analyzing competitive effects.

Most important to the analysis here, OB services are offered under different competitive conditions than those applicable to the other services included in the GAC inpatient hospital services cluster market: one of the four Lucas County hospital providers (UTMC) does not offer OB services. *See* IDF 110; Answer ¶¶ 4, 15, 20. The availability of competitive alternatives for consumers of OB services therefore differs substantially from that for consumers of services in the cluster. Thus, including OB services in the GAC inpatient hospital services cluster market would be inconsistent with the goal of market definition: the accurate assessment of competitive effects.

Commissioner Rosch’s concurring statement suggests that defining a separate relevant product market for OB services would be redundant, since OB services are part of the bundle of inpatient hospital services that MCOs purchase. We disagree. If we were to place inpatient OB services within the GAC inpatient hospital services cluster market, in analyzing anticompetitive effects we still would need to evaluate the effect of decreasing the number of OB suppliers from three to two. The record clearly shows that there are reimbursement rate carve-outs for OB services. *See* IDF 317-18; Sheridan, Tr. 6683-84 (during 2010 negotiations between ProMedica and United, case rates and per diem rates for OB services were the subject of separate negotiation); Radzialowski, Tr. 752 (Aetna specifically negotiates rates for maternity care); PX00365 at 030, *in camera* (contract between ██████████ and ██████████ for ██████████ contains ██████████); PX00366 at 030, *in camera* (contract between ██████████ and ██████████ for ██████████ contains ██████████); PX02520 at 003-005, *in camera* (update on negotiations between Aetna and ProMedica shows ██████████

██████████). This dictates that we must account for the different market conditions at some stage of our analysis. We believe the analysis will prove more transparent if we address the issue in defining the relevant product market rather than deferring it to the examination of competitive effects.

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Commissioner Rosch's concurrence also expresses discomfort with the fact that there is no judicial precedent for defining a separate OB services market. We are not daunted by this observation, however, because every case that comes before the Commission is fact-specific and merits independent examination. Moreover, contrary to footnote 2 of Commissioner Rosch's concurring opinion, there is judicial precedent for the underlying rationale we use in this case to treat OB services as a separate relevant product market. This includes case law finding a separate cluster market for particular inpatient services in addition to the GAC inpatient hospital services market where the group of suppliers for that group of services differs from the suppliers of GAC inpatient hospital services. *See Butterworth*, 946 F. Supp. at 1291 (court agreeing with FTC that there is a separate relevant product market for primary care inpatient hospital services in addition to the GAC inpatient hospital services market, based on the existence of a differing group of suppliers for those services).<sup>27</sup>

In any event, the outcome of this case is the same whether or not OB services are included in the GAC inpatient hospital services market.

**B. Relevant Geographic Market**

The ALJ found that the relevant geographic market for GAC inpatient hospital services is Lucas County, Ohio,<sup>28</sup> ID 145-46, and we agree. Moreover, there is agreement between the parties that the relevant geographic market for the GAC inpatient hospital

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<sup>27</sup> The Sixth Circuit affirmed the district court's decision and in no sense rejected the district court's product market finding. *See FTC v. Butterworth Health Corp.*, 1997-2 Trade Cas. (CCH) ¶ 71,863 (6<sup>th</sup> Cir. 1997).

<sup>28</sup> Judge Chappell found that "the evidence establishes: no MCO has marketed a health plan to Lucas County customers without including at least one Lucas County hospital; a hypothetical monopolist controlling every hospital in Lucas County could increase the price of GAC inpatient services in Lucas County by at least 5 to 10 percent, a small but significant amount; with extremely rare exceptions, Lucas County residents do not use more distant providers of GAC inpatient hospital services; and hospitals in counties adjacent to Lucas County are not acceptable alternatives for one MCO's Lucas County members." ID 145-46.

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services market is Lucas County, Ohio. Complaint ¶ 16; Resp. to Compl. Counsel's Req. for Admiss. 7; Tr. 7683 (Guerin-Calvert).

Similarly, we also conclude that the relevant geographic market for OB inpatient hospital services is Lucas County. *See* Town, Tr. 3593-94. The ALJ determined that for the "GAC inpatient services market, which includes OB services," the proper geographic market is Lucas County. ID 145. If patients do not travel beyond Lucas County for GAC inpatient hospital services such as scheduled diagnoses and surgeries, patients are even less likely to travel outside Lucas County for delivery of a baby. *See* Sheridan, Tr. 6682; *cf.* Town, Tr. 3632 (stating, "if you have an acute condition . . . time matters"), 3694-95 (finding average patient travel time for OB services was 11.3 minutes).

## **VII. THE JOINDER IS PRESUMPTIVELY ILLEGAL**

Ultimately, whether we accept Complaint Counsel's or Respondent's definition of the relevant markets does not affect our analysis of this transaction's likely competitive effects. As the ALJ found, regardless of which market definition is used, market shares and concentration levels exceed the thresholds for presumptive illegality provided in the 2010 **HORIZONTAL MERGER GUIDELINES** and the case law. IDF 368-70; ID 151. Respondent does not dispute this.

In the GAC inpatient hospital services market as defined above, ProMedica's acquisition of St. Luke's reduced the number of competitors from four to three, combining St. Luke's 11.5 percent market share with ProMedica's 46.8 percent market share and giving ProMedica a post-acquisition market share of 58.3 percent based on patient days.<sup>29</sup> IDF 364. The acquisition increased the HHI in the GAC inpatient hospital services market by 1,078 points, resulting in an HHI of 4,391 based on patient days.<sup>30</sup> IDF 368. In the OB inpatient services market, the acquisition reduced the number of competitors from three to two, adding St. Luke's 9.3 percent market share to ProMedica's 71.2

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<sup>29</sup> Patient days measure how long a patient stays in a hospital. IDF 346.

<sup>30</sup> IDF 364. Mercy's share was 28.7 percent; UTMC's share was 13.0 percent. *Id.*

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percent market share and giving ProMedica an 80.5 percent market share based on patient days.<sup>31</sup> PX02148 at 143, *in camera*. The acquisition increased HHIs in the OB services market by 1,323 points, resulting in an HHI of 6,854. *Id.* These concentration data are more than sufficient to create a presumption that the merger is anticompetitive. *See Heinz*, 246 F.3d at 716 (increase in HHI of 510 in market with HHI of 4,775 created a presumption “by a wide margin”); *Univ. Health*, 938 F.2d at 1211 n.12, 1219 (*prima facie* case established where merger reduced competition from five to four and resulted in a combined market share of 43 percent, an HHI increase of 630 points, and a post-merger HHI of 3200); 2010 **HORIZONTAL MERGER GUIDELINES** § 5.3 (post-acquisition HHI above 2500 and HHI increase of more than 200 points “will be presumed to be likely to enhance market power”).<sup>32</sup>

Of course, statistics concerning market share and concentration are not conclusive proof of competitive harm. *Gen. Dynamics*, 415 U.S. at 498. Nonetheless, where concentration levels are high, as they are in this case, Respondent bears the burden of demonstrating that the HHIs and market share data are unreliable in predicting a transaction’s competitive consequences. *See Heinz*, 246 F.3d at 715; *Univ. Health*, 938 F.2d at 1218. As the Supreme Court has explained, “a merger which produces a firm controlling an undue percentage share of the relevant market, and results in a significant increase in the concentration of firms in that market is so inherently likely to lessen competition substantially that it must be enjoined in the absence of evidence clearly showing that the merger is not likely to have such anticompetitive effects.” *Philadelphia Nat’l Bank*, 374 U.S. at

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31 PX 02148 at 143, *in camera*. Mercy’s share was 19.5 percent. *Id.*

32 Although Respondent’s expert did not calculate HHIs for the GAC inpatient hospital services market as she defined it, she conceded that, even under her relevant market definition, the acquisition increased concentration in an already highly concentrated market to levels deemed presumptively anticompetitive under the 2010 **HORIZONTAL MERGER GUIDELINES**. IDF 369; Guerin-Calvert, Tr. 7730. ProMedica’s and St. Luke’s own assessments of market shares in internal documents reinforce the conclusions that, however the relevant market is defined, it was highly concentrated before the acquisition, and the acquisition significantly increased concentration. IDF 361-63; PX00270 at 025-026; PX01236 at 002, 054.

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363. “The more compelling the prima facie case” – including other evidence presented by Complaint Counsel that reinforces the structural presumption – “the more evidence the defendant must present to rebut it successfully.” *Baker Hughes*, 908 F.2d at 991; *accord Chicago Bridge & Iron*, 534 F.3d at 426.

**VIII. RESPONDENT’S ATTEMPTED REBUTTAL: ST. LUKE’S AS A WEAKENED COMPETITOR**

The ALJ found that “[t]he totality of the evidence supports the conclusions . . . that St. Luke’s was struggling financially as a stand-alone entity during the years leading up to the Joinder and faced significant financial obstacles to going forward as an independent hospital.” ID 186. However, he also found that St. Luke’s financial position had improved prior to the Joinder; that its cash reserves would likely allow it to fund necessary capital projects and pay off its obligations; and that “the evidence does not warrant the conclusion that St. Luke’s was likely to undertake service cuts absent the Joinder.” ID 187-88, 188 n.24. On balance, he found that while St. Luke’s “future viability beyond the next several years is uncertain” it “was not in imminent danger of failure.” ID 188. He concluded that “current case law, applied to the facts of this case, does not provide support for allowing the Joinder to proceed on the basis of St. Luke’s weakened financial condition.” ID 190.

We agree. Since *General Dynamics*, 415 U.S. 486, evidence of an acquired firm’s anticipated competitive weakness may, in certain cases, be sufficient to rebut the government’s *prima facie* case. However, it is also clear that the courts have imposed an extremely heavy burden on defendants seeking to rebut the structural presumption on this ground. Thus, for example, in *FTC v. Arch Coal*, 329 F. Supp. 2d 109 (D.D.C. 2004), the case chiefly relied on by Respondent, the court explained that “the evidence of financial or other weakness must genuinely undercut the statistical showing of anticompetitive market concentration.” *Id.* at 154. “[F]inancial difficulties,” the court continued, “are relevant only where they indicate that market shares would decline in the future and by enough to bring the merger below the threshold of presumptive illegality.” *Id.* at 154, *quoting* 4 AREEDA ET AL., ANTITRUST LAW ¶ 963(a)(3), at 13 (1998)). “Indeed,” the court summarized, “[f]inancial weakness, while perhaps relevant in

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some cases, is probably the weakest ground of all for justifying a merger,' and 'certainly cannot be the primary justification' for permitting one." *Arch Coal*, 329 F. Supp. 2d at 154, quoting *Kaiser Aluminum*, 652 F.2d at 1339, 1341.

The Eleventh Circuit in *University Health* explained why this is so:

Since weak firms are not in grave danger of failure – if so, they would be failing, rather than weak, companies, and the analysis might differ . . . it is not certain that their weakness “will cause a loss in market share beyond what has been suffered in the past, or that [such weakness] cannot be resolved through new financing or acquisition by other than a leading competitor...” Moreover, “[t]he acquisition of a financially weak company in effect hands over its customers to the financially strong, thereby deterring competition by preventing others from acquiring those customers, making entry into the market more difficult.”

938 F.2d at 1221, quoting 4 P. AREEDA & D. TURNER, ANTITRUST LAW, p. 1221 ¶ 935b at 140 (1980) and *Kaiser Aluminum*, 652 F.2d at 1339. Thus, said the court, “[t]o ensure that competition and consumers are protected, we will credit such a defense only in rare cases, when the defendant makes a substantial showing that the acquired firm’s weakness, which cannot be resolved by any competitive means, would cause that firm’s market share to reduce to a level that would undermine the government’s prima facie case.” *Univ. Health*, 936 F.2d at 1221; see also *FTC v. Warner Commc’ns, Inc.*, 742 F.2d 1156, 1164 (9th Cir. 1984) (explaining that the financial weakness defense is disfavored because it “would expand the failing company doctrine, a defense which has strict limits”).

Here, the record shows that St. Luke’s was experiencing some financial difficulties in the years prior to the Joinder, and the ALJ so found. ID 182-87; IDF 784-919. However, it is also clear that St. Luke’s, under Mr. Wakeman’s leadership, was making significant improvements in its performance, and was *growing* prior to the Joinder. Thus, although Respondent asserts that St.

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Luke's market share will decrease, RAppB 38, it does not point to any evidence to substantiate that assertion. In fact, St. Luke's market share was increasing – not declining – in the years before the Joinder;

*See* PX00159 at 005, 012 *in camera*;  
PX01235 at 003.

St. Luke's improved performance reflected its implementation of a strategic plan shortly after Mr. Wakeman was hired as St. Luke's CEO in February 2008. IDF 920. St. Luke's achieved most of the growth goals set out in that plan, increasing its "inpatient net revenue by more than \$3.5 million per year on average" and its "outpatient net revenue by more than \$5 million per year on average" (IDF 924-25), and achieving a 40 percent market share in its core service area. IDF 928. Its overall occupancy rate in the twelve months prior to the Joinder increased by about percent. IDF 930. As patient volumes and patient care revenues improved, St. Luke's succeeded in getting its variable costs under control, and its operating margins consequently improved. IDF 949-54, 957-58.

Although St. Luke's did not achieve the financial goals set out in the strategic plan, IDF 936-41, it was making significant progress. In his last regular monthly report for St. Luke's as an independent hospital, Mr. Wakeman reported:

We have experienced activity in excess of the Operating Financial Plan (OFP) and last years' activity. That activity has finally exceeded our fixed expense . . . .

Inpatient, (up 7.5%) and outpatient, (up 6.1%), activity was running hot all month. While we still have capacity for outpatient, especially in the offsite centers, inpatient capacity is limited except for weekends. . . .

. . . .

If there was one pillar we attained a high level of success in our strategic plan in the past two years,

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it would be growth. The hard numbers prove that out, and almost every service. . . .

Cardiac, pulmonary, surgery, emergency department, primary life systems, medical/surgical, imaging . . . , lab testing and especially obstetrics have experienced great growth in the past two years.

Significantly, Mr. Wakeman added:

The high activity produced a positive operating margin of \$7000 on \$36.7 million in gross revenue. It is not impressive, but it is better than a loss. *This positive margin confirms that we can run in the black if activity stays high. After much work, we have built our volume up to a point where we can produce an operating margin and keep our variable expenses under control.*

PX000170, at 001, 006-007 (emphasis added). Summarizing what St. Luke's had accomplished, CEO Wakeman concluded:

The entire St. Luke's family has much to be proud of with the accomplishments in the past three years. We went from an organization with declining activity to near capacity. Our leadership status in quality, service and low cost stayed firmly in place. In the past six months our financial performance has improved significantly. The volume increase and awareness of expense control were key.

*Id.* at 007. Other evidence likewise points to significant improvements in St. Luke's financial performance in the months prior to the Joinder. *See* Black, Tr. 5684-85 (St. Luke's Board of Directors Chairman testifying that St. Luke's financials were



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Respondent does not deny that these improvements occurred. JSLF ¶¶ 27-36; Uyl Tr., 6562 (Respondent's expert testifying that St. Luke's financial performance had improved in the six months leading up to the Joinder); Hanley, Tr. 4701-02 (ProMedica's CFO testifying that St. Luke's had experienced a positive trend in patient revenues since 2008). Rather it downplays the significance of those improvements, contending that St. Luke's, while improving, was still operating at a loss throughout most of 2010; that its profit margin in August 2010 was only about \$7,000; and that, although St. Luke's was able to increase its patient volumes in 2010, it continued to lose money on every patient it treated. RAppB 39; RRB 20. Additionally, Respondent argues that an independent St. Luke's would not have been able to fund necessary capital improvements in the future and that St. Luke's would have had to implement deep service cuts unless it affiliated with another hospital. RAppB 10, 39. Respondent also contends that St. Luke's "location in Lucas County will become less competitively significant." RAppB 38. Thus, Respondent argues, "It is likely that, absent the joinder, St. Luke's market share would be reduced to zero (if it exited the market) or nearly zero if it made the service cuts that it considered absent the joinder." RRB 19; *see also* RAppB 38, 40.

We find Respondent's arguments unpersuasive and lacking in evidentiary support. Although a \$7,000 operating profit in August 2010 may be "not impressive" as Mr. Wakeman observed, PX 00170 at 001, the evidence shows that St. Luke's had made significant improvements and was on a positive trajectory at the time of the Joinder. Respondent asserts that St. Luke's achieved an operating profit in August 2010 only because of "two large, unusual, and non-recurring additions to St. Luke's operating income," RRB 20, but the record as a whole suggests that St. Luke's was moving toward, not away from, a sustainable path.<sup>33</sup>

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<sup>33</sup> The increase in patient volumes and revenues for St. Luke's resulted largely from its successful physician recruiting efforts and its renewed participation in the Anthem network in July 2009. IDF 957. In 2005 ProMedica had persuaded Anthem to exclude St. Luke's from its network in return for greater rate discounts at ProMedica hospitals. *See* Wakeman, Tr. 2528-32, 3030-31. However, in July 2009 Anthem readmitted St. Luke's to its network, and Anthem-insured patients once again could receive care at St. Luke's. *Id.* at 2530-31. There is no reason to believe that St. Luke's will not continue to be able to participate in the Anthem network in the future. As to the recruiting of

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See PX00171 at 001 (St. Luke's CEO Wakeman concluding, based on the results through the time of the Joinder, that St. Luke's "can run in the black if activity stays high").

Respondent's argument that "St. Luke's lost money, on average, for each patient that walked through its door" and that this undermined any showing that St. Luke's was "rebounding" in the months before the Joinder, RRB 20, is likewise unpersuasive. While the record shows that St. Luke's payments from all payors – MCOs, self-pay, and government – were too low to cover its costs, IDF 373, 377, St. Luke's cost coverage ratios, like other aspects of its financial performance, were improving significantly in the months before the Joinder.<sup>34</sup> Moreover, we are not persuaded that St. Luke's would not have been able to negotiate more favorable rates with the MCOs – especially with \_\_\_\_\_, which accounted for a significant portion of St. Luke's commercially-insured patient volume, but whose reimbursement rates were significantly below St. Luke's costs.<sup>35</sup> The

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physicians, St. Luke's already had achieved what was necessary. See PX000170 at 001 ("we have built our volume up to a point where we can produce an operating margin"). Respondent offers no reason why, having achieved this recruiting success, the resulting volume and revenue benefits would be "non-recurring."

34 St. Luke's overall cost coverage ratio for all payors was \_\_\_\_\_ for 2007, \_\_\_\_\_ for 2008, \_\_\_\_\_ for 2009 and \_\_\_\_\_ for the first eight months of 2010. IDF 373. However, there were significant disparities between the cost coverage ratios for different payors. St. Luke's cost coverage ratios for Medicare and Medicaid, which represented about \_\_\_\_\_ percent of St. Luke's revenues, were \_\_\_\_\_ IDF 375. According to one witness,

Sheridan, Tr. 6647-48,

*in camera* (testifying that

\_\_\_\_\_ Among the MCOs, only \_\_\_\_\_ and \_\_\_\_\_ had below-cost reimbursement rates for St. Luke's in 2009, and in 2010 only \_\_\_\_\_ did. IDF 376. Negotiating a more favorable contract with only one large payor – \_\_\_\_\_ – would have gone a long way toward solving St. Luke's financial problems.

35 In 1995, under its prior CEO, St. Luke's had negotiated a long-term contract with \_\_\_\_\_ which saddled St. Luke's with low rates that were insufficient to meet its costs of care. IDF 540; Black, Tr. 5580-81; \_\_\_\_\_ Tr. 2345-46, *in camera* \_\_\_\_\_). According to Mr. Black, St. Luke's Chairman of the Board, St. Luke's

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representative testified that

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■<sup>37</sup> Accordingly, we cannot conclude that St. Luke's would not have been able to negotiate rates sufficient to cover its costs if it had not decided instead to pursue the Joinder with ProMedica.

Respondent's argument that St. Luke's would not be able to fund capital projects and meet its other obligations also is unpersuasive. The record shows that at the time of the Joinder St. Luke's had enough cash reserves to fund its existing capital needs and to meet its financial obligations; that it had a low debt load; and that it could borrow at reasonable rates if it chose to do so.<sup>38</sup> While it is true that St. Luke's had been dipping into its cash reserves to fund its operating losses and capital improvements in the years before the Joinder, and that it could not continue to do so indefinitely, we cannot assume, based on the record before us, that St. Luke's could not have funded needed capital improvements in the future, especially in view of its significantly improved operating performance in 2010.

We likewise are unpersuaded by Respondent's argument that, in the absence of an affiliation, St. Luke's necessarily would have

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financial problems came to light after the prior CEO retired. Black, Tr. 5560-62.

36 , Tr. 2229-36, *in camera*. The record shows that

*Id.* at 2354-55.

*Id.* at 2356; IDF 541-45.

*see* IDF 546-49,  
Instead, St. Luke's pursued an affiliation

with ProMedica.

37 , Tr. 2353, *in camera*.

38 ID 187. As of the date of the Joinder, St. Luke's owed less than \$11 million in total outstanding debt, and held at least \$65 million in cash and investments. JSLF ¶¶ 34-35.

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had to implement deep service cuts, and that this would have led to St. Luke's decline within, and even possible disappearance from, the Lucas County market. As the case law discussed above establishes, to prevail Respondent must show not only that the acquired firm's financial difficulties would result in a decline in its market share in the future, but also that those declines would be enough to bring the merger below the threshold of presumptive illegality. That means that St. Luke's market share of the GAC inpatient hospital services market would have to decline from 11.5 percent to 2.1 percent or less and that its share of the OB services market would have to decline from 9.3 percent to 1.4 percent or less. *See* CCAnsB 29. Respondent does not dispute either the legal standard or the underlying calculations. Rather Respondent argues that we should assume that, in the absence of the Joinder, St. Luke's would have had to implement deep service cuts and that such service cuts would result in a continuing deterioration in St. Luke's position sufficient to meet any required thresholds. RRB 19-21.

This we decline to do. In support of its argument on service cuts, Respondent relies primarily on one document, PX01018, *in camera*, an August 2009 presentation by Mr. Wakeman to the St. Luke's Board of Directors. That document identifies and discusses three options to address St. Luke's financial condition. The first of these options is to "[r]emain independent. Surgically remove all financially losing services/ programs until accepted margin is realized." *Id.* at 008. The presentation identified "Heart? Obstetrics?" as possibilities for cuts. *Id.*

Mr. Wakeman's presentation, however, was made at the nadir of St. Luke's financial difficulties before St. Luke's significantly improved operating performance in 2010. Notably, Mr. Wakeman recognized this improvement in a memorandum to the St. Luke's Board in September 2010 when he identified both cardiac and OB services (two of the services identified as possibilities for cuts) as experiencing especially high growth during the two years prior to the Joinder. *See* PX000170 at 006. Moreover, the options presented to the Board in August 2009 were not limited only to service cuts or the Joinder with ProMedica, as Respondent suggests. RRB 19-21. Rather, the presentation also identified as options attempting to increase St.

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Luke's reimbursement rates and affiliating with Mercy or UTMC. PX01018 at 009-0013, 015-017, *in camera*. Critically, the evidence shows that the St. Luke's Board determined not to undertake service cuts. IDF 401. St. Luke's Chairman of the Board, James Black, testified that potential service cuts were not "a major topic of discussion" because the idea was distasteful to the Board. Black, Tr. 5703-04. Mr. Black further testified that pursuing rate increases was one of the major goals of the three-year plan implemented by Mr. Wakeman. Black, Tr. 5706.

Finally, even if St. Luke's would have made some service cuts in the absence of the Joinder, Respondent has not presented evidence to show that such cuts would have led to a decline in St. Luke's market shares *to the required levels*. For example, Mercy St. Anne offers neither OB services nor advanced heart services; yet there is no contention or evidence that St. Anne is not a viable competitor in the Lucas County market.

Thus, while PX01018 appears to reflect Mr. Wakeman's view in 2009 that cutting services was one option to address St. Luke's financial condition, it does not support Respondent's positions that, absent the Joinder with ProMedica, deep service cuts were inevitable, or that the depth of those cuts would render St. Luke's competitively insignificant. Notably, in late 2009 Mr. Wakeman advised the Board that St. Luke's would be able to survive three to five years under then current conditions, with no payor rate increases, and four to seven years if it was able to generate rate increases from two of its largest payors. Wakeman, Tr. 2624-25 (explaining that that was his estimate "[g]iven the information we had at the end of 2009"). Mr. Wakeman elaborated further that "[a]ll other issues being equal," improvements in the equity markets and in St. Luke's financial performance during the first eight months of 2010 "could have extended our time to stay independent." *Id.* at 2627.

Likewise, Respondent's contention that St. Luke's "location in Lucas County will become less competitively significant," RAppB 38, is contradicted by the evidence. As the ALJ found, the southwest sector of Lucas County has favorable demographic characteristics that make it a "desirable area for a hospital to be located." IDF 472-74. Witnesses, including Mr. Wakeman and Mr. Oostra, ProMedica's CEO, testified to St. Luke's favorable

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location. Wakeman, Tr. 2477, 2481 (St. Luke's is "in an optimal or better part of the community in the sense of growth and economic potential"); Oostra, Tr. 6037-38. MCO witnesses likewise testified to the importance of having geographic coverage in the growing and more affluent southwest sector. *See, e.g.,* Pirc, Tr. 2195-96; Pugliese, Tr. 1442-43. Elsewhere in its briefs, Respondent recognizes that "[f]or ProMedica, the joinder provided an opportunity to expand its services in southwest Lucas County." RAppB 1. Respondent has failed to demonstrate that St. Luke's location will become competitively less significant, and one of its own rationales for acquiring St. Luke's belies its argument.

For all of these reasons, Respondent has not shown that St. Luke's financial condition so reduces its competitive significance as to undermine Complaint Counsel's *prima facie* case. Further, Respondent has not shown that there were no other competitive means by which St. Luke's could have addressed its financial difficulties. *See Univ. Health*, 938 F.2d at 1221 (requiring that "defendant make[] a substantial showing that the acquired firm's weakness, *which cannot be resolved by any competitive means*, would cause that firm's market share to reduce to a level that would undermine the government's *prima facie* case." (Emphasis added)).

The record shows that the primary source of St. Luke's financial weakness was its low reimbursement rates. ID 186, IDF 372-77. In light of St. Luke's reputation as a high-quality provider and its advantage of being the only hospital in the growing and more affluent sector of Lucas County, *see* IDF 472-74, it is likely that St. Luke's would have succeeded in negotiating more favorable reimbursement rates had it remained independent, especially since St. Luke's had identified negotiation of higher reimbursement rates as a major goal. Respondent concedes this. *See* RRB 15 ("it would be ridiculous to expect that St. Luke's prices will hold steady or decrease" in view of their low current levels); Oral Arg. Tr. 68-69 (Marx).<sup>39</sup> In addition, St.

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<sup>39</sup> *See also* \_\_\_\_\_, Tr. 2229-36, 2353, *in camera*

¶ St. Luke's mixed record in

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Luke's could have affiliated with an out-of-market hospital system, which would not pose competitive issues,<sup>40</sup> or with UTMC,<sup>41</sup> which would pose significantly fewer competitive concerns than a Joinder with ProMedica, the self-described dominant system in Lucas County.

In sum, Respondent's "weakened competitor" showing falls far short of what the courts have demanded. Comparison to *Arch Coal*, 329 F. Supp. 2d 109, is telling. *Arch Coal* involved the acquisition of one coal company, Triton, by another, Arch Coal. There, as here, the defendant argued that the acquiree was a weak competitor and that its competitive significance was overstated. *Id.* at 153-57. The *Arch Coal* court concluded that the FTC's claims of Triton's competitive significance were in fact "far overstated." *Id.* at 157. The facts of *Arch Coal*, however, bear no resemblance to those here. For example, in *Arch Coal*, the presumption of competitive harm was weak (*id.* at 129, noting

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negotiating higher rates before the Joinder is not persuasive as to the future. St. Luke's pre-Joinder efforts were made in the context of trying to *renegotiate* rates in existing contracts where St. Luke's bargaining leverage would presumably be less than it would be on contract expiration. *See* IDF 541-49.

40 Respondent contends that "St. Luke's also investigated affiliating with other entities but either they were not interested or St. Luke's determined an affiliation was not in its or the community's best interest." RRB 21 n.11. Respondent identifies discussions with only three out-of-market systems – the University of Michigan, the Cleveland Clinic and McClaren Health Care. *See id.*; Wakeman, Tr. 2541-48. Mr. Wakeman also testified that St. Luke's held "general discussions" regarding a possible affiliation with other local community hospitals controlled by diverse organizations but did not pursue the arrangement after determining that it would have required unacceptably complex, time-consuming negotiations. Wakeman, Tr. 2548-51. The history of these limited efforts fails to establish that St. Luke's asserted competitive weakness cannot be resolved through affiliation with an out-of-market buyer.

41 Prior to entering exclusive discussions with ProMedica in January 2010, St. Luke's had been engaging in on-going discussions with both Mercy and UTMC about possible affiliation arrangements, and the presentations made to the St. Luke's Board discussed the pros and cons of affiliating with each of them. *See* PX01018, *in camera*; PX01030, *in camera*; PX01016, *in camera*. In fact, St. Luke's and UTMC had drafted a Memorandum of Affiliation Terms in August 2009 (PX02205). Up to the time when St. Luke's cut off talks with them in late 2009, both Mercy and UTMC remained interested in pursuing an affiliation with St. Luke's. Wakeman, Tr. 2552-55, 2559.

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that “HHI increases are far below those typical of antitrust challenges brought by the FTC and DOJ” and that “the FTC’s prima facie case is not strong”); here, in contrast, the presumption is very strong, and the evidence required to rebut the statistical case is accordingly greater. *Id.*, quoting *Baker Hughes*, 908 F.2d at 991 (“[t]he more compelling the prima facie case, the more evidence the defendant must present to rebut it successfully”). Whereas in *Arch Coal*, there were no prospects for improvement, 329 F.Supp. 2d at 157, St. Luke’s was improving its financial performance, and its market share was increasing, not declining. Whereas in *Arch Coal* prospects for finding an alternative buyer were “dim,” *id.* at 156, here that is far from clear.<sup>42</sup> In short, this is not one of those “rare cases,” *Univ. Health*, 938 F.2d at 1221, where Respondent has met its burden of showing that financial weakness rebuts the presumption of illegality based on the government’s structural case.

**IX. SUBSTANTIAL RECORD EVIDENCE BUTTRESSES  
THE STRUCTURAL CASE**

The evidence of market structure discussed above establishes a strong presumption that the Joinder will substantially lessen competition. Respondent has failed to present a showing of financial weakness sufficient to rebut that presumption. Nor, as discussed below, does Respondent provide evidence that entry or repositioning by competitors would be timely, likely or sufficient to deter or counteract the Joinder’s likely anticompetitive effects or that other actions by market participants would be likely to constrain an exercise of market power.

Complaint Counsel, however, have not rested their case on market structure alone. They have gone on to present substantial evidence of likely competitive harm that buttresses their structural showing. This evidence includes documents, testimony, and business conduct of the merging parties that demonstrates their understanding that the Joinder will enhance market power. It includes a demonstration that the Joinder will increase the

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<sup>42</sup> In *Arch Coal*, the court emphasized that the acquired firm had conducted a comprehensive, but ultimately unsuccessful, search for an alternate buyer over a multi-year period. 329 F. Supp.2d at 156-57. The same is not true here.

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bargaining leverage of the combined ProMedica/St. Luke's hospital system by detracting from the alternatives available to MCOs in negotiations with the combined system, and, consequently, can be expected to generate unilateral anticompetitive effects in the form of higher prices at both St. Luke's and the ProMedica legacy hospitals.<sup>43</sup> In addition, Complaint Counsel present econometric analysis quantifying the price impacts. This additional analysis – while unnecessary, particularly in light of the strength of Complaint Counsel's *prima facie* case – is nonetheless helpful because it is tailored to the unique competitive dynamics of hospital markets, stemming from the bargaining between hospitals and MCOs over inclusion in MCO networks.

#### **A. Bargaining Leverage and Hospital Reimbursement Rates**

The rates and terms of contracts that hospitals (or hospital systems) negotiate with MCOs are determined in large part by the bargaining leverage that each party brings to bear. IDF 554. The bargaining leverage of each party and, therefore, the terms of the agreement depend principally upon how each party evaluates the consequences of a failure to conclude an agreement with the other party. IDF 556; Town, Tr. 3641. The MCO's bargaining leverage will depend upon how the hospital provider would fare if it could not participate in the MCO (and therefore lacked ready access to the MCO's members as patients); the hospital provider's bargaining leverage will depend upon how the MCO would fare if its network did not include the hospital provider (and therefore became less attractive to potential members who prefer that provider's services).<sup>44</sup>

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43 Unilateral competitive effects require no change in the behavior of non-merging parties. 2010 **HORIZONTAL MERGER GUIDELINES** § 1.

44 Town, Tr. 3641-43, 3647-50. Thus, "MCOs estimate what it would cost to have a network without a particular hospital, *i.e.*, how much business would the MCO lose." IDF 287. The desirability and demand for a particular hospital provider affects the MCO's loss from forming a network without that provider, and hence affects the hospital provider's bargaining leverage. *See* IDF 295. The more hospitals that a provider controls, the more bargaining leverage it has. This is because failure to reach an agreement results in more hospitals

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A hospital provider's bargaining leverage is affected by the available substitutes for its hospitals. Town, Tr. 3644. These are the hospitals to which the MCO can turn if it is unable to conclude an agreement with the first provider. If there are close substitutes, failure to conclude an agreement may have little impact on the MCO's marketability, so the hospital provider may have little bargaining leverage. *Id.* The less desirable the MCO's set of alternative hospitals, the more the MCO is injured if its network excludes the first provider, and the greater the hospital provider's bargaining leverage. *See* IDF 294, 298. The alternative network that the MCO can construct if it fails to reach an agreement with the first provider is referred to as the "walk-away network." Town, Tr. 3655.

A merger may increase a hospital provider's bargaining leverage by removing substitute hospitals and thereby changing the MCO's cost of failing to reach an agreement. *Id.* at 3651-52. When the merger reduces the value of the alternatives available if the MCO fails to reach an agreement with the first provider, it reduces the desirability of the MCO's walk-away network. *Id.* at 3652.

The rates that emerge from a negotiation will be a function of the parties' bargaining leverage. *Id.* at 3641. If a merger increases the hospital provider's bargaining leverage by increasing the MCO's loss from failing to reach an agreement with the provider, the MCO will be willing to pay more to have that hospital provider in its network.<sup>45</sup> Generally speaking, an increase in the hospital provider's bargaining leverage translates to an increase in its reimbursement rates. *Id.* at 3649-50. IDF 293-94.

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leaving the network, which decreases the marketability of the MCO's network, and results in greater potential loss of business. IDF 298.

<sup>45</sup> *Id.* at 3655 (discussing the concept of "willingness to pay"); IDF 288 ("The reimbursement rates and other terms an MCO will agree to are based primarily on whether the MCO believes it can still sell its plans without that hospital in its network, and what losses the MCO would incur if the hospital were out of network."); *see Evanston Nw. Healthcare Corp.*, 2007 WL 2286195 at \*61 (FTC 2007) ("If a significant portion of an MCO's members view a hospital that raises its prices as particularly important, the MCO likely will be more willing to pay some or all of the increase.").

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**B. MCO Evidence Demonstrates That the Joinder Will Significantly Increase ProMedica's Bargaining Leverage**

Even before the Joinder, ProMedica, as the dominant hospital system in Lucas County, had significant bargaining leverage, which allowed it to command among the highest rates, not only in Lucas County, but also the entire state of Ohio. IDF 524-25. MCO witnesses attributed ProMedica's ability to command such high rates to the size of its system and its market power, rather than to competitively-benign factors such as higher costs or better quality.<sup>46</sup> At the same time MCO witnesses characterized St. Luke's as a cost-effective, high quality hospital located in an especially desirable location. Pirc, Tr. 2194-96; McGinty, Tr. 1190-92, 1205; Pugliese, Tr. 1443-46.

The MCOs testified that the Joinder would further increase ProMedica's bargaining leverage, thereby leading to even higher rates. For example, an \_\_\_\_\_ representative testified that

\_\_\_\_\_, Tr. 1524-25, *in camera*; PX01919 at 014 ( \_\_\_\_\_ Dep. at 51), *in camera*. Aetna's witness testified that the Joinder has made the prospect of walking away from ProMedica substantially less attractive; post-Joinder, if Aetna failed to reach an agreement with ProMedica, it would face the loss of not only ProMedica's three legacy hospitals, but also the loss of St. Luke's, which would leave Aetna without coverage in southwestern Lucas County. IDF 570, Radzialowski, Tr. 664, 712-13, *in camera*; PX01917 at 020, 023 (Radzialowski, Dep. at 75-76, 86), *in camera*. A Humana representative testified that the Joinder increased ProMedica's "ability to leverage us [Humana] for rates for all of their hospitals and St. Luke's now as well." IDF 573, McGinty, Tr. 1209; PX02073 at 004 (¶ 15) (McGinty, Decl.), *in camera*. Similarly, the \_\_\_\_\_ witness testified that "ProMedica would find its bargaining power greater after the acquisition than before."

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<sup>46</sup> IDF 527; Pirc, Tr. 2238-42, *in camera*; see also McGinty, Tr. 1251, 1253; Radzialowski, Tr. 663, 696, *in camera*.

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explaining that it would be more difficult for \_\_\_\_\_ to serve its membership without ProMedica and St. Luke's than without ProMedica's pre-Joinder hospital network in Lucas County. IDF 574, \_\_\_\_\_, Tr. 6687, 6698-6700, *in camera*.

The MCO witnesses also testified that a network composed only of UTMC and Mercy – the only two remaining providers in Lucas County after the Joinder – would not be commercially viable. Thus, the \_\_\_\_\_ witness testified that

\_\_\_\_\_ Tr. 2261-63, *in camera*. Other MCO witnesses likewise testified that a network composed only of UTMC and Mercy would not be commercially viable. IDF 566-68; Radzialowski, Tr. 715-716, *in camera*; Pugliese, Tr. 1477-78; Sandusky, Tr. 1351, *in camera*. This is consistent with observed marketing patterns: as Respondent's own expert acknowledged, no MCO has marketed a network composed only of UTMC and Mercy in at least the last ten years. Guerin-Calvert, Tr. 7895; IDF 565.

Respondent, however, urges us to disregard all the MCO testimony on the grounds that it is “[u]nsubstantiated, [b]iased, and [s]peculative.” RAppB 30; RRB 14. In particular, Respondent contends that, because the MCOs “did not perform *any* analyses to support their beliefs about their ability to sell narrower networks or send their insureds to other hospitals in the event of a post-joinder price increase,” their testimony “is speculative and unsupported by any analysis.” RAppB 30-31; RRB 14.

We disagree. The mere fact that the MCOs had not performed tailor-made studies geared to litigation is no reason to discredit their testimony. The ALJ determined that “the MCOs used general market knowledge, feedback from the field, and/or claims utilization data to determine the attractiveness and marketability of their offerings and provided explanations to support their beliefs.” ID 165 (citation omitted). The MCO witness testimony was based directly on years of relevant experience in designing and marketing networks in Lucas County. The MCO witnesses

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testified at length about how they rely on constant feedback from their sales and marketing teams regarding prospective enrollees' hospital coverage needs, as well as the analysis of various data sets, including utilization reports, claims data, Medicare cost reports, and hospital quality studies, in order to inform their assessments of which hospitals to include in their networks and what negotiating strategies to use with the hospitals. *See, e.g.*, Radzialowski, Tr. 582-83, 587-93, 600-04; Pirc, Tr. 2160-62, 2165-72; Pugliese, Tr. 1420-27.

The precedents relied on by Respondent in urging us to disregard the MCO testimony are clearly distinguishable. Thus, in *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1131 (N.D. Cal. 2004), the court noted that the customer witnesses testified with a "kind of rote," offering "speculation" unsupported by "credible and convincing testimony" but "little or no" testimony about what they "would or could do or not do to avoid a price increase"; in *FTC v. Arch Coal*, 329 F. Supp. 2d 109, 145-46 (D.D.C. 2004), the court found that customer testimony simply reflected general "anxiety" about having one fewer supplier but provided no persuasive reason for finding post-merger coordination more likely; and in *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1054 (8th Cir. 1999), the court discredited MCO testimony that the MCOs could not resist price increases where the evidence showed that they could and that it was in their interest to do so. Here the MCO witnesses gave detailed testimony on why they believed that the Joinder would increase ProMedica's bargaining leverage and why they would not be able to resist rate increases sought by ProMedica in the future. We see no reason to discredit their testimony as a buttress to Complaint Counsel's structural case.

We likewise reject Respondent's contention that the "MCOs have an inherent bias against ProMedica" because "ProMedica owns Paramount, against which MCOs compete for members," and "have an interest in continuing to extract low, often below-cost rates from St. Luke's." RRB 16; RAppB 31. Respondent has offered no proof of bias, and the MCO witnesses testified under oath that they were appearing pursuant to subpoena, and that they had good business relationships with ProMedica and every incentive to maintain those relationships. Radzialowski, Tr.

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611-12; Sandusky, Tr. 1299-1300; Pugliese, Tr. 1427-29; Pirc, Tr. 2162-64. In short, we have no reason to believe that the MCO witnesses gave false, misleading, or biased testimony against ProMedica, St. Luke's or the Joinder, or that any of the MCO testimony should be disregarded on that ground.

**C. The Evidence Demonstrates that Prices Will Likely Increase at St. Luke's as a Result of the Joinder**

The unilateral effects evidence is consistent with the presumption that the Joinder is likely to result in higher prices at St. Luke's. Testimony from St. Luke's officials, contemporaneous St. Luke's documents, MCO testimony, and economic evidence all confirm the presumption.

**1. St. Luke's Anticipated that the Joinder Would Raise its Rates**

St. Luke's own documents make it clear that one of the chief benefits expected from the Joinder was obtaining the significantly higher rates that the ProMedica hospitals were able to command. An August 10, 2009 St. Luke's planning document noted as one option

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PX1390 at 002, *in camera*. A presentation made the following month to St. Luke's Board of Directors by CEO Wakeman and other members of St. Luke's leadership team states, "An SLH affiliation with ProMedica has the greatest potential for higher hospital rates. A ProMedica-SLH partnership would have a lot of negotiating clout." PX1030 at 020, *in camera*; IDF 598. As St. Luke's CEO testified,

Wakeman, Tr. 2698-2700, *in camera*. Other St. Luke's documents likewise establish that among the chief advantages of affiliating with ProMedica was the ability to  
*See* PX01125 at 002, *in camera* (noting the advantages of ProMedica's

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; PX01018 at 014, *in camera* (noting as “Option 3: Affiliate with ProMedica. What do they bring? Strong managed care contracts.”). Indeed, Respondent concedes that St. Luke’s rates would increase after the Joinder and that St. Luke’s thought that it would get more from affiliating with ProMedica than with other possible partners. *See* RRB 15; Oral Arg. Tr. at 37 (Marx).

Likewise, both Mr. Wakeman and Mr. Black, St. Luke’s Chairman of the Board, testified to the hope or expectation that

Wakeman, Tr.  
2685-86, 2700-01, *in camera*; Black Tr. 5714-15, 5718, *in camera*. Indeed, another St. Luke’s document indicates that St. Luke’s anticipated as much as

– as a result of joining ProMedica. PX01231, *in camera*; IDF 603. In short, St. Luke’s clearly anticipated that its rates would increase as a result of the Joinder, and ProMedica’s superior negotiating clout with the MCOs was among the primary reasons St. Luke’s joined the ProMedica system.

## 2. MCOs Expect that the Joinder Will Raise St. Luke’s Rates

Numerous MCO representatives similarly testified that they expect St. Luke’s rates to rise as a result of the Joinder. Thus, Aetna expected that its post-Joinder rates for St. Luke’s initially will rise to the level of Aetna’s rates for ProMedica, and that all ProMedica rates will then rise above pre-Joinder levels based on the additional leverage gained from the Joinder. PX01938 at 023 (Radzialowski, Dep. at 88-89), *in camera*. An Aetna analysis of the impact of the initial change projected a increase in rates to St. Luke’s, accounting for differences of severity between ProMedica and St. Luke’s. IDF 591; Radzialowski, Tr. 704, *in camera*. █: in early

Tr. 717, *in camera*.

Similarly, Humana believed that the Joinder would enable ProMedica to leverage rates for St. Luke’s as well as for the

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ProMedica legacy hospitals. IDF 594. expected rates at St. Luke's to rise because post-Joinder ProMedica would have greater bargaining power than pre-Joinder St. Luke's. IDF 595.

expected that after the Joinder, ProMedica could seek "extraordinary" rates because of the lessening of competition. IDF 587-88. And expected rates at St. Luke's, which were than the rates paid to ProMedica's community hospitals, to rise to the higher ProMedica rates.

Tr. 1506, 1517, *in camera*. An analysis calculated that an to the rate levels at ProMedica's Flower and Bay Park hospitals would be , roughly between and Tr. 1517-19, *in camera*; PX02380, *in camera*.

### **3. Economic Evidence Demonstrates that the Joinder Will Likely Raise Reimbursement Rates at St. Luke's**

As discussed above, the reimbursement rates that a particular hospital provider can extract from an MCO depend on the alternative network of hospitals that the MCO would be able to assemble – the "walk-away network" – if the MCO fails to reach an agreement with that hospital provider.

As a result of the Joinder, the possible alternative network available to MCOs if they do not reach agreement with the combined ProMedica-St. Luke's has changed. Pre-Joinder, if an MCO failed to reach agreement with St. Luke's, the MCO could form a network consisting of the three ProMedica hospitals, the three Mercy hospitals and UTMC. IDF 576. After the Joinder, if an MCO fails to reach agreement with the combined ProMedica-St. Luke's, the MCO can form a network consisting of only the three Mercy hospitals and UTMC. IDF 578. "Because ProMedica's Lucas County hospitals are valued by health plan members, an MCO's failure to contract with St. Luke's has become much more costly for an MCO as a result of the Joinder, because their walk-away network must exclude both St. Luke's and ProMedica's Lucas County hospitals, and is less valuable than a network that excludes only St. Luke's." IDF 580. As part of the integrated ProMedica hospital system, reimbursement rates at St. Luke's would be expected to rise to the level that, based on

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the combined system's leverage, will be charged by ProMedica's community hospitals.

The price increase associated with this enhanced leverage would be substantial. Even prior to the Joinder, ProMedica had by far the highest prices for GAC inpatient services in Lucas County. IDF 606 (citing PX02148 at 143, 145, *in camera*). Complaint Counsel's economic expert, Professor Robert Town, examined pre-Joinder hospital prices in Lucas County. After controlling for case-mix, severity, and patient demographics across hospitals,<sup>47</sup> Professor Town found that ProMedica's average price was higher than Mercy's, higher than UTMC's, and higher than St. Luke's. PX02148 at 037, 145, *in camera*. MCOs confirmed Town's analysis of relative prices; they testified that ProMedica's rates are the highest, and rates at St. Luke's the lowest, in Lucas County.<sup>48</sup>

Moreover, Professor Town provided evidence linking pricing in Lucas County to market structure. Prior to the Joinder, ProMedica had the highest market share and the highest prices in

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<sup>47</sup> A case-mix adjustment controls for variation in case-mix, severity, and patient demographics across hospitals and allows an apples-to-apples comparison of prices. IDF 607 (citing PX02148 at 037, *in camera*). MCOs also utilize comparable case-mix adjustments in their analyses of hospitals. *See, e.g.*, Radzialowski, Tr. 684, 687-88, 698-700, *in camera*; Sandusky, Tr. 1338-48, 1350, *in camera*; Pugliese, Tr. 1512-13, *in camera*; Pirc, Tr. 2238-42, *in camera*; *see also* Wakeman, Tr. 3036-37.

<sup>48</sup> *See* Pirc, Tr. 2238-2242, *in camera*; Radzialowski, Tr. 684, 687-88, 698-700, *in camera*; Sandusky, Tr. 1338-48, 1350, *in camera*; PX02296 at 001, *in camera*; Pugliese, Tr. 1512-13, *in camera*; McGinty, Tr. 1210. Respondent, nonetheless, suggests that Professor Town's price analysis is flawed. Respondent's concern that the analysis "computed prices for patients at hospitals where the patients were not actually treated," RAppB 6, portrays a virtue as a sin: computing average prices for each hospital based on a hypothetical hospital population is precisely what controls for differences in case-mix, severity, and demographics that enables a valid comparison. Respondent's further point, that the results could vary when broken down hospital by hospital and MCO by MCO, RAppB 7, is to be expected. There are always data points above and below a computed average; the average, nonetheless, remains useful for overall comparison.

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Lucas County.<sup>49</sup> Professor Town linked ProMedica's high prices to its high market share. He demonstrated a close correlation between market shares and case-mix adjusted prices, PX02148 at 039, *in camera* (showing that Lucas County hospital providers' rank by market share was identical to their rank by price) and concluded that: "ProMedica's dominant share of the market has contributed to its significant bargaining power with MCOs. ProMedica leveraged this bargaining power to charge MCOs the highest case-mix adjusted prices of any hospital or hospital system in Lucas County." PX02148 at 037, *in camera*. Although, as Respondent argues, the correlation between market shares and price levels does not in itself rule out benign explanations for the price differences, Professor Town separately examined and rejected the chief alternative explanations, showing that the correlation cannot be explained either by quality<sup>50</sup> or cost differences.<sup>51</sup> MCOs confirmed the link between pricing and bargaining leverage. *See* IDF 583, 589, 594-95; Pirc, Tr. 2262, *in camera*.

As the Commission explained in *Evanston*, an analysis predicated on increases in bargaining leverage and the resulting higher prices is consistent with traditional unilateral effects theory. *See Evanston*, 2007 WL 2286195 at \*51-52, *citing U.S. DEPT. OF JUSTICE & FED. TRADE COMM'N, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES* 34-36 (Mar. 2006), *available at* <http://www.ftc.gov/os/2006/03/CommentaryontheHorizontalMergerGuidelinesMarch2006.pdf>

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49 Indeed, ProMedica acknowledged its market dominance in Lucas County in its ordinary course of business documents. *See, e.g.*, PX00270 at 025 (Standard & Poor's credit presentation); PX00319 at 001 (TTH Medical Executive Committee SWOT Analysis Results 2007).

50 Hospital quality does not explain the ranking of average price levels at the Lucas County hospitals. St. Luke's was considered to be a high quality hospital, *see* IDF 758-64, 766; PX01018 at 012, *in camera*; Wakeman, Tr. 2482-83, 2494. It is "regularly recognized by third-party quality ratings organizations that rank St. Luke's within the top 10% of hospitals nationally, based on outcomes, cost, and patient satisfaction." PX00390 at 001 (ProMedica News Release May 26, 2010).

51 *See* PX02148-038, *in camera* (citing documents that

PX01850 at 057-059, *in camera*.



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(“**COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES**”) (“bargaining markets are quite common and fully consistent with unilateral effects theory” based on choices among substitutes and “for hospital markets . . . bilateral negotiations between MCOs and hospitals determine prices that often are unique to the particular negotiation.”); *see also* Concurring Opinion of Commissioner J. Thomas Rosch, *In the Matter of Evanston Northwestern Healthcare Corp.*, Docket No. 9315 (“the law and the facts in this case squarely support complaint counsel’s theory of anticompetitive effects. That theory is based on the unique competitive dynamics of hospital markets, stemming from the bargaining between hospitals and managed care organizations . . . over inclusion in MCO networks . . .”). Combining competitors for which consumers view the firms’ products as significant substitutes may enable the merged firm profitably to increase prices. It reduces the value of an MCO’s walk-away network and consequently reduces its bargaining leverage. The extent of direct competition between the merging parties is the key: “Unilateral price effects are greater, the more the buyers of products sold by one merging firm consider products sold by the other merging firm to be their next choice.” 2010 **HORIZONTAL MERGER GUIDELINES** § 6.1.

In this case, both ProMedica and St. Luke’s CEOs testified that before the Joinder, St. Luke’s viewed ProMedica as a close competitor. IDF 440; Wakeman, Tr. 2511 (based on OB services market shares, ProMedica is St. Luke’s most significant competitor), 2523-27 (based on inpatient and OB services market shares, ProMedica is St. Luke’s most significant competitor in core service area); Oostra, Tr. 6040 (St. Luke’s viewed ProMedica as a significant competitor). Moreover, Mr. Wakeman testified that after joining St. Luke’s in 2008, one of his goals was to regain volume from ProMedica in St. Luke’s core and primary service areas. Wakeman, Tr. 2504-05. Discussion of its core service area in St. Luke’s internal analyses and documents similarly depicts ProMedica as St. Luke’s closest competitor. *See* IDF 494-95.



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analysis of \_\_\_\_\_ is based on \_\_\_\_\_ data, when \_\_\_\_\_ had just become an in-network hospital at \_\_\_\_\_ in \_\_\_\_\_. \_\_\_\_\_ enrollees would be expected to modify their hospital choice and admission decisions over time in response to the availability of a broader network. ID 159 n.19; PX02148 at 047, *in camera*; PX01850 at 017-018, *in camera*. The data supports this explanation. From \_\_\_\_\_ diversion rates for \_\_\_\_\_ enrollees from \_\_\_\_\_ increased each year following \_\_\_\_\_ and the increased patient diversion to \_\_\_\_\_ precisely corresponded to \_\_\_\_\_

*See id.* at 017-019, *in camera*. Over time, as patients continue to adjust to the in-network availability of ProMedica, ProMedica is becoming a more significant alternative to St. Luke's among \_\_\_\_\_ enrollees, and \_\_\_\_\_

Finally, Respondent contends that any price increases at St. Luke's would merely raise St. Luke's low rates to competitive levels and therefore would not cause competitive harm. Post-Joinder, absent action by the Commission, St. Luke's reimbursement rates can be expected to rise to the level that will be charged by ProMedica's community hospitals post-Joinder. This will likely result in a price increase that encompasses, and exceeds, ProMedica's pre-Joinder price levels, since the combined hospital system will have even greater leverage than ProMedica had pre-Joinder. Respondent's claim would thus require that we find that ProMedica's pre-Joinder hospital reimbursement rates did not reflect its substantial pre-existing market power. *See* PX02148 at 036-040, *in camera*. We would also have to conclude that (i) the rates at Mercy and UTMC, which are also substantially below ProMedica's rates, *see id.* at 145, *in camera* (case-mix adjusted prices); Tr. 2238-2242, *in camera*, are also substantially below competitive levels; and (ii) rates at the vast majority of Ohio hospitals are all below competitive levels. *See* Oostra, Tr. 5996 (Anthem informed ProMedica that its rates were among the highest in the state); PX00153 at 001. We would also have to ignore St. Luke's own market assessment when it sought higher rates from MCOs before joining with ProMedica. St. Luke's approached MCOs with the argument that they could either pay St. Luke's the "little bit more"

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that it sought in order to sustain its position or pay later “at the other hospital system contractual rates.”<sup>55</sup> In other words, St. Luke’s believed, and thought MCOs would credibly accept, that the price increase from a potential merger would take reimbursement rates beyond a competitive level. For all these reasons, we are not persuaded that a price increase at St. Luke’s to the price levels that will be charged by ProMedica’s community hospitals would merely raise St. Luke’s reimbursement rates to competitive levels.

**D. Evidence Demonstrates that, as a Result of the Joinder, Price Increases at ProMedica are Likely**

**1. MCOs Expect that the Joinder Will Likely Raise ProMedica’s Rates**

A number of MCO representatives testified that the Joinder likely will allow ProMedica to command higher rates at its legacy hospitals as well as at St. Luke’s. Thus, an Aetna witness testified that additional leverage from the Joinder would give ProMedica the ability to raise reimbursement rates – as a first step, ProMedica will increase Aetna’s rates to St. Luke’s to the level of Aetna’s rates to ProMedica, and, as a second step, it will use the additional leverage “to raise all of ProMedica’s rates.” Radzialowski, Tr. 712-13, *in camera*; PX01938 at 023 (Radzialowski, Dep. at 88-89, *in camera*). Similarly, a Humana representative testified that, prior to the Joinder, Humana had used its negotiated rates with St. Luke’s as a benchmark in negotiations with ProMedica, and that the Joinder, by eliminating St. Luke’s independence against ProMedica, increased ProMedica’s “ability to leverage us [Humana] for rates for all of their hospitals and St. Luke’s now as well.” McGinty, Tr. 1209; PX02073 at 003 (¶ 11) (McGinty, Decl.), *in camera*. Likewise, an \_\_\_\_\_ witness testified that *ProMedica’s* increased leverage from the Joinder would permit it to “really name their price” that is, to seek “extraordinary” reimbursement rates for inpatient

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<sup>55</sup> See PX01018 at 009, *in camera* (“Push the payors. Provide compelling argument to raise SLH reimbursement rates to an acceptable margin; In essence, the message would be pay us now (a little bit more) or pay us later (at the other hospital system contractual rates).”).

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services. Tr. 2262, *in camera*; PX01944 at 013-014 ( Dep. at 49-50), *in camera*.

**2. Economic and Course-of-Business Evidence Demonstrates that the Joinder Will Likely Raise ProMedica's Rates**

As with the analysis of pricing at St. Luke's, bargaining theory suggests that the Joinder will enable ProMedica to extract higher reimbursement rates from MCOs. The Joinder alters the alternative network available if an MCO fails to reach an agreement covering ProMedica's legacy hospitals. Prior to the Joinder, MCOs that failed to reach agreement with ProMedica still would have been able to form a network composed of Mercy, UTMC, and St. Luke's. Post-Joinder, the walk-away network is limited to Mercy plus UTMC; without an agreement with ProMedica, an MCO no longer can offer a network that includes the first choice for the many patients who use St. Luke's. By decreasing the desirability of an MCO's walk-away network, the Joinder increases ProMedica's bargaining leverage. Exercise of this increased leverage would enable ProMedica to win higher rates for its legacy hospitals.

Unilateral effects evidence supports this conclusion. Again, the extent of direct competition between ProMedica and St. Luke's is a key. From the viewpoint of ProMedica's legacy hospitals, the competition provided by St. Luke's was substantial. While Mercy was the next best substitute for the legacy hospitals for the largest number of patients, St. Luke's was the next best substitute for a substantial and important fraction of ProMedica's patients, stemming from St. Luke's advantageous location in southwest Lucas County. IDF 472-498.

ProMedica's documents and business conduct both attest to its recognition that St. Luke's was a close and significant competitor. ProMedica's internal assessments reflected its understanding that St. Luke's was capable of taking significant patient volume from ProMedica's hospitals. IDF 467-69, 471. Thus, ProMedica estimated that commercial inpatient admissions at ProMedica hospitals would be diverted from ProMedica to St. Luke's in the first year if St. Luke's were added to Paramount's network. IDF 468; *cf.* IDF 470 (finding that St. Luke's also

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expected to gain patients from ProMedica if St. Luke's were readmitted to Paramount). Similarly, ProMedica estimated that St. Luke's readmission to Anthem's network would cost ProMedica \_\_\_\_\_ in gross margin annually. IDF 471; PX00333 at 002, *in camera*. In exchange for its loss of exclusivity with Anthem, ProMedica insisted that Anthem pay \_\_\_\_\_ higher rates at \_\_\_\_\_ when St. Luke's was added to Anthem's network in 2009. PX00231 at 015, *in camera*; Pugliese, Tr. 1497-98, *in camera*. This followed a four-year period in which ProMedica's contract with Anthem explicitly offered discounted rates conditional on Anthem's agreement not to include St. Luke's in Anthem's provider network, JSLF ¶ 18, a further indication that ProMedica believed St. Luke's would have taken patients from ProMedica.

Both parties' documents depict particularly intense competition within St. Luke's core service area. *See, e.g.*, PX01418 at 005, *in camera* (St. Luke's cost and revenue presentation showing that within its core service area, St. Luke's had the largest market share for GAC services and ProMedica had the second largest share); PX00333 at 002, *in camera* (showing ProMedica's expectation that \_\_\_\_\_ would lose patient volume within St. Luke's core service area if St. Luke's became a participating provider in the Anthem network). Similarly, analysis of market shares by zip codes shows that ProMedica and St. Luke's are the most important hospitals for patients in southwest Lucas County. *See* PX02148 at 042-044, 161, *in camera* (showing that St. Luke's and ProMedica have the highest market shares among patients located in the geographic area in southwest Toledo surrounding St. Luke's); Town, Tr. 3645-46, 3753-54, *in camera* (explaining that market shares reflect patient preferences).<sup>56</sup>

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<sup>56</sup> IDF 450-52. Respondent argues that we should not consider this limited geographic area because it is smaller than the relevant geographic market defined in this case. RRB 3-4. However, MCOs, as well as St. Luke's and ProMedica, focus on this area in the ordinary course of business. MCOs consistently testified about the importance of their ability to meet members' demand for hospital coverage in this area. IDF 477-81. In addition, both St. Luke's and ProMedica consider patients in this limited geographic area in their internal analyses of competition. *See, e.g.*, PX01418 at 005, *in camera*; PX00333 at 002, *in camera*. Our focus on this part of Lucas County

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Professor Town's diversion analysis confirms that St. Luke's is a significant substitute for ProMedica's legacy hospitals. The analysis examined patient-level hospital claims data obtained from MCOs to predict to which other hospitals a specific hospital's patients would go if that hospital were not available. PX02148 at 047, *in camera*; IDF 453. The analysis shows that for five payors –

- St. Luke's was the next closest substitute for between percent and percent of ProMedica's patients. PX02148 at 046-047 *in camera*; PX01850 at 018-019, *in camera*. For each of the MCOs analyzed, St. Luke's was the preferred alternative for the second largest number of ProMedica patients; only three-hospital system Mercy would draw a larger number if ProMedica were unavailable. *Id.*

Thus, the parties' documents, their business conduct, market-share evidence, and diversion analysis all show substantial head-to-head competition between ProMedica and St. Luke's and demonstrate that St. Luke's was ProMedica's closest substitute for a large number of customers. Respondent attempts to refute this conclusion with two arguments. First, it insists that, because Mercy is a closer substitute for ProMedica,<sup>57</sup> unilateral anticompetitive effects at ProMedica's legacy hospitals are impossible. RRB 2, 13-14. Second, it argues that Complaint Counsel and the ALJ erred by analyzing substitution based on the preferences of patients, rather than MCOs. RAppB 14-15; RRB 2-3.

Both of these arguments are misplaced, for they fail to acknowledge the manner in which unilateral effects evidence is relevant in this case. In a more conventionally-structured market, in which sellers deal directly with the consumers of the goods in question, a unilateral effects analysis turns on whether the merged

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appropriately parallels the focus of MCOs and the merging parties. *See generally* Concurring Opinion of Commission J. Thomas Rosch, *In the Matter of Evanston Northwestern Healthcare Corp.*, Docket No. 9315.

57 No one, including Complaint Counsel, disputes that more ProMedica patients would be diverted to Mercy's three hospitals if ProMedica's three hospitals were not available. *See* PX01850 at 018 (Town Rebuttal Report), *in camera*.

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entity will enjoy a net benefit from a unilateral price increase. This will depend, in large part, on the relative numbers of sales that will be recaptured by the acquired entity, or lost to other players – and that, in turn, will depend importantly on various consumers’ preferences in terms of which sellers are the closest substitutes. *See, e.g.*, 2010 **HORIZONTAL MERGER GUIDELINES** § 6.1. We recognize that, in such an analysis, the strong view of even a substantial minority of consumers that one seller is their next closest substitute *might* be outstripped by the preference of a majority for a different next closest substitute. Even in such a situation, however, the merging parties do not need to be each other’s closest rival for a merger to have unilateral anticompetitive effects. *Town, Tr. 3782, in camera*. As the 2010 **HORIZONTAL MERGER GUIDELINES** explain, “[a] merger may produce significant unilateral effects for a given product even though many more sales are diverted to products sold by non-merging firms than to products previously sold by the merger partner.” 2010 **HORIZONTAL MERGER GUIDELINES** at § 6.1. “Substantial unilateral price elevation post-merger,” the Guidelines explain, “normally requires that a *significant fraction* of the customers purchasing that product view products formerly sold by the other merging firm as their next-best choice.” *Id.* (emphasis added). There is no general necessity that that “significant fraction . . . approach a majority.” *Id.* Cases and commentary have agreed. *See United States v. H & R Block*, 2011 WL 5438955, at \*39 (D.D.C. 2011) (“The fact that [a third party] may be the closest competitor for both [merging parties] also does not necessarily prevent a finding of unilateral effects for this merger.”); *Evanston*, 2007 WL 2286195, at \*50 (explaining that if customers accounting for a “significant share of sales” view the merging parties as their first and second choices, a merger can enable the merged firm to raise prices unilaterally, and “it is not necessary for the merged firms to be the closest substitutes for all customers, or even a majority of customers”); Phillip E. Areeda & Herbert Hovenkamp, 4 *Antitrust Law* ¶ 914 at 77-80 (2009) (explaining that the merging parties need not be closest rivals for the merged firm to be able to increase price profitably and thereby cause unilateral anticompetitive effects); *see also* Concurring Opinion of Commission J. Thomas Rosch, *In the Matter of Evanston Northwestern Healthcare Corp.*, Docket No. 9315.

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But we are not analyzing whether ProMedica could sustain a unilateral price increase if it were selling directly to patients. We are analyzing the impact of the preferences of a substantial and important minority of patients within the market on the ability of ProMedica to sustain a unilateral price increase to MCOs, which depends on the Joinder's impact on ProMedica's bargaining leverage, which in turn depends on the effect on the value of the MCOs' walk-away networks of removing the preferred hospital of that substantial and important minority. And that inquiry, contrary to ProMedica's supposition, must begin with an examination of substitutability between hospitals at the patient level. As the Commission explained in *Evanston*, and the ALJ explained in the Initial Decision here, "an MCO's demand for hospital services is largely derived from an aggregation of the preferences of its employer and employee members." *Evanston*, 2007 WL 2286195, at \*61; ID 156. Here, "the record demonstrates that . . . St. Luke's and ProMedica were close substitutes for employers and MCO's members, and thus for the MCOs." ID 157-58.<sup>58</sup>

Nonetheless, building on its MCO-oriented focus, Respondent advances the notion that MCO demand for hospitals must be analyzed in terms of one-for-one substitutions of hospital providers, *e.g.*, replacing ProMedica with St. Luke's. Respondent is correct that in fashioning hospital networks, no MCO would substitute one-hospital St. Luke's for the three-hospital ProMedica. Since ProMedica is much larger than St. Luke's and one of its three hospitals provides tertiary services, having access to ProMedica's three hospitals gives more value to patients than having access to St. Luke's alone. *See Town, Tr. 228-29* (July 19, 2011). This is particularly true since MCOs require at least one

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58 Respondent's contention that defining the relevant product market as GAC inpatient hospital services *sold to commercial health plans* requires a focus on MCO contracts rather than on demand for services and substitution at the patient level similarly lacks merit. The description "sold to commercial health plans" is not intended to define health plans as the only relevant actors for purposes of analyzing demand and substitution. Rather, the description is intended to exclude patients covered by Medicare and Medicaid from the analysis of competitive effects. Reimbursement rates for these patients are not negotiated by providers; they are established by the Centers for Medicare and Medicaid Services, IDF 43, and will not be affected by the Joinder.

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hospital in their network to offer advanced services, including tertiary services. IDF 274. But Respondent's observation that MCOs would not accept a one-for-one swap of St. Luke's for the ProMedica system does not say anything about whether there nonetheless has been close and significant competition between St. Luke's and ProMedica over inclusion in MCO hospital networks. As we previously described, in order to satisfy the needs of employers who have employee members spread out across a geographic region and in need of access to a full range of hospital services, MCOs build networks that include multiple hospital providers. An MCO's decision on whether to include a hospital system in its network involves an assessment of whether the remaining alternative hospitals can constitute a marketable network. *See* Town, Tr. 3784-85, *in camera*; IDF 273-74, 276-77; ID 157. Thus, an MCO's selection of one hospital provider in its network need not result in excluding another provider. In fact, most MCO networks in Lucas County currently include all Lucas County hospitals. *See* IDF 135, 156, 191, 204, 222, 233.

Consequently, our conclusion that St. Luke's is ProMedica's closest substitute for a large and important number of Lucas County patients supports a finding of a unilateral anticompetitive effect.<sup>59</sup> The cost to most MCOs of failing to reach an agreement with ProMedica has been increased by removing from their walk-away network the hospital most preferred by \_\_\_\_\_ percent of

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59 Commissioner Rosch's Concurring Opinion mistakenly takes the view that since all six testifying MCOs stated that Mercy, not St. Luke's, was ProMedica's next best substitute, a unilateral effects theory of liability does not apply in this case. For this conclusion he cites some of the same authorities we rely on -- the 2010 **HORIZONTAL MERGER GUIDELINES** § 6.1, *H & R Block*, 2011 WL 5438955, and *Evanston*, 2007 WL 2286195. As we point out above, however, each of these authorities specifically notes that a unilateral effects theory of liability does not require the merged firms be closest substitutes for the majority of customers. Moreover, the asymmetric relationship between competing firms that creates the situation in this case - where for the majority of patients, St. Luke's is not ProMedica's closest competitor, yet ProMedica is St. Luke's closest competitor - is not at all uncommon, particularly in markets involving competitors of varied size. The application of unilateral effects analysis in these situations merely takes into consideration the realities of the marketplace. We find the application of unilateral effects analysis particularly probative in this case, where the theory is supported by and consistent with the evidence, or the story told out of the mouths of the parties, as well as described in their documents.

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their enrollees, too much to just dismiss as insignificant. Added to the substantial MCO testimony, the teachings of bargaining theory, the parties' business behavior and their contemporaneous, ordinary-course-of-business documents, all showing close head-to-head competition, we find ample basis to conclude that the Joinder is indeed likely to raise reimbursement rates at ProMedica's legacy hospitals.

### 3. Econometric Evidence

Economic evidence further supports the conclusion that price increases are likely at ProMedica as a result of the Joinder. Professor Town quantified the Joinder's effect on bargaining leverage and estimated the impact on price. While these analyses are not central to our reasoning – we would reach the same conclusions about the Joinder's anticompetitive effects even without these final pieces of evidence – their presence further confirms our conclusions.

As discussed above, a hospital provider's bargaining leverage depends on the value that it brings to the MCO's network. Professor Town measured the bargaining leverage of the hospital system by estimating the value that patients place on having access to that hospital system, given the alternative hospitals available. Town, Tr. 30-31 (July 19, 2011). His measure, labeled "willingness to pay," reflects the fact that the more desirable the hospital is to the MCO's enrollees, the higher the price an MCO is willing to pay to include a hospital in its network. See PX02148 at 105, *in camera*. Using patient-discharge data obtained from the MCOs, Town estimated the value that individual patients place on having access to different hospitals from the actual hospital choices made by patients with commercial health care coverage. Town, Tr. 35-37 (July 19, 2011). His model estimates patients' preferences for various hospitals given the geographic proximity to both patients and alternative hospitals, patients' diagnoses and demographics, and attributes of the hospital, such as capacity, technology, and perceived quality that could influence patients' choice of hospital. PX02148 at 106-107, *in camera*; Town, Tr. 34-35 (July 19, 2011). He found that the bargaining leverage of a combination of ProMedica and St. Luke's increased by almost 13.5 percent as a result of the Joinder. Town, Tr. 41 (July 19, 2011); PX02148 at 165, *in camera*.

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Professor Town then used these results to estimate the effect on hospital prices from the Joinder. He employed a linear regression model to determine the effect of willingness to pay per person and various control variables on case-mix adjusted prices. The control variables included a measure of MCO bargaining leverage; hospital costs (both case-mix adjusted cost and number of interns per bed); systematic differences across MCOs; and time trends.<sup>60</sup> To assess the impact of the Joinder, Professor Town compared the predictions of an estimation for a three-hospital, pre-Joinder ProMedica system with a recalculated result that included St. Luke's as a fourth hospital in ProMedica's system. PX02148 at 109-10, *in camera*. Town found that the increased bargaining leverage attributable to the elimination of competition between ProMedica and St. Luke's results in a 16.2 percent increase in prices, on an aggregate basis, for the four hospitals. PX02148 at 179, *in camera*; Town, Tr. 58-59 (July 19, 2011). This predicted price increase arises only from the change in bargaining leverage resulting from the Joinder. Town, Tr. 60-61 (July 19, 2011). When Town allocated that aggregate 16.2 percent price increase between ProMedica and St. Luke's, he found that prices at St. Luke's would be expected to rise by 38.38 percent from the pre-Joinder level, and prices at ProMedica's legacy hospitals would be expected to rise by 10.75 percent. PX02148 at 179, *in camera*; Town, Tr. 59-60 (July 19, 2011).

Professor Town's results provide additional confirmation that the Joinder will have anticompetitive effects, confirming the strength of the structural presumption and the substantial amount of buttressing evidence already discussed. Respondent launches a host of attacks on Town's regression analysis, but none of the claims deprives Town's study of all confirming weight, and in view of our finding of anticompetitive effects based on other evidence, none has an impact on our ultimate conclusion.

For example, Respondent argues that Professor's Town's work has not been peer-reviewed. Yet the methodology of his

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60 Town, Tr. 52-54 (July 19, 2011). The model shows that willingness to pay per person – which, as described above, indicates a hospital's bargaining leverage derived from patients' preferences for the hospital or hospital system – is statistically significant for explaining case-mix adjusted prices. See PX02148 at 175, *in camera*.

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analysis has been peer-reviewed. *See* IDF 633; Town, Tr. 30 (July 19, 2011); Guerin-Calvert, Tr. 7172; PX02148 at 102 n.4, *in camera*; PX1850 at 059, 059 n.148, *in camera*. It is hardly persuasive to demand that the specific model and variables used for a particular merger litigation be peer-reviewed before they can be given weight as evidence – the model, variables, and data are necessarily case-specific.

Respondent also contends that the merger simulation fails to distinguish between Joinder and non-Joinder explanations for price. In fact, Town’s simulation specifically isolates and identifies the effect of the Joinder on prices. The predicted price effect assesses only the change in bargaining leverage that arises from the Joinder, holding everything else constant. Town, Tr. 60-61, 65-66 (July 19, 2011); PX02148 at 058, 060, 110, *in camera*.

Respondent argues that adding five variables would reduce the price effect of the willingness-to-pay variable from a statistically significant 16.2 percent to 7.3 percent, which would lack statistical significance at the 5 percent level. But the price effect would still be significant at the 5.5 percent level. *See* RX71(A) *in camera* at 000216 (indicating a p value equal to 1.92). Addition of the five variables is itself highly questionable: some of the added variables appear closely correlated with variables already in Town’s regression. *See* PX1850 at 067-072, *in camera*; Town, Tr. 68-72 (July 19, 2011). For example, Respondent added case mix index as an explanatory variable, despite the fact that prices are already case-mix adjusted. *See* Town, Tr. 69-71 (July 19, 2011); PX01850 at 068-069; RX71(A) at 000216. To the extent that the added variables are correlated with the existing variables and fail to measure an additional causal relationship, adding them decreases the statistical significance of the existing variables without adding explanatory power. Town, Tr. 68-69 (July 19, 2011); PX01850 at 067, *in camera* (Professor Town’s expert report stating that “[a] well-known means to challenge the size and significance of any regression coefficient is to include additional variables in the regression that are correlated with the variable of interest, but add no explanatory power that is not already captured by the variables already included in the model.”). Moreover, adding even four of the variables would leave the willingness-to-pay result significant at the 5 percent

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level. *See* RX71(A) at 000216. Finally, some of the results with Respondent's specification are counter-intuitive. *See* Town, Tr. 73-75 (July 19, 2011); PX01850 at 070-071. For example, Respondent's expert adds variables for a hospital's percentage of discharges that are Medicare and Medicaid patients on the rationale that hospitals may increase commercial prices to cost-shift and cover these patients, but the revised model predicts that commercial prices would decrease as Medicare share increases, precisely the opposite of the rationale for including the variable. *See* PX01850 at 069-070, *in camera*. This suggests that the revised model, with the additional variables proposed by Respondent's expert, is not correctly specified.

Respondent's claim that Town was arbitrary in dividing the 16.2 percent aggregate result between ProMedica and St. Luke's is hardly compelling. Town explained that the allocation was calculated based on the diversion between the hospitals; that is, Town attributed a greater share of the predicted price effect to the hospital whose bargaining incentives are likely to change more, as measured by the estimated diversion to the other hospital. Town, Tr. 59-60 (July 19, 2011). Since the estimated diversions from St. Luke's to ProMedica are generally greater than those from ProMedica to St. Luke's, Town allocated a greater share of the predicted price effect to St. Luke's. *Id.*; PX02148 at 108, *in camera*. More fundamentally, however the price increase is allocated between the hospitals, Town's finding provides confirming evidence for the conclusion that the increased bargaining leverage created by the Joinder will lead to higher prices.

**E. The Evidence Demonstrates that Prices Will Likely Increase for OB Services as a Result of the Joinder**

The anticompetitive effects of the Joinder will, if anything, be even more severe in the OB services market than in the overall GAC market. Before the Joinder, there were three competing hospital providers of inpatient OB services. Now there remain only two – ProMedica and Mercy. Thus, the Joinder is a merger

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to duopoly in the Lucas County market for inpatient OB services.<sup>61</sup>

Moreover, for OB services, Mercy – now ProMedica’s only remaining competition – is relatively weak in comparison with ProMedica. Post-Joinder Mercy has only a 19.5 percent market share of the OB inpatient services market in Lucas County; ProMedica has 80.5 percent. PX02148 at 143, *in camera* (Ex. 6) (Town Expert Report). In St. Luke’s core service area, ProMedica’s strength is even more pronounced – its share is about 87 percent. *Id.* at 161 (Ex. 11). Beyond the mere share statistics, one of the three Mercy hospitals, St. Anne, no longer provides any OB services<sup>62</sup> and the remaining two Mercy hospitals, as Catholic facilities, cannot offer a full complement of inpatient OB services. Shook, Tr. 1065-66. Accordingly, ProMedica, as a result of the Joinder, is now the *only* hospital provider in Lucas County that is able to offer a full complement of OB services.

The Joinder would eliminate head-to-head competition between ProMedica and St. Luke’s for inpatient OB services. St. Luke’s understood that it was a desirable alternative for some ProMedica OB patients. *See* Rupley, Tr. 2010, *in camera* (St. Luke’s Marketing and Planning Director testifying that St. Luke’s believed that if it were

Indeed, St. Luke’s was ProMedica’s closest competitor with respect to OB services in St. Luke’s core service area. Town, Tr. at 3760-61, *in camera*; PX01077 at 013 (2008 patient preference survey showing that the top three preferences for patients in St. Luke’s core service area for OB services were St. Luke’s and ProMedica’s TTH and Flower). Similarly, for many OB patients in southwest

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61 UTMC does not offer inpatient OB services and has no plans to offer such services in the future. Gold, Tr. 60-62.

62 Mercy St. Anne discontinued offering OB services in 2008 after it experienced a significant decrease in deliveries and no longer performed enough deliveries to maintain quality standards or break even financially. IDF 94, *citing* Shook, Tr. 901, 958, 1047. A Mercy representative testified that it is “highly unlikely” that St. Anne will reinstate OB services in the future. Shook, Tr. 958-60. St. Anne, located in west Toledo, is the closest hospital to ProMedica’s Flower Hospital. Shook, Tr. 917; Oostra, Tr. 5802-03.



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**F. ProMedica's Claims that MCOs or Competitors Will Constrain any Price Increases Are Not Persuasive****1. MCOs' Inability to Prevent ProMedica from Exercising Market Power**

Respondent argues that MCOs have countervailing bargaining leverage in their negotiations with hospitals and are well positioned to prevent ProMedica from exercising market power gained from the Joinder. To illustrate, Respondent cites instances in which MCOs have obtained favorable results in contract negotiations, including both pre-and post-Joinder contracts that MCOs negotiated with ProMedica and St. Luke's. Respondent further contends that a combination of factors – excess hospital capacity, patient willingness to travel, and the fact that most physicians have admitting privileges at competing hospitals – enables MCOs to credibly threaten to shift large volumes of patients away from ProMedica and thereby resist any post-Joinder supracompetitive price increase. RAppB 32-36.

There is no question that MCOs have leverage of their own in negotiations with hospitals. The record shows, however, that MCOs likely will find it harder to resist ProMedica's price demands after the Joinder. As already discussed, the Joinder increases ProMedica's bargaining leverage – and concomitantly disadvantages MCOs – because the addition of St. Luke's to the ProMedica hospital system makes it considerably more difficult for MCOs to walk away from ProMedica. *See supra* at Sections IX.C-D. Although Respondent suggests that MCOs will be able to obtain lower rates from ProMedica by threatening to enter into exclusive agreements with rival hospitals, the evidence shows that MCOs do not consider a network composed solely of UTMC and Mercy – the only rivals remaining after the Joinder – to be commercially viable.<sup>63</sup> *See supra* at Section IX.B. This evidence

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<sup>63</sup> Respondent specifically mentions “most favored nations” (“MFN”) provisions obtained by MCOs. RAppB 35. MFN provisions prohibit a hospital provider under contract with one MCO from agreeing to lower rates with a competing MCO without extending the same rates to the first MCO. IDF 502. The evidence, however, suggests that such provisions are not likely to be employed in the future. In 2008, the State of Ohio placed a moratorium on the use of MFN provisions in health care contracts. Pugliese, Tr. 1580. In addition, in 2010, the Antitrust Division of the U.S. Department of Justice filed

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likewise undermines Respondent's contentions that excess capacity and overlapping physician admitting privileges enable MCOs to exclude ProMedica from their networks and thereby defeat any supracompetitive price increase.

The record also fails to support the proposition that, without excluding ProMedica from their networks, MCOs can defeat price increases by ProMedica through "steering" – that is, by providing financial incentives to health plan members and physicians to use lower-cost hospitals. The evidence shows that MCOs have not employed steering in the past to discipline Lucas County hospital prices, including ProMedica's already-high prices. IDF 702, 704-05, 715-17.<sup>64</sup> MCOs testified that patients dislike steering and hospitals resist it. IDF 699-700. Significantly, ProMedica has used its leverage in the past to obtain anti-steering provisions in its contracts with \_\_\_\_\_ and \_\_\_\_\_ the \_\_\_\_\_ health plans in Lucas County along with ProMedica's own MCO, Paramount. IDF 718-19. Now that ProMedica has greater leverage in negotiations with MCOs as a result of the Joinder, it is even more likely to be able to obtain such contractual provisions to protect itself against steering in the future.

Additionally, we find no merit to Respondent's argument that contracts negotiated by ProMedica on behalf of St. Luke's after the Joinder demonstrate that the Joinder is not likely to result in supracompetitive prices. It is settled law that such post-

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a complaint challenging the MFN provisions in hospital contracts for Blue Cross Blue Shield of Michigan. See Complaint in *United States v. Blue Cross Blue Shield of Mich.*, Civil Action No. 2:10-cv-15155-DPH-MKM (E.D. Mich., filed Oct. 18, 2010). In light of the moratorium and pending DOJ suit, Anthem, which is the Blue Cross Blue Shield affiliate in Ohio, testified in this matter that

Pugliese, Tr.

1668-69, *in camera*.

64 The sole exception to this lack of steering by MCOs – a small pilot program started by Aetna in January 2011 for up to 100 of its employees – has not yielded sufficient data to evaluate its success. IDF 708, 710. Although some MCOs provide pricing information to members and physicians to try to influence where care is provided (referred to as "soft steering," IDF 682), such programs "don't have teeth, [so] they haven't had [an] impact." Radzialowski, Tr. 723-24; IDF 701, 706-07.

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acquisition evidence is of limited probative value because “violators could stave off such [Section 7] actions merely by refraining from aggressive or anticompetitive behavior when such a suit was threatened or pending.” *United States v. Gen. Dynamics Corp.*, 415 U.S. 486, 504-05 (1974), *see Chicago Bridge & Iron Co. v. FTC*, 534 F.3d 410, 434-35 (5th Cir. 2008); *Hospital Corp. of Am. v. FTC*, 807 F.2d 1381, 1384 (7th Cir. 1986). Although Respondent protests that no manipulation was involved in those contract negotiations, an absence of proof of actual manipulation is not determinative – post-acquisition evidence “is deemed of limited value whenever such evidence *could arguably* be subject to manipulation.” *Chicago Bridge*, 534 F.3d at 435 (emphasis in original). Such is the case here. Moreover, all post-Joinder rates here have been negotiated while the Hold Separate Agreement was in place. That agreement permits an MCO to continue its existing contract beyond expiration, rather than negotiating a new contract with new rates. *See* PX00069. Thus, the Hold Separate Agreement constrains ProMedica’s bargaining leverage, with the result that the post-Joinder contracts do not reflect the full market power that ProMedica will be able to exercise as a result of the Joinder.

## 2. Repositioning By Competitors

Respondent also argues that repositioning by competitors will constrain post-Joinder price increases. RAppB 36-37. The 2010 Horizontal Merger Guidelines note that “[i]n some cases, non-merging firms may be able to reposition their products to offer close substitutes for the products offered by the merging firms” and thereby “deter or counteract what otherwise would be significant anticompetitive unilateral effects from a differentiated products merger.” 2010 **HORIZONTAL MERGER GUIDELINES** § 6.1. Repositioning is evaluated like entry. *Id.* Thus, Respondent must show that the purported repositioning will be timely, likely, and sufficient to constrain prices post-Joinder. 2010 **HORIZONTAL MERGER GUIDELINES** §§ 6.1, 9; *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 55 (D.D.C. 1998). Respondent’s burden is to produce evidence sufficient to show that the likelihood of entry “reaches a threshold ranging from ‘reasonable probability’ to ‘certainty.’” *Chicago Bridge*, 534 F.3d at 430 n.10.

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As evidence of repositioning, Respondent points to Mercy's so-called \_\_\_\_\_ a program to \_\_\_\_\_

See IDF 747-48. Respondent contends that Mercy's \_\_\_\_\_ will put approximately \_\_\_\_\_ of St. Luke's billed charges \_\_\_\_\_

\_\_\_\_\_ and that this risk of loss will deter any anticompetitive price increase. RAppB 37.<sup>65</sup> The ALJ found Respondent's argument unpersuasive, concluding that the evidence did not show that such repositioning is likely to replace the competition lost by the Joinder or would be either timely or sufficient. ID 177-78.

We likewise find that the record does not support Respondent's argument. Notably, Mercy's \_\_\_\_\_

IDF 750. Rather, Mercy's \_\_\_\_\_ purportedly will provide competition for inpatient services by \_\_\_\_\_

IDF 753. At the time of the hearing, however, the prospects for this program were very much in question. Mercy did not meet its 2010 \_\_\_\_\_ goals for \_\_\_\_\_, had not succeeded in \_\_\_\_\_ in furtherance of its 2011 goals, and \_\_\_\_\_

Tr. 983-84, 987, *in camera*

Mercy had not yet \_\_\_\_\_ Tr. 986, *in camera*. Although Mercy initially had a tentative deadline **{through 2015}** for accomplishing its \_\_\_\_\_ at the time of the \_\_\_\_\_

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<sup>65</sup> Respondent also makes passing reference to UTMC's facility renovations and "outreach activity," RAppB at 37 n.8, but makes no effort to show that these undertakings will constrain ProMedica's post-Joinder prices (and certainly not with regard to OB services, which UTMC does not provide).

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hearing, it IDF 754.  
 This evidence casts doubt on whether Mercy is likely to  
 accomplish such repositioning and suggests that its  
 will not provide a timely constraint to ProMedica's  
 post-Joinder exercise of market power.<sup>66</sup>

Furthermore, regardless of whether such repositioning would  
 be likely and timely, Respondent has failed to show that it would  
 be sufficient to mitigate the Joinder's anticompetitive effects.  
 There is no evidence that

even comes close to replicating the  
 competition for GAC and OB inpatient hospital services  
 eliminated by the Joinder. Respondent points to its expert's  
 calculation of the potential diversion of billed charges from St.  
 Luke's to Mercy *if* Mercy were to succeed in increasing its market  
 share. Guerin-Calvert, Tr. 7389-92, *in camera*. Respondent  
 implicitly invites us to *assume* that Mercy's limited repositioning  
 activities will significantly increase its market share for inpatient  
 hospital services.<sup>67</sup> But such assumption or speculation does not  
 suffice to support an entry argument. *See Cardinal Health*, 12 F.  
 Supp. 2d at 57 (rejecting entry argument that was "theoretical at  
 best," noting that "the Court cannot engage in such speculation").  
 Respondent's further argument that the mere threat of  
 repositioning by competitors is sufficient to constrain  
 ProMedica's post-Joinder pricing likewise is theoretical only and  
 devoid of actual evidentiary support. *See Chicago Bridge*, 534  
 F.3d at 430 n.10 (rejecting a claim that the mere threat of entry  
 was sufficient to deter anticompetitive effects and stressing the  
 need for evidentiary support).

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66 Respondent emphasizes that Mercy developed its  
 specifically in response to the Joinder, but, even if this is so, this does not  
 suffice to show that such repositioning is likely to be accomplished or will be  
 timely, particularly where evidence suggests otherwise.

67 As of the time of the hearing, Mercy had not noticed any measurable market  
 share impact as a result of its  
 IDF 756. *See* Tr. 987, *in camera* (describing Mercy's  
 prospects for achieving a substantial market share increase  
 during the next two years as **D**).

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Thus, we find that Respondent has failed to show that repositioning by competitors will be likely, timely, and sufficient to counteract any anticompetitive price increases.

**X. REMEDY**

To remedy Respondent's violation of Section 7, the ALJ ordered divestiture of St. Luke's to a Commission-approved buyer. ID 204-11. Respondent argues that, assuming we find liability, divestiture is not necessary to restore the competition eliminated by the Joinder. Respondent urges us, instead, to select an injunctive remedy that requires ProMedica to establish separate and independent managed care contract negotiating teams for St. Luke's and ProMedica's legacy hospitals. Respondent asserts that its proposed remedy, which is patterned after the Commission's remedy in *Evanston*, cures any anticompetitive effects of the Joinder while addressing concerns about St. Luke's viability as an independent hospital. Respondent also argues that an order that requires ProMedica to divest St. Luke's to an acquirer, instead of allowing the parties simply to unwind the Joinder, goes beyond restoring competition to its pre-Joinder state and is, therefore, overbroad and punitive. RAppB 40-45.

The purpose of relief in a Section 7 case is to restore competition lost through the unlawful acquisition. *Ford Motor Co. v. United States*, 405 U.S. 562, 573 n.8 (1972); *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 607 (1957). Structural remedies are preferred in such cases. *See United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 329 (1961) (calling divestiture "a natural remedy" when a merger violates the antitrust laws). As we explained in *Evanston*, "[d]ivestiture is desirable because, in general, a remedy is more likely to restore competition if the firms that engage in pre-merger competition are not under common ownership," and there are "usually greater long term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution." *Evanston*, 2007 WL 2286195 at \*77. The manner and scope of divestiture are subject to the Commission's broad discretion. *See Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611-13 (1946); *Chicago Bridge*, 534 F.3d at 440-42.

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In accordance with these well-established principles, we conclude that divestiture is the most appropriate remedy to restore the competition eliminated by the Joinder. Unlike *Evanston*, this case does not present special circumstances that warrant a departure from the preferred structural remedy. In that case, the lengthy amount of time – seven years – that had elapsed since the merger, during which the acquired hospital had been fully integrated into the larger hospital system, led the Commission to conclude that divestiture would be a “complex, lengthy, and expensive process,” *Evanston*, 2007 WL 2286195 at \*79, and “much more difficult, with a greater risk of unforeseen costs and failure,” *id.* at \*78. The Commission was also concerned that divestiture could reduce or eliminate significant public benefits from improvements made to the acquired hospital during that time. *Id.* The Commission specified that its reasoning for an injunctive remedy in that case would not necessarily apply in a future challenge to a consummated merger, including a consummated hospital merger, and that, “where it is relatively clear that the unwinding of a hospital merger would be unlikely to involve substantial costs, all else being equal, the Commission likely would select divestiture as the remedy.” *Id.* at \*79.

The circumstances in this case are markedly different than *Evanston*. Here, the Hold Separate Agreement entered by ProMedica has limited the integration of St. Luke’s into ProMedica’s hospital system. *See* IDF 12-13. Indeed, the Commission staff sought the Hold Separate Agreement precisely for the purpose of preserving St. Luke’s as an independent and viable competitor, should the transaction be found illegal.<sup>68</sup>

Respondent contends, however, that divestiture of St. Luke’s would entail certain “unique costs.” Specifically, Respondent argues that, if divestiture is ordered: (i) St. Luke’s will not likely survive as a “full-fledged competitor,” given its pre-Joinder financial difficulties; (ii) St. Luke’s will not likely meet “meaningful use” requirements relating to the use of Electronic

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<sup>68</sup> *See* Compl. for TRO and Prelim. Inj. at 19, *FTC v. ProMedica Health System, Inc.*, No. 3:11-cv-00047-DAK (N.D. Ohio, filed Jan. 7, 2011), available at <http://www.ftc.gov/os/caselist/1010167/110107promedicacmpt.pdf>.

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Medical Records (“EMR”), *see* IDF 822, and was not well-positioned for health care reform in general without significant capital assistance; and (iii) benefits from the shift of St. Luke’s inpatient rehabilitation services to Flower will be lost. RAppB 43.

At the outset, we note that the first two items, premised as they are on St. Luke’s pre-Joinder financial difficulties, are unlikely to present a concern if St. Luke’s is divested to a third-party acquirer with adequate financial resources. But, even if the Joinder is merely unwound, we find that the record does not support Respondent’s assessment of the costs.

As we have discussed at length, the evidence as a whole does not bear out Respondent’s dire predictions of St. Luke’s financial prospects and future competitiveness absent the Joinder. *See supra* Section VIII. Although we cannot say for certain what St. Luke’s viability as an independent hospital will be over the long term, its viability in the foreseeable future is not seriously at risk. Going forward, St. Luke’s will have various options available, as it did before the Joinder, to address its financial needs, fund needed capital improvements (including those required by health care reform), and remain competitive. *See, e.g.*, PX01018 at 009-013, 015-017, *in camera*.

Respondent’s claims about St. Luke’s purported inability, if divested, to meet the demands of health care reform are undermined by other evidence as well. For example, St. Luke’s own assessment prior to the Joinder was that it was “uniquely positioned for a smooth transition to expected health care reform.” PX01072 at 001 (“The hospital already focuses on quality and cost – key components of reform.”). The evidence also shows that, prior to the Joinder, St. Luke’s fully intended to begin implementing EMR in 2010 to meet “meaningful use” requirements and had budgeted \_\_\_\_\_ million for it in 2010, but stopped the process because of the Joinder.<sup>69</sup>

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<sup>69</sup> IDF 838-40, 997. The ALJ was unable to conclude that St. Luke’s could not have implemented these measures but for the Joinder. ID 193.

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We are also unpersuaded by Respondent's argument concerning the cost of unwinding the consolidation of inpatient rehabilitation services at Flower.<sup>70</sup> That integration was undertaken by the parties knowing full well that, depending on the outcome of this case, it might be only temporary. Any unwinding of a consummated merger found to be unlawful is bound to entail some costs, but that in itself is not sufficient reason to forgo requiring divestiture. Respondent has not shown that the costs entailed by divestiture here are so substantial or "unique" as to justify abandonment of the preferred structural remedy in favor of injunctive relief – which has its own costs, including the cost of monitoring compliance.

We turn finally to Respondent's argument that it should be allowed to unwind the Joinder, as opposed to divesting to a third-party acquirer. Complaint Counsel do not oppose an unwinding of the Joinder, but take the view that the ALJ's order already allows this because the acquirer under the terms of the order could be the previously-independent St. Luke's organization. CCAnsB 42. We agree with Complaint Counsel. The Final Order which the Commission is issuing in this case, like the ALJ's order, is sufficiently broad to permit an unwinding, with St. Luke's restored to its status as an independent hospital.<sup>71</sup> The merits of a specific divestiture proposal, including any proposal to unwind the Joinder, are appropriately examined when ProMedica applies for Commission approval of a proposed divestiture in accordance with the agency's established procedures. *See* 16 C.F.R. § 2.41(f).

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70 Indeed, the ALJ found that there were countervailing costs as a result of this consolidation, because patients who had previously chosen to go to St. Luke's inpatient rehabilitation center no longer have that option and, instead, must now go to the more expensive Flower Hospital. ID 197; IDF 1063, 1065.

71 We take issue, however, with Respondent's contention that an order requiring divestiture to a third-party acquirer would be "overbroad and punitive." The Commission is not bound to replicate precisely the pre-Joinder market but has the discretion to enter broader relief if it finds that such relief would serve the goal of restoring competition. *See Chicago Bridge*, 534 F.3d at 440-42.

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**XI. CONCLUSION**

For the foregoing reasons, the Commission has concluded that the Joinder of ProMedica Health System, Inc. and St. Luke's Hospital is likely to substantially lessen competition in the market for the sale of general acute-care inpatient hospital services to commercial health plans – and in a separate relevant market consisting of inpatient OB services sold to commercial health plans – in Lucas County, Ohio, and therefore violates Section 7 of the Clayton Act, 15 U.S.C. 18. To remedy the violations found, the Commission has determined to issue the attached Final Order requiring ProMedica, *inter alia*, to divest St. Luke's to an approved buyer in accordance with established Commission procedures.

**FINAL ORDER**  
**[PUBLIC VERSION]**

The Commission has heard this matter upon the appeals of Respondent and Complaint Counsel from the Initial Decision, and upon briefs and oral argument in support thereof and in opposition thereto. For the reasons stated in the accompanying Opinion of the Commission, the Commission has determined to sustain the Initial Decision, with certain modifications:

**IT IS ORDERED** that the Initial Decision of the administrative law judge be, and it hereby is, adopted as the Findings of Fact and Conclusions of Law of the Commission, to the extent not inconsistent with the findings of fact and conclusions contained in the accompanying Opinion.

Other findings of fact and conclusions of law of the Commission are contained in the accompanying Opinion.

**IT IS FURTHER ORDERED** that the following Order to cease and desist be, and it hereby is, entered:

Final Order

**ORDER**

**I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “ProMedica” means ProMedica Health System, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including, but not limited to, ProMedica Health Insurance Corporation), divisions, groups, and affiliates controlled by ProMedica Health System, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “St. Luke’s Hospital” means the Acute-Care Hospital operated at 5901 Monclova Road, Maumee, Ohio 43537.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer” means the Person that acquires, with the prior approval of the Commission, the St. Luke’s Hospital Assets from ProMedica pursuant to Paragraph II, or from the Trustee pursuant to Paragraph VII of this Order.
- E. “Acquirer Hospital Business” means all activities relating to general Acute-Care Hospital services and other related health-care services to be conducted by the Acquirer in connection with the St. Luke’s Hospital Assets.
- F. “Acute-Care Hospital” means a health-care facility licensed as a hospital, other than a federally-owned facility, having a duly organized governing body with overall administrative and professional responsibility, and an organized professional staff, that provides 24-hour inpatient care, that may also provide outpatient services, and having as a primary function the

## Final Order

provision of General Acute-Care Inpatient Hospital Services.

- G. “Direct Cost” means the cost of direct material and direct labor used to provide the relevant assistance or service.
- H. “Divestiture Agreement” means any agreement, including all exhibits, attachments, agreements, schedules and amendments thereto, that has been approved by the Commission pursuant to which the St. Luke’s Hospital Assets are divested by ProMedica pursuant to Paragraph II, or by the Divestiture Trustee pursuant to Paragraph VII of this Order.
- I. “Divestiture Trustee” means the Person appointed pursuant to Paragraph VII of this Order to divest the St. Luke’s Hospital Assets.
- J. “Effective Date of Divestiture” means the date on which the divestiture of the St. Luke’s Hospital Assets to an Acquirer pursuant to Paragraph II or Paragraph VII of this Order is completed.
- K. “General Acute-Care Inpatient Hospital Services” means a broad cluster of basic medical and surgical diagnostic and treatment services for the medical diagnosis, treatment, and care of physically injured or sick persons with short term or episodic health problems or infirmities, that includes an overnight stay in the hospital by the patient. General Acute-Care Inpatient Hospital Services include what are commonly classified in the industry as primary, secondary, and tertiary services, but exclude: (i) services at hospitals that serve solely military and veterans; (ii) services at outpatient facilities that provide same-day service only; (iii) those services known in the industry as specialized tertiary services and quaternary services; and (iv) psychiatric, substance abuse, and rehabilitation services.

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- L. “Hospital Provider Contract” means a contract between a Payor and any hospital to provide General Acute-Care Inpatient Hospital Services and related health-care services to enrollees of health plans.
- M. “Intangible Property” means intangible property relating to the Operation of St. Luke’s Hospital including, but not limited to, Intellectual Property, the St. Luke’s Hospital Name and Marks, logos, and the modifications or improvements to such intangible property.
- N. “Intellectual Property” means, without limitation: (i) all patents, patent applications, inventions, and discoveries that may be patentable; (ii) all know-how, trade secrets, software, technical information, data, registrations, applications for governmental approvals, inventions, processes, best practices (including clinical pathways), formulae, protocols, standards, methods, techniques, designs, quality-control practices and information, research and test procedures and information, and safety, environmental and health practices and information; (iii) all confidential or proprietary information, commercial information, management systems, business processes and practices, patient lists, patient information, patient records and files, patient communications, procurement practices and information, supplier qualification and approval practices and information, training materials, sales and marketing materials, patient support materials, advertising and promotional materials; and (iv) all rights in any jurisdiction to limit the use or disclosure of any of the foregoing, and rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation, or breach of any of the foregoing.
- O. “Joinder” means the Operation of St. Luke’s Hospital by ProMedica pursuant to the Joinder Agreement.
- P. “Joinder Agreement” means the agreement by and among ProMedica Health System, Inc., OhioCare

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Health System, Inc., St. Luke's Hospital, and St. Luke's Hospital Foundation, Inc., dated May 25, 2010, and all subsequent amendments thereto, including, but not limited to the First and Second Amendments, each dated August 18, 2010, the Third Amendment, dated August 31, 2010, and the Side Agreement, dated September 1, 2010.

- Q. "Licensed Intangible Property" means Intangible Property licensed to ProMedica or to St. Luke's Hospital from a third party relating to the Operation of St. Luke's Hospital including, but not limited to, Intellectual Property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality-control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property that are licensed to ProMedica or to St. Luke's Hospital ("Licensed Intangible Property" does not mean modifications and improvements to intangible property that are not licensed to ProMedica).
- R. "Monitor" means the Person appointed pursuant to Paragraph VI of the Order and with the prior approval of the Commission.
- S. "Monitor Agreement" means the agreement ProMedica enters into with the Monitor and with the prior approval of the Commission.
- T. "Operation of St. Luke's Hospital" means all activities relating to the business of St. Luke's Hospital, operating as an Acute-Care Hospital, including, but not limited to, the activities and services provided at outpatient facilities.
- U. "Ordinary Course of Business" means actions taken by any Person in the ordinary course of the normal day-to-day Operation of St. Luke's Hospital that is consistent with past practices of such Person in the

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Operation of St. Luke's Hospital, including, but not limited to, past practice with respect to amount, timing, and frequency.

- V. "Payor" means any Person that purchases, reimburses for, or otherwise pays for medical goods or services for themselves or for any other person, including, but not limited to: health insurance companies; preferred provider organizations; point-of-service organizations; prepaid hospital, medical, or other health-service plans; health maintenance organizations; government health-benefits programs; employers or other persons providing or administering self-insured health-benefits programs; and patients who purchase medical goods or services for themselves.
- W. "Person" means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- X. "Physician" means a doctor of allopathic medicine ("M.D.") or a doctor of osteopathic medicine ("D.O.").
- Y. "ProMedica Medical Protocols" means medical protocols promulgated by ProMedica, whether in hard copy or embedded in software, that have been in effect at any ProMedica Hospital, excluding St. Luke's Hospital, at any time since Joinder; provided, however, that "ProMedica's Medical Protocols" does not mean medical protocols adopted or promulgated, at any time, by any Physician or by any Acquirer, even if such medical protocols are identical, in whole or in part, to medical protocols promulgated by ProMedica.
- Z. "Post-Joinder Hospital Business" means all activities relating to the provision of General Acute-Care Inpatient Hospital Services and other related health-care services conducted by ProMedica after Joinder including, but not limited to, all health-care services, including outpatient services, offered in connection with the St. Luke's Hospital Business.

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- AA. “Pre-Joinder St. Luke’s Hospital Business” means all activities relating to the provision of General Acute-Care Inpatient Hospital Services and other related health-care services that St. Luke’s Hospital was offering as an Acute-Care Hospital prior to Joinder.
- BB. “Real Property of St. Luke’s Hospital” means all real property interests (including fee simple interests and real property leasehold interests including all rights, easements and appurtenances, together with all buildings, structures, and facilities) that ProMedica acquired pursuant to the Joinder Agreement, whether or not located at St. Luke’s Hospital or whether or not related to the Operation of St. Luke’s Hospital. Real Property of St. Luke’s Hospital includes, but is not limited to, the assets which are identified and listed on Appendix 1 to this Order.
- CC. “St. Luke’s Hospital Assets” means all of ProMedica’s right, title, and interest in and to St. Luke’s Hospital and all related health-care and other assets, tangible or intangible, business, and properties, including any improvements or additions thereto made subsequent to Joinder, relating to the operation of the Post-Joinder Hospital Business, including, but not limited to:
1. All Real Property of St. Luke’s Hospital;
  2. All Tangible Personal Property, including Tangible Personal Property related to the Operation of St. Luke’s Hospital, whether or not located at St. Luke’s Hospital, and Tangible Personal Property located at the Real Property of St. Luke’s Hospital;
  3. All consumable or disposable inventory, including but not limited to, janitorial, office, and medical supplies, and at least thirty (30) treatment days of pharmaceuticals;
  4. All rights under any contracts and agreements (*e.g.*, leases, service agreements such as dietary and housekeeping services, supply agreements,

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and procurement contracts), including, but not limited to, all rights to contributions, funds, and other provisions for the benefit of St. Luke's Hospital pursuant to the Joinder Agreement;

5. All rights and title in and to use of the St. Luke's Hospital Name and Marks on a permanent and exclusive basis;
6. St. Luke's Medicare and Medicaid provider numbers, to the extent transferable;
7. All Intellectual Property; provided, however, that St. Luke's Hospital Medical Protocols do not include ProMedica Medical Protocols;
8. All governmental approvals, consents, licenses, permits, waivers, or other authorizations to the extent transferable;
9. All rights under warranties and guarantees, express or implied;
10. All items of prepaid expense; and
11. Books, records, files, correspondence, manuals, computer printouts, databases, and other documents relating to the Operation of St. Luke's Hospital, electronic and hard copy, located on the premises of St. Luke's Hospital or in the possession of the ProMedica Employee responsible for the Operation of St. Luke's Hospital (or copies thereof where ProMedica has a legal obligation to maintain the original document), including, but not limited to:
  - a. documents containing information relating to patients (to the extent transferable under applicable law), including, but not limited to, medical records, including, but not limited to, any electronic medical records system,

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- b. financial records,
  - c. personnel files,
  - d. St. Luke's Hospital Physician Contracts, Physician lists, and other records of St. Luke's Hospital dealings with Physicians,
  - e. maintenance records,
  - f. documents relating to policies and procedures,
  - g. documents relating to quality control,
  - h. documents relating to Payors,
  - i. documents relating to Suppliers, and
  - j. copies of Hospital Provider Contracts and contracts with Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of ProMedica to make such disclosure.
- DD. "St. Luke's Hospital Contractor" means any Person that provides Physician or other health-care services pursuant to a contract with St. Luke's Hospital or ProMedica (including, but not limited to, the provision of emergency room, anesthesiology, pathology, or radiology services) in connection with the Operation of St. Luke's Hospital.
- EE. "St. Luke's Hospital Physician Contracts" means all agreements to provide the services of a Physician in connection with the Operation of St. Luke's Hospital, regardless of whether any of the agreements are with a Physician or with a medical group, including, but not limited to, agreements for the services of a medical director for St. Luke's Hospital and joiner agreements with Physicians in the same medical practice as a medical director of St. Luke's Hospital.

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- FF. “St. Luke’s Hospital Employee” means any individual who was employed by St. Luke’s Hospital prior to Joinder or was employed by ProMedica after Joinder in connection with the Operation of St. Luke’s Hospital, and who has worked part-time or full-time on the premises of St. Luke’s Hospital at any time since Joinder, regardless of whether that individual has also worked on the premises of ProMedica.
- GG. “St. Luke’s Hospital License” means: (i) a worldwide, royalty-free, paid-up, perpetual, irrevocable, transferable, sublicensable, exclusive license under all Intellectual Property owned by or licensed to St. Luke’s Hospital relating to operation of the Post-Joinder Hospital Business at St. Luke’s Hospital (that is not included in the St. Luke’s Hospital Assets) and (ii) such tangible embodiments of the licensed rights (including, but not limited to, physical and electronic copies) as may be necessary or appropriate to enable the Acquirer to utilize the rights.
- HH. “St. Luke’s Hospital Medical Protocols” means medical protocols promulgated by St. Luke’s Hospital, whether in hard copy or embedded in software, that were in effect at any time prior to Joinder with ProMedica.
- II. “St. Luke’s Hospital Medical Staff Member” means any Physician or other health-care professional who: (1) is not a St. Luke’s Hospital Employee and (2) is a member of the St. Luke’s Hospital medical staff, including, but not limited to, any St. Luke’s Hospital Contractor.
- JJ. “St. Luke’s Hospital Name and Marks” means the name “St. Luke’s Hospital” and any variation of that name, in connection with the St. Luke’s Hospital Assets, and all other associated trade names, business names, proprietary names, registered and unregistered trademarks, service marks and applications, domain names, trade dress, copyrights, copyright registrations and applications, in both published works and

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unpublished works, relating to the St. Luke's Hospital Assets.

- KK. "Software" means executable computer code and the documentation for such computer code, but does not mean data processed by such computer code.
- LL. "Supplier" means any Person that has sold to ProMedica any goods or services, other than Physician services, for use in connection with the Operation of St. Luke's Hospital; provided, however, that "Supplier" does not mean an employee of ProMedica.
- MM. "Tangible Personal Property" means all machinery, equipment, spare parts, tools, and tooling (whether customer specific or otherwise); furniture, office equipment, computer hardware, supplies and materials; vehicles and rolling stock; and other items of tangible personal property of every kind whether owned or leased, together with any express or implied warranty by the manufacturers, sellers or lessors of any item or component part thereof, and all maintenance records and other documents relating thereto.
- NN. "Transitional Administrative Services" means administrative assistance with respect to the operation of an Acute-Care Hospital and related health-care services, including but not limited to assistance relating to billing, accounting, governmental regulation, human resources management, information systems, managed care contracting, and purchasing.
- OO. "Transitional Clinical Services" means clinical assistance and support services with respect to operation of an Acute-Care Hospital and related health-care services, including but not limited to cardiac surgery, oncology services, and laboratory and pathology services.

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- PP. “Transitional Services” means Transitional Administrative Services and Transitional Clinical Services.

**II.****IT IS FURTHER ORDERED** that:

## A. ProMedica shall:

1. No later than one hundred and eighty (180) days from the date this Order becomes final and effective, divest absolutely and in good faith, and at no minimum price, the St. Luke’s Hospital Assets to an Acquirer that receives the prior approval of the Commission and in a manner, including pursuant to a Divestiture Agreement, that receives the prior approval of the Commission;
2. Comply with all terms of the Divestiture Agreement approved by the Commission pursuant to this Order, which agreement shall be deemed incorporated by reference into this Order; and any failure by ProMedica to comply with any term of the Divestiture Agreement shall constitute a failure to comply with this Order. The Divestiture Agreement shall not reduce, limit or contradict, or be construed to reduce, limit or contradict, the terms of this Order; provided, however, that nothing in this Order shall be construed to reduce any rights or benefits of any Acquirer or to reduce any obligations of ProMedica under such agreement; provided further, that if any term of the Divestiture Agreement varies from the terms of this Order (“Order Term”), then to the extent that ProMedica cannot fully comply with both terms, the Order Term shall determine ProMedica’s obligations under this Order. Notwithstanding any paragraph, section, or other provision of the Divestiture Agreement, any failure to meet any condition precedent to closing (whether waived or not) or any modification of the Divestiture

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Agreement, without the prior approval of the Commission, shall constitute a failure to comply with this Order.

- B. Prior to the Effective Date of Divestiture, ProMedica shall not rescind the Joinder Agreement or any term of the Joinder Agreement necessary to comply with any Paragraph of this Order.
- C. Prior to the Effective Date of Divestiture, ProMedica shall restore to St. Luke's Hospital any assets of St. Luke's Hospital as of the date of Joinder that were removed from St. Luke's Hospital at any time from the date of Joinder through the Effective Date of Divestiture, other than Inventories consumed in the Ordinary Course of Business. To the extent that:
  - 1. The St. Luke's Hospital Assets as of the Effective Date of Divestiture do not include (i) assets that ProMedica acquired on the date of Joinder, (ii) assets that replaced those acquired on the date of Joinder, or (iii) any other assets that ProMedica acquired and has used in or that are related to the Post-Joinder Hospital Business, then ProMedica shall add to the St. Luke's Hospital Assets additional assets (of a quality that meets generally acceptable standards of performance) to replace the assets that no longer exist or are no longer controlled by ProMedica;
  - 2. After the date of Joinder and prior to the Effective Date of Divestiture, if ProMedica terminated any clinical service, clinical program, support function, or management function (i) performed by the Pre-Joinder St. Luke's Hospital Business, or (ii) performed by the Post-Joinder Hospital Business, then ProMedica shall restore such service, program, or function (to a quality level that meets generally acceptable standards of care or performance), no later than the Effective Date of Divestiture of the St. Luke's Hospital Assets or

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any other date that receives the prior approval of the Commission.

*Provided, however,* that ProMedica shall not be required to replace any asset or to restore any service, program, or function described by Paragraphs II.C.1. or II.C.2. of this Order if and only if in each instance ProMedica demonstrates to the Commission's satisfaction: (i) that such asset, service, program, or function is not necessary to achieve the purpose of this Order; and (ii) that the Acquirer does not need such asset, service, program, or function to effectively operate the Acquirer Hospital Business in a manner consistent with the purpose of this Order, and if and only if the Commission approves the divestiture without the replacement or restoration of such asset, service, program, or function.

- D. No later than the Effective Date of Divestiture, ProMedica shall grant to the Acquirer a St. Luke's Hospital License for any use in the Acquirer Hospital Business, and shall take all actions necessary to facilitate the unrestricted use of the St. Luke's Hospital License.
- E. ProMedica shall take all actions and shall effect all arrangements in connection with the divestiture of the St. Luke's Hospital Assets necessary to ensure that the Acquirer can conduct the Acquirer Hospital Business in substantially the same manner as St. Luke's Hospital has operated as the Post-Joinder Hospital Business, and in full compliance with the March 29, 2011, order issued by Judge Katz in *Federal Trade Commission, et al. v. ProMedica Health System*, Civil No. 3:11 CV 47, at St. Luke's Hospital, with an independent full-service medical staff capable of providing General Acute-Care Inpatient Hospital Services, and an independent full-service hospital staff and management, including, but not limited to, providing:

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1. Assistance necessary to transfer to the Acquirer all governmental approvals needed to operate the St. Luke's Hospital Assets as an Acute-Care Hospital;
  2. Transitional Services;
  3. The opportunity to recruit and employ St. Luke's Hospital Employees; and
  4. The opportunity to recruit, contract with, and extend medical staff privileges to any St. Luke's Hospital Medical Staff Member, including as provided in Paragraphs II.I, II.J, and II.K of this Order.
- F. ProMedica shall convey as of the Effective Date of Divestiture to the Acquirer the right to use any Licensed Intangible Property (to the extent permitted by the third-party licensor), if such right is needed for the Operation of St. Luke's Hospital by the Acquirer and if the Acquirer is unable, using commercially-reasonable efforts, to obtain equivalent rights from other third parties on commercially-reasonable terms and conditions.
- G. ProMedica shall:
1. Place no restrictions on the use by the Acquirer of the St. Luke's Hospital Assets;
  2. On or before the Effective Date of Divestiture, provide to the Acquirer contact information about Payors and Suppliers for the St. Luke's Hospital Assets;
  3. Not object to the sharing of Payor and Supplier contract terms relating to the St. Luke's Hospital Assets: (i) if the Payor or Supplier consents in writing to such disclosure upon a request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with ProMedica not to disclose the information to any third party; and

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4. With respect to contracts with St. Luke's Hospital Suppliers, at the Acquirer's option and as of the Effective Date of Divestiture:
    - a. if such contract can be assigned without third-party approval, assign its rights under the contract to the Acquirer; and
    - b. if such contract can be assigned to the Acquirer only with third-party approval, assist and cooperate with the Acquirer in obtaining:
      - i. such third-party approval and in assigning the contract to the Acquirer; or
      - ii. a new contract.
- H. At the request of the Acquirer, for a period not to exceed twelve (12) months from the Effective Date of Divestiture, except as otherwise approved by the Commission, and in a manner (including pursuant to an agreement) that receives the prior approval of the Commission:
1. ProMedica shall provide Transitional Services to the Acquirer sufficient to enable the Acquirer to conduct the Acquirer Hospital Business in substantially the same manner that ProMedica has conducted the Post-Joinder Hospital Business at St. Luke's Hospital; and
  2. ProMedica shall provide the Transitional Services required by this Paragraph II.H. at substantially the same level and quality as such services are provided by ProMedica in connection with its operation of the Post-Joinder Hospital Business.

*Provided, however,* that ProMedica shall not (i) require the Acquirer to pay compensation for Transitional Services that exceeds the Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Transitional Services because of

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a material breach by the Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) include a term in any agreement to provide Transitional Services that limits the type of damages (such as indirect, special, and consequential damages) that the Acquirer would be entitled to seek in the event of ProMedica's breach of such agreement.

- I. ProMedica shall allow the Acquirer an opportunity to recruit and employ any St. Luke's Hospital Employee in connection with the divestiture of the St. Luke's Hospital Assets so as to enable the Acquirer to establish an independent, full-service medical staff, hospital staff and management, including as follows:
  1. No later than five (5) days after execution of a divestiture agreement, ProMedica shall (i) identify each St. Luke's Hospital Employee, (ii) allow the Acquirer an opportunity to interview any St. Luke's Hospital Employee, and (iii) allow the Acquirer to inspect the personnel files and other documentation relating to any St. Luke's Hospital Employee, to the extent permissible under applicable laws.
  2. ProMedica shall (i) not offer any incentive to any St. Luke's Hospital Employee to decline employment with the Acquirer, (ii) remove any contractual impediments that may deter any St. Luke's Hospital Employee from accepting employment with the Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with ProMedica that would affect the ability of the St. Luke's Hospital Employee to be employed by the Acquirer, and (iii) not otherwise interfere with the recruitment of any St. Luke's Hospital Employee by the Acquirer, including, but not limited to, by refusing or threatening to refuse to extend medical staff privileges at any ProMedica Acute-Care Hospital.

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3. ProMedica shall (i) vest all current and accrued pension benefits as of the date of transition of employment with the Acquirer for any St. Luke's Hospital Employee who accepts an offer of employment from the Acquirer no later than thirty (30) days from the Effective Date of Divestiture and (ii) if the Acquirer has made a written offer of employment to any key personnel, as identified and listed on confidential Appendix 2 to this Order, provide such key personnel with reasonable financial incentives to accept a position with the Acquirer at the time of the Effective Date of Divestiture, including, but not limited to (and subject to Commission approval), payment of an incentive equal to up to three (3) months of such key personnel's base salary to be paid only upon such key personnel's completion of one (1) year of employment with the Acquirer.
4. For a period ending two (2) years after the Effective Date of Divestiture, ProMedica shall not, directly or indirectly, solicit, hire, or enter into any arrangement for the services of any St. Luke's Hospital Employee employed by the Acquirer, unless such St. Luke's Hospital Employee's employment has been terminated by the Acquirer; provided, however, this Paragraph II.I.4 shall not prohibit ProMedica from: (i) advertising for employees in newspapers, trade publications, or other media not targeted specifically at the St. Luke's Hospital Employees, (ii) hiring employees who apply for employment with ProMedica, as long as such employees were not solicited by ProMedica in violation of this Paragraph II.I.4, or (iii) offering employment to a St. Luke's Hospital Employee who is employed by the Acquirer in only a part-time capacity, if the employment offered by ProMedica would not, in any way, interfere with that employee's ability to fulfill his or her employment responsibilities to the Acquirer.

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- J. ProMedica shall allow the Acquirer an unimpeded opportunity to recruit, contract with, and otherwise extend medical staff privileges to any St. Luke's Hospital Medical Staff Member in connection with the divestiture of the St. Luke's Hospital Assets so as to enable the Acquirer to establish an independent, complete, full-service medical staff, including as follows:
1. No later than the date of execution of a divestiture agreement, ProMedica shall (i) identify each St. Luke's Hospital Medical Staff Member, (ii) allow the Acquirer an opportunity to interview any St. Luke's Hospital Medical Staff Member, and (iii) allow the Acquirer to inspect the files and other documentation relating to any St. Luke's Hospital Medical Staff Member, to the extent permissible under applicable laws.
  2. ProMedica shall (i) not offer any incentive to any St. Luke's Hospital Medical Staff Member to decline to join the Acquirer's medical staff; (ii) remove any contractual impediments that may deter any St. Luke's Hospital Medical Staff Member from joining the Acquirer's medical staff, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with ProMedica that would affect the ability of the St. Luke's Hospital Medical Staff Members to be recruited by the Acquirer; and (iii) not otherwise interfere with the recruitment of any St. Luke's Hospital Medical Staff Member by the Acquirer, including, but not limited to, by refusing or threatening to refuse to extend medical staff privileges at any ProMedica Acute-Care Hospital.
- K. With respect to each Physician who has provided services to St. Luke's Hospital pursuant to any St. Luke's Hospital Physician Contract in effect at any time preceding the Effective Date of Divestiture ("Contract Physician"), ProMedica shall not offer any incentive to the Contract Physician, the Contract

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Physician's practice group, or other members of the Contract Physician's practice group to decline to provide services to St. Luke's Hospital, and shall eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the St. Luke's Hospital Assets any information relating to the Operation of St. Luke's Hospital.

- L. Except in the course of performing its obligations under this Order, ProMedica shall:
1. not provide, disclose, or otherwise make available any trade secrets or any sensitive or proprietary commercial or financial information relating to the Acquirer or the Acquirer Hospital Business to any Person other than the Acquirer, and shall not use such information for any reason or purpose;
  2. disclose trade secrets or any sensitive or proprietary commercial or financial information relating to the Acquirer or the Acquirer Hospital Business to any Person other than the Acquirer (i) only in the manner and to the extent necessary to satisfy ProMedica's obligations under this Order and (ii) only to Persons who agree in writing to maintain the confidentiality of such information; and
  3. enforce the terms of this Paragraph II.L as to any Person and take such action as is necessary, including training, to cause each such Person to comply with the terms of this Paragraph II.L., including any actions that ProMedica would take to protect its own trade secrets or sensitive or proprietary commercial or financial information.
- M. No later than the Effective Date of Divestiture, ProMedica shall assign to the Acquirer any Hospital Provider Contract for the provision of services in

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connection with the Operation of St. Luke's Hospital that is in effect as of the date the divestiture provisions of this Order become final and effective; provided, however, that nothing in this Paragraph II.M. shall preclude ProMedica from completing any post-termination obligations relating to any Hospital Provider Contract.

- N. The purpose of the divestiture of the St. Luke's Hospital Assets is to ensure the continued Operation of St. Luke's Hospital by the Acquirer, independent of ProMedica, and to remedy the lessening of competition resulting from ProMedica's acquisition of St. Luke's Hospital.

**III.**

**IT IS FURTHER ORDERED** that:

- A. From the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein) until the Effective Date of Divestiture, ProMedica shall not:
1. Sell or transfer any St. Luke's Hospital Assets, other than in the Ordinary Course of Business;
  2. Eliminate, transfer, or consolidate any clinical service offered in connection with the Post-Joinder Hospital Business;
  3. Fail to maintain the employment of all St. Luke's Hospital Employees or otherwise fail to keep the Post-Joinder Hospital Business staffed with sufficient employees; provided, however, that ProMedica may terminate employees for cause consistent with the Operation of St. Luke's Hospital on the day before Joinder (in which event ProMedica shall replace such employees);
  4. Modify, change, or cancel any Physician privileges in connection with the Post-Joinder Hospital

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Business; provided, however, that ProMedica may revoke the privileges of any individual Physician consistent with the practices and procedures in place in connection with the Operation of St. Luke's Hospital on the day before Joinder; or

5. Terminate, or cause or allow termination of any contract between any Payor and St. Luke's Hospital. For any contract between a Payor and St. Luke's Hospital that expires during the term of this Order, ProMedica shall offer to extend such contract at rates for services in connection with the Post-Joinder Hospital Business that shall be increased no more than the highest year-over-year escalator percentage as provided in such contract.

**IV.****IT IS FURTHER ORDERED** that:

- A. From the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein) until the Effective Date of Divestiture, ProMedica shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the St. Luke's Hospital Assets and the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets. Among other things that may be necessary, ProMedica shall:
  1. Maintain the operations of the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets in the Ordinary Course of Business and in accordance with past practice (including regular repair and maintenance of the St. Luke's Hospital Assets).
  2. Use best efforts to maintain and increase revenues of the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets, and to maintain at budgeted levels for the year 2010 or the current year, whichever are higher, all administrative,

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technical, and marketing support for the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets.

3. Use best efforts to maintain the current workforce and to retain the services of employees and agents in connection with the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets, including payment of bonuses as necessary, and maintain the relations and goodwill with patients, Physicians, Suppliers, vendors, employees, landlords, creditors, agents, and others having business relationships with the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets.
  4. Assure that ProMedica's employees with primary responsibility for managing and operating the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets are not transferred or reassigned to other areas within ProMedica's organization, except for transfer bids initiated by employees pursuant to ProMedica's regular, established job-posting policy (in which event ProMedica shall replace such employees).
  5. Provide sufficient working capital to maintain the Post-Joinder Hospital Business relating to the St. Luke's Hospital Assets as an economically viable and competitive ongoing business and shall not, except as part of a divestiture approved by the Commission pursuant to this Order, remove, sell, lease, assign, transfer, license, pledge for collateral, or otherwise dispose of the St. Luke's Hospital Assets.
- B. No later than thirty (30) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), ProMedica shall file a verified written report to the Commission that identifies (i) all assets included in the St. Luke's Hospital Assets, (ii) all assets originally

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acquired or that replace assets originally acquired by ProMedica as a result of Joinder, (iii) all assets relating to the Post-Joinder Hospital Business that are not included in the St. Luke's Hospital Assets, and (iv) all clinical services, support functions, and management functions that ProMedica discontinued at St. Luke's Hospital after Joinder (hereafter "Accounting").

**V.**

**IT IS FURTHER ORDERED** that no later than five (5) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), ProMedica shall provide a copy of this Order and Complaint to each of ProMedica's officers, employees, or agents having managerial responsibility for any of ProMedica's obligations under Paragraphs II, III, and IV of this Order.

**VI.**

**IT IS FURTHER ORDERED** that:

- A. At any time after this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), the Commission may appoint a Person ("Monitor") to monitor ProMedica's compliance with its obligations under this Order, consult with Commission staff, and report to the Commission regarding ProMedica's compliance with its obligations under this Order.
- B. If a Monitor is appointed pursuant to Paragraph VI.A of this Order, ProMedica shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
  - 1. The Monitor shall have the power and authority to monitor ProMedica's compliance with the terms of this Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor pursuant to the terms of this Order and in a manner consistent with

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the purposes of this Order and in consultation with the Commission or its staff.

2. Within ten (10) days after appointment of the Monitor, ProMedica shall execute an agreement that, subject to the approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor ProMedica's compliance with the terms of this Order in a manner consistent with the purposes of this Order. If requested by ProMedica, the Monitor shall sign a confidentiality agreement prohibiting the use or disclosure to anyone other than the Commission (or any Person retained by the Monitor pursuant to Paragraph VI.B.5. of this Order), of any competitively-sensitive or proprietary information gained as a result of his or her role as Monitor, for any purpose other than performance of the Monitor's duties under this Order.
3. The Monitor's power and duties under this Paragraph VI shall terminate three (3) business days after the Monitor has completed his or her final report pursuant to Paragraph VI.B.8. of this Order or at such other time as directed by the Commission.
4. ProMedica shall cooperate with any Monitor appointed by the Commission in the performance of his or her duties, and shall provide the Monitor with full and complete access to ProMedica's books, records, documents, personnel, facilities, and technical information relating to compliance with this Order, or to any other relevant information, as the Monitor may reasonably request. ProMedica shall cooperate with any reasonable request of the Monitor. ProMedica shall take no action to interfere with or impede the Monitor's ability to monitor ProMedica's compliance with this Order.

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5. The Monitor shall serve, without bond or other security, at the expense of ProMedica, on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have the authority to employ, at the expense of ProMedica, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for his or her services, subject to the approval of the Commission.
6. ProMedica shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Monitor's gross negligence or willful misconduct. For purposes of this Paragraph VI.B.6., the term "Monitor" shall include all Persons retained by the Monitor pursuant to Paragraph VI.B.5. of this Order.
7. If at any time the Commission determines that the Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve, the Commission may appoint a substitute to serve as Monitor in the same manner as provided by this Order.
8. The Monitor shall report in writing to the Commission (i) every sixty (60) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), (ii) no later than thirty (30) days from the date ProMedica completes its

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obligations under this Order, and (iii) at any other time as requested by the staff of the Commission, concerning ProMedica's compliance with this Order.

- C. ProMedica shall submit the following reports to the Monitor: (i) no later than twenty (20) days after the date the Monitor is appointed by the Commission pursuant to Paragraph VI.A. of this Order, a copy of the Accounting required by Paragraph IV.B. of this Order; and (ii) copies of all compliance reports filed with the Commission.
- D. ProMedica shall provide the Monitor with: (i) prompt notification of significant meetings, including date, time and venue, scheduled after the execution of the Monitor Agreement, relating to the regulatory approvals, marketing, sale and divestiture of the St. Luke's Hospital Assets, and such meetings may be attended by the Monitor or his representative, at the Monitor's option or at the request of the Commission or staff of the Commission; and (ii) the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of ProMedica.
- E. The Commission may, on its own initiative or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order.
- F. The Monitor appointed pursuant to this Order may be the same Person appointed as Divestiture Trustee pursuant to Paragraph II of this Order.

**VII.****IT IS FURTHER ORDERED** that:

- A. If ProMedica has not divested, absolutely and in good faith, the St. Luke's Hospital Assets pursuant to the requirements of Paragraph II of this Order, within the

## Final Order

time and manner required by Paragraph II of this Order, the Commission may at any time appoint one or more Persons as Divestiture Trustee to divest the St. Luke's Hospital Assets, at no minimum price, and pursuant to the requirements of Paragraph II of this Order, in a manner that satisfies the requirements of this Order.

- B. In the event that the Commission or the Attorney General of the United States brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, ProMedica shall consent to the appointment of a Divestiture Trustee in such action. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph VII shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including appointment of a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by ProMedica to comply with this Order.
- C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VII, ProMedica shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to effect the divestiture pursuant to the requirements of Paragraph II of this Order and in a manner consistent with the purposes of this Order.
  2. Within ten (10) days after appointment of the Divestiture Trustee, ProMedica shall execute an agreement that, subject to the prior approval of the Commission and, in the case of a court-appointed Divestiture Trustee, of the court, transfers to the

## Final Order

Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture and perform the requirements of Paragraph II of this Order for which he or she has been appointed.

3. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the agreement described in Paragraph VII.C.2. of this Order to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve-month period the Divestiture Trustee has submitted a plan of divestiture or believes that divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or, in the case of a court appointed Divestiture Trustee, by the court.
4. ProMedica shall provide the Divestiture Trustee with full and complete access to the personnel, books, records, and facilities related to the assets to be divested, or to any other relevant information, as the Divestiture Trustee may request. ProMedica shall develop such financial or other information as the Divestiture Trustee may reasonably request and shall cooperate with the Divestiture Trustee. ProMedica shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by ProMedica shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
5. The Divestiture Trustee shall use his or her best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, but shall divest expeditiously at no minimum price. The divestiture shall be made only to an Acquirer that receives the prior approval of the Commission, and the divestiture shall be

## Final Order

accomplished only in a manner that receives the prior approval of the Commission; provided, however, if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity or entities selected by ProMedica from among those approved by the Commission; provided, further, that ProMedica shall select such entity within ten (10) business days of receiving written notification of the Commission's approval.

6. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of ProMedica, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of ProMedica, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of ProMedica, and the Divestiture Trustee's power shall be terminated. The Divestiture Trustee's compensation may be based in part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets.
7. ProMedica shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties,

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including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph VII.C.7., the term “Divestiture Trustee” shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph VII.C.6. of this Order.

8. If the Divestiture Trustee ceases to act or fails to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph VII for appointment of the initial Divestiture Trustee.
  9. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets to be divested.
  10. The Divestiture Trustee shall report in writing to the Commission every sixty (60) days concerning the Divestiture Trustee’s efforts to accomplish the divestiture.
- D. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- E. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as the Monitor pursuant to Paragraph VI of this Order.

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**VIII.**

**IT IS FURTHER ORDERED** that:

- A. ProMedica shall file a verified written report with the Commission setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order (i) no later than thirty (30) days from the date this Order becomes final and effective (without regard to the finality of the divestiture requirements herein), and every thirty (30) days thereafter until the divestiture of the St. Luke's Hospital Assets is accomplished, and (ii) thereafter, every sixty (60) days (measured from the Effective Date of Divestiture) until the date ProMedica completes its obligations under this Order; provided, however, that ProMedica shall also file the report required by this Paragraph VIII at any other time as the Commission may require.
- B. ProMedica shall include in its compliance reports, among other things required by the Commission, a full description of the efforts being made to comply with the relevant Paragraphs of this Order, a description (when applicable) of all substantive contacts or negotiations relating to the divestiture required by Paragraph II of this Order, the identity of all parties contacted, copies of all written communications to and from such parties, internal documents and communications, and all reports and recommendations concerning the divestiture, the date of divestiture, and a statement that the divestiture has been accomplished in the manner approved by the Commission.

**IX.**

**IT IS FURTHER ORDERED** that ProMedica shall notify the Commission at least thirty (30) days prior to (1) any proposed dissolution of ProMedica, (2) any proposed acquisition, merger, or consolidation of ProMedica, or (3) any other change in ProMedica that may affect compliance obligations arising out of

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this Order, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in ProMedica.

**X.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice, ProMedica shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of ProMedica, and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession, or under the control, of ProMedica relating to compliance with this Order, which copying services shall be provided by ProMedica at its expense; and
- B. To interview officers, directors, or employees of ProMedica, who may have counsel present, regarding such matters.

By the Commission.

**Final Order Appendix 1**

**(Redacted from the Public Version But Incorporated by Reference)**

## Concurring Statement

**Final Order Confidential Appendix 2**

**(Redacted from the Public Version But Incorporated by Reference)**

**Concurring Opinion of Commissioner J. Thomas Rosch**

I concur with the Commission's decision finding that ProMedica Health System's acquisition of St. Luke's Hospital violates Section 7 of the Clayton Act. I also concur with the Commission's conclusion that the appropriate remedy for this violation is divestiture of St. Luke's. I write separately because (1) I would have affirmed the ALJ's finding that the general acute care inpatient services product market includes tertiary services, (2) I would have affirmed the ALJ's rejection of a separate market for inpatient obstetrical services, and (3) I would not have relied on any "willingness to pay" econometric models to establish liability, as the ALJ did.

**I.**

As to the first issue, the parties agreed, consistent with Commission and judicial precedent, that the relevant product market in this case consisted of general acute care (GAC) inpatient services sold to managed care organizations (MCOs). (Complaint ¶ 12; Answer ¶ 12; IDF 299, 306; *Evanston Nw. Healthcare Corp.*, 2007 FTC LEXIS 210, at \*146-151 (2007) (citing six hospital merger decisions).) The Commission has previously concluded that an inpatient GAC market includes tertiary services. In *Evanston*, the Commission defined the relevant product market to include all of the inpatient services provided by Evanston Northwestern Hospital, which offered primary, secondary, and tertiary care services, and Highland Park Hospital, which offered *only* primary and secondary services. *Id.* at \*23-24. The ALJ's relevant product market definition thus accords with the prior teaching of the courts and of this

## Concurring Statement

Commission, and there was no need for the Commission to revisit this issue.<sup>1</sup>

**II.**

As to the second issue, I would have also affirmed the ALJ's conclusion that there is not a separate market for inpatient obstetrical services. These services are already reflected in the inpatient GAC cluster market. Defining a separate market for obstetrical services would therefore be redundant.<sup>2</sup> Furthermore, neither Complaint Counsel nor the majority can point to any judicial precedent for defining a obstetrical services market separate from an overall inpatient GAC market.<sup>3</sup>

In sum, insofar as the Commission would reverse the ALJ as to the role of tertiary and obstetrical services in the relevant market, the Commission would not only depart from the case law,

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1 The majority does not dispute that in *Evanston*, the Commission concluded that the relevant product market included tertiary care services even though only the acquiring hospital offered those services. The majority just asserts that the Commission did not need to reach that conclusion because the issue was not raised in the briefs. In fact, Jonathan Baker, on whom the majority relies, says that such a market definition may be supported simply by "convenience," even where there are "substantial" differences in market shares across services in the cluster market. Jonathan B. Baker, *The Antitrust Analysis of Hospital Mergers and the Transformation of the Hospital Industry*, 51 L. & Contemp. Probs. 93, 137-38 & n.212 (1988).

2 The majority takes issue with the notion that inclusion of OB services with other inpatient services is redundant. But the majority acknowledges that whether OB services are included with other inpatient services makes no difference to the outcome of this case. The majority simply asserts that it would be more "transparent" to treat OB services as a separate market and cites to *Butterworth* as precedent for a separate OB market. However, neither the district court nor the Sixth Circuit (which, incidentally, did not affirm or even address the district court's conclusions regarding the relevant market) in that case held that a separate OB market could be carved out. *See FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1290-91 (W.D. Mich. 1996), *aff'd*, 1997-2 Trade Cas. (CCH) ¶ 71,863 (6th Cir. 1997).

3 If, as the majority says, getting the relevant market right is "important from the standpoint of analytical precision and guidance for future cases," it matters whether OB Services are a separate market. That is precisely why avoiding "gerrymandering" is important.

## Concurring Statement

but also risk accusations of “gerrymandering” the relevant product market so as to make it more susceptible to a structural presumption of liability.

**III.**

As to the third issue, Complaint Counsel and their economist Dr. Town proffered a study linking hospital concentration to prices in the relevant geographic market (IDF 605-11), an MCO “willingness-to-pay” econometric model (IDF 612-34), and a diversion analysis purporting to show that ProMedica was the closest substitute for St. Luke’s patients (IDF 453-61). Respondent and its economist, Ms. Guerin-Calvert, disputed Dr. Town’s “willingness to pay” model and adjusted its specifications in an attempt to correct some of its alleged flaws.<sup>4</sup> (RX 71(A).) Thus, there ended up being two competing econometric “willingness to pay” models. As a result, the parties presented competing, and very different, predictions respecting MCOs’ “willingness to pay.”

**A.**

Insofar as the Commission relies on Dr. Town’s study linking concentration to prices, it supports a “structural” theory of Section 7 liability. *See United States v. Baker Hughes Inc.*, 908 F.2d 981 (1990). The traditional way of challenging a merger is to demonstrate that the merger is reasonably likely to lessen competition or create a monopoly by further concentrating an already concentrated market. If the change in concentration resulting from the merger is sufficiently high, this “structural” theory creates a presumption of liability. That presumption stands unless it is rebutted. *See United States v. Philadelphia Nat’l Bank*, 374 U.S. 321 (1963); *United States v. Baker Hughes Inc.*, 908 F.2d 981 (1990). In this case, the pre-transaction and post-transaction HHIs and the increase in the same are more than

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4 Ms. Guerin-Calvert’s modifications to Dr. Town’s “willingness to pay” econometric model do not constitute a waiver of arguments challenging the propriety of the model. As counsel for Respondent explained, Ms. Guerin-Calvert’s modifications to Dr. Town’s model were only submitted to rebut his model, and Ms. Guerin-Calvert continued to insist that Dr. Town’s model was fatally flawed. (Oral Arg. Tr. 27.)

## Concurring Statement

sufficient to trigger the presumption of liability established by the Supreme Court. *See Philadelphia Nat'l Bank*, 374 U.S. at 363-67. The ALJ found that even using Respondent's proposed market definition, the pre-merger HHIs meet the Merger Guidelines' presumption of a highly concentrated market (IDF 368-69) and that "the Joinder significantly increases concentration in the already highly concentrated Lucas County GAC inpatient service market" (IDF 370).

Moreover, the majority correctly concluded that Respondent had failed to produce evidence that St Luke's was in such bad shape that its market shares would be diluted enough in the future to fall below the level of presumptive illegality. *United States v. Gen. Dynamics Corp.*, 415 U.S. 486 (1974). For example, St. Luke's CEO informed his Board in August 2010—one month prior to the closing of the Joinder Agreement—that the hospital had "high activity" compared to the prior year and "produced a positive operating margin." (IDF 790-91, 948.) He also acknowledged that by the time of the Joinder, St. Luke's had achieved 4 of the 5 "pillars" set forth in its Three-Year Plan. (IDF 931; *see also* IDF 920-41.) Among other things, St. Luke's increased inpatient and outpatient net revenue, increased its occupancy rate, and increased its market share in its core service area. (IDF 924-28.) A variety of other financial metrics also improved in the two years leading up to the Joinder Agreements. (IDF 950-54.) Finally, ProMedica's documents and testimony contradict its assertion that, absent the Joinder, it would need to build a costly new hospital at its Arrowhead property and a new tower at its Flower Hospital. (IDF 1122, 1124, 1126, 1127.)

The structural case—and indeed, the anticompetitive effects of this change in structure—was also buttressed by numerous admissions made by the merging parties in their testimony and documents. For example, ProMedica's CEO acknowledged that before the Joinder, the parties competed to attract patients and also competed to attract and retain physicians. (IDF 464-65.) ProMedica's internal assessments viewed St. Luke's as a capable competitor that could take away patient volume. (IDF 467-71, 1020.) St. Luke's CEO testified that after he came to St. Luke's in 2008, his goal was to regain volume from ProMedica in St. Luke's primary service area. (IDF 441.)

## Concurring Statement

St. Luke's also acknowledged that it entered into the Affiliation Agreement with ProMedica in part based on its expectation of higher reimbursement rates from managed care organizations (MCOs). (IDF 396, 421, 597-603.) A presentation from St. Luke's CEO to the Board of Directors stated that an "affiliation with ProMedica has the greatest potential for higher hospital rates. A ProMedica-[St. Luke's] partnership would have a lot of negotiating clout." (IDF 598.) The same presentation noted that an affiliation with ProMedica could "[h]arm the community by forcing higher hospital rates on them." (IDF 598.) Other merger planning documents noted St. Luke's belief that a ProMedica affiliation would allow it to "force[] high rates on employers and insurance companies" and lead to "outstanding pricing on managed care agreements." (IDF 599-600.)

**B.**

*First*, the "willingness to pay" model is not an appropriate basis on which to find that the transaction will result in unilateral effects.<sup>5</sup> The fundamental premise of the unilateral effects theory of liability has long been that customers accounting for a "significant share of sales" in the market must view the merging parties as each other's closest substitutes. *See* 1992 Merger Guidelines § 2.21 ("Substantial unilateral price elevation in a market for differentiated products requires that there be a significant share of sales in the market accounted for by consumers who regard the products of the merging firms as their first and second choices . . . ."); 2010 Merger Guidelines § 6.1; *United States v. H&R Block*, 2011 U.S. Dist. LEXIS 130219 (D.D.C. 2011) (unilateral effects in differentiated product market

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<sup>5</sup> The majority asserts that asymmetric unilateral effects – where only one party is the other's closest competitor – are "not at all uncommon particularly in markets involving competitors of varied size." But the majority has failed to cite a single case where a "willingness to pay" study was considered probative in a "bargaining" market like this one. Indeed, the majority ignores the teaching of *Evanston* that such a model "potentially creates sticky and unsettled issues for merger analysis [in such a market], most significantly, determining the percentage of the merged firm's revenues that must come from customers who are harmed by the merger for the transaction to violate Section 7." 2007 FTC LEXIS 210, at \*167. Additionally, the majority ignores the other prudential reasons for eschewing such a study.

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requires that “the products controlled by the *merging* firms must be close substitutes, *i.e.*, a substantial number of the customers of one firm would turn to the other in response to a price increase” (quoting *CCC Holdings Inc.*, 605 F. Supp. 2d 26, 68 (D.D.C. 2009), and *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1117-18 (N.D. Cal. 2004)); *Evanston*, 2007 FTC LEXIS 210, at \*158 (“A merger between firms in a differentiated product market can enable the merged firm to raise prices unilaterally if customers accounting for ‘a significant share of sales’ view the merging parties as their first and second choices for a particular need.”). In *Evanston*, the Commission explained that this principle applied to “bargaining markets” like hospital markets. *Evanston*, 2007 FTC LEXIS 210, at \*167 (“In a bargaining market, a merger may allow the merged firm to exercise market power against a subset of customers who view the merging parties as their first and second choices . . .”).

This fundamental premise does not exist in this case. Each and every one of the six MCOs who testified admitted that *Mercy*, not St. Luke’s, was *ProMedica’s* next best substitute. (IDF 442-449; *see also* IDF 437.) Complaint Counsel do not seriously dispute this. (Complaint Counsel Answering Brief at 12 (“Complaint Counsel does not deny that *Mercy* is, in all likelihood, the *ProMedica* system’s closest substitute.”)) The ALJ also found that “from the perspective of the MCOs when constructing a marketable network, the *Mercy* hospital system is the closest substitute to the *ProMedica* hospital system.” (ID at 157; *see also* ID at 159 (“MCOs, when constructing a network, viewed the hospital systems of *ProMedica* and *Mercy* to be each other’s closest substitute . . .”))

As stated above, in *Evanston* the Commission indicated that “willingness to pay” econometric models could apply in “bargaining” markets. But the Commission warned that “[t]he potential for a merger in a bargaining market to have disparate effects on different customers” was significantly different in such markets than it was in a “single-price market.” *See Evanston*, 2007 FTC LEXIS 210, at \*167. The Commission went on to warn that that “potentially creates sticky and unsettled issues for merger analysis, most significantly, determining the percentage of the merged firm’s revenues that must come from customers who

## Concurring Statement

are harmed by the merger for the transaction to violate Section 7.”  
*Id.*

**C.**

*Second*, the Commission should not needlessly resolve all of the thorny issues that surround the “willingness to pay” models or saddle an appellate court with those issues either. Those issues begin with the reliability of the models themselves. They are a form of “simulation” study. Critics have charged that such studies always predict a price increase if there is any degree of substitution between the merging parties’ products. *See* Statement of Commissioner J. Thomas Rosch on the Release of the 2010 Horizontal Merger Guidelines at 3-4 (Aug. 19, 2010). And even the Commission has stated that such studies are not “conclusive” in themselves. *See* 2010 Guidelines § 6.1. For another thing, it is not easy to choose between Dr. Town’s model and the modifications that Ms. Guerin Calvert made to that model. Dr. Town’s model in its original form and as modified predict very different levels of price increase and degrees of statistical significance. But these issues need not be resolved.

**D.**

*Third* and finally, the Commission has tried to persuade staff of the virtues of “telling a story” predominantly out of the mouths of the parties and their documents. This is how the top-flight plaintiff’s lawyers try their cases. We have much to learn from them. The Commission should be reluctant to focus attention instead on economic models especially when the Commission has devoted so much time and effort to insisting that staff focus on the real world as contrasted with the theoretical world. *See generally* Vaughn R. Walker, *Merger Trials: Looking for the Third Dimension*, 5 *Competition Policy Int’l* 35 (2009) (observing that if economic evidence is to be persuasive, it must be communicated in a way that a generalist can understand it and must be consistent with other evidence).

Complaint

IN THE MATTER OF

**UPROMISE, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4351; File No. 102 3116*  
*Complaint, March 27, 2012 – Decision, March 27, 2012*

This consent order addresses Upromise, Inc.'s advertising, marketing, and operation of an optional feature of that Toolbar, the "personalized offers" feature. The complaint alleges that the Targeting Tool collected the names of all websites visited; all links clicked; information that consumers entered into some web pages such as usernames, passwords, and search terms; and, from July 2009 through mid-January 2010, consumers' interactions with forms on secure web pages. The complaint further alleges that Upromise engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for the personal information it collected and maintained. The consent order requires Upromise to disclose to consumers – before the download or installation of software that records or transmits information about any activity occurring on a computer involving the computer's interactions with websites, services, applications, or forms – the types of information collected and how the information will be used.

*Participants*

For the *Commission*: Katrina Blodgett and Ruth Yodaiken.

For the *Respondent*: J. Beckwith ("Becky") Burr, Wilmer Cutler Pickering Hale and Dorr LLP.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Upromise, Inc. ("Upromise" or "respondent"), a corporation, has violated the Federal Trade Commission Act ("FTC Act"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Upromise is a Delaware corporation with its principal office at 95 Wells Avenue, Suite 160, Newton, Massachusetts 02459.

## Complaint

2. The acts and practices of respondent, as alleged herein, have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act.

**RESPONDENT’S BUSINESS PRACTICES AND  
REPRESENTATIONS TO CONSUMERS**

3. Upromise offers a membership service to consumers. A consumer who is a member of Upromise and purchases products and services from Upromise partner merchants can receive cash rebates. Upromise places these cash rebates into a college savings account for the consumer.

4. Since 2005, Upromise disseminated or caused to be disseminated through its website, [www.upromise.com](http://www.upromise.com), a software toolbar referred to as the Upromise TurboSaver Toolbar (the “Toolbar”) for consumers to download and install onto their computers. Among other things, the Toolbar highlighted Upromise partner companies in consumers’ search results, so that consumers could more easily determine which companies were Upromise partners. (*See* Exhibit 1).

5. The Toolbar incorporated a “personalized offers” feature that, when enabled, would collect and transmit information through the consumer’s browser. The personalized offers feature used consumer browsing information to provide targeted advertising to consumers through the browser. Upromise engaged a service provider to develop the Toolbar and the personalized offers feature.

6. During the download process for the Toolbar, where the personalized offers feature was offered users were presented with one of several versions of a pop-up window that contained a check-box next to text stating “Enable Personalized Offers,” (*See, e.g.*, Exhibits 2- 4). Until mid-January 2010, Upromise provided the following description of the personalized offers feature, either directly in the pop-up window or if the consumer clicked on a hyperlink labeled “Show”:

By enabling the Personalized Offers feature, information about the web sites you visit will be

## Complaint

collected. This information is used to provide college savings opportunities tailored to you.

*See, e.g.,* Exhibit 2, Exhibit 3 (operational from approximately July 2009 to January 2010), and Exhibit 4 (operational from approximately October 2008 to May 2009).

In some instances, the check-box to “Enable Personalized Offers” was pre-checked to enable the personalized offers feature by default. (*See, e.g.,* Exhibit 2, operational from approximately July 2009 to January 2010).

7. When the personalized offers feature was enabled, the feature modified the Toolbar to collect extensive information about consumers’ online activities and transmit it to the service provider for analysis. (Hereafter this modified version of the Toolbar with the personalized offers feature enabled is referred to as the “Targeting Tool.”) The Targeting Tool collected the names of all websites visited, all links clicked, and information that consumers entered into some web pages such as usernames, passwords, and search terms. The Targeting Tool’s data collection occurred in the background as a consumer used the Internet, and there was no way for consumers – without special software and technical expertise – to discover the extent of the data collection. Moreover, from July 2009 to mid-January 2010, the Targeting Tool was reconfigured to include consumers’ interactions with forms on secure web pages, which companies such as banks and online retailers provide to safeguard consumer data. The Targeting Tool was enabled on at least 150,000 consumers’ computers.

8. The Upromise TurboSaver<sup>TM</sup> Privacy Statement, which was available on the Upromise website and at times through a link during the download process, stated that the Toolbar might “infrequently” collect some personal information. It further stated that a filter, termed a “proprietary rules engine,” would “remove any personally identifiable information” prior to transmission. (*See, e.g.,* Exhibit 5, operational from approximately October 2008 to September 2009). The TurboSaver<sup>TM</sup> Privacy Statement also stated that “every commercially viable effort” would be made

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“to purge their databases of any personally identifiable information.”

9. In fact, although a filter was used to instruct the Targeting Tool to avoid certain data, the filter was too narrow and improperly structured. For example, although the filter was intended to prevent the collection of financial account personal identification numbers and would have prevented collection of that data if a website used the field name “PIN,” the filter would not have prevented such collection if a website used field names such as “personal ID” or “security code.”

10. The Targeting Tool transmitted the information it gathered – including in some cases credit card and financial account numbers, security codes and expiration dates, and Social Security numbers entered into web pages, including secure web pages – over the Internet in clear text. Tools for capturing data in transit, for example over unsecured wireless networks such as those often provided in coffee shops and other public spaces, are commonly available, making such clear-text data vulnerable to interception. The misuse of such information – particularly financial account information and Social Security numbers – can facilitate identity theft and related consumer harms.

11. On approximately January 21, 2010, Upromise halted all data collection through the Targeting Tool after a security researcher disclosed the scope of the information collected and the fact that it was transmitted in clear text.

12. In addition to the representations made in the download process and in the Upromise TurboSaver™ Privacy Statement, respondent has disseminated or caused to be disseminated the Upromise Privacy Statement, which was available on the Upromise website and through a link in the TurboSaver™ Privacy Statement. The Upromise Privacy Statement stated:

Upromise is committed to earning and keeping your trust. We understand the need for our customers’ personal information to remain secure and private and we have implemented policies and procedures designed to safeguard your information.

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Exhibit 6 (operational from approximately June 2008 to January 2010).

13. Similarly, the Upromise Security Statement, also available on the Upromise website, stated:

Our members' security and privacy are critically important issues for Upromise. We are proud of the innovations we have made to protect your data and personal identity throughout the Upromise service. Upromise protects your data by... SSL, Data, and Password encryption technology....

Using the Secure Sockets Layer protocol (SSL), Upromise automatically encrypts your sensitive information in transit from your computer to ours.

\* \* \*

Upromise security architecture and security procedures are audited and inspected by industry leaders specializing in security processes and technologies.

Exhibit 7 (operational from approximately January 2008 to January 2010).

14. Respondent engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for consumer information collected and transmitted by the Targeting Tool. Among other things, respondent:

- a. created unnecessary risks of unauthorized access to consumer information by the Targeting Tool transmitting sensitive information from secure web pages, such as financial account numbers and security codes, in clear readable text over the Internet;
- b. failed to use readily available, low-cost measures to assess and address the risk that the Targeting Tool would collect such sensitive consumer information it was not authorized to collect. For example,

### Complaint

respondent did not test the Targeting Tool before distributing it to consumers or monitor the Targeting Tool's operation thereafter to verify that the information it collected was consistent with respondent's policies;

- c. failed to ensure that employees responsible for the information collection program received adequate guidance and training about security risks and respondent's privacy and security policies; and
- d. failed to take adequate measures to ensure that its service provider employed reasonable and appropriate measures to protect consumer information and to implement the information collection program in a manner consistent with the respondent's privacy and security policies and contractual provisions designed to protect consumer information.

## **VIOLATIONS OF THE FTC ACT**

### **Count 1**

15. Through the means described in Paragraph 6, respondent has represented, expressly or by implication, that the Targeting Tool would collect and transmit information about the websites consumers visit. Respondent failed to disclose that the Targeting Tool would also collect and transmit much more extensive information about the Internet behavior that occurs on consumers' computers, and, for the period between July 2009 and January 2010, information consumers provided in secure sessions when interacting with third-party websites, shopping carts, and online accounts – such as credit card and financial account numbers, security codes and expiration dates, and Social Security numbers consumers entered into such web pages. These facts would be material to consumers. Respondent's failure to disclose these facts, in light of the representations made, was, and is, a deceptive practice.

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**Count 2**

16. Through the means described in Paragraph 13, respondent has represented, expressly or by implication, that information transmitted by the Toolbar would be encrypted in transit.

17. In truth and in fact, as described in Paragraph 10, information transmitted by the Toolbar was not encrypted in transit. Therefore, the representation set forth in paragraph 13 was, and is, false or misleading and constitutes a deceptive act or practice.

**Count 3**

18. Through the means described in Paragraphs 12 and 13, respondent has represented, expressly or by implication, that it employs reasonable and appropriate measures to protect data obtained from consumers from unauthorized access.

19. In truth and in fact, as described in Paragraph 14, respondent did not implement reasonable and appropriate measures to protect data obtained from consumers from unauthorized access. Therefore, the representations set forth in Paragraphs 12 and 13 were, and are, false or misleading and constitutes a deceptive act or practice.

**Count 4**

20. As described in Paragraphs 9, 10, and 14, respondent's failure to employ reasonable and appropriate measures to protect consumer information – including credit card and financial account numbers, security codes and expiration dates, and Social Security numbers – caused or was likely to cause substantial injury to consumers that is not offset by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers. This practice was, and is, an unfair act or practice.

21. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

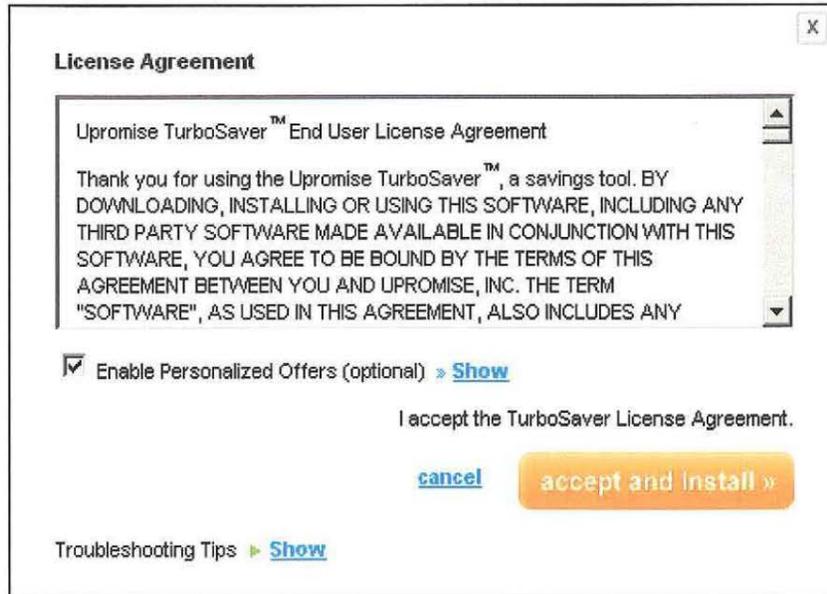
Complaint

**THEREFORE**, the Federal Trade Commission this twenty-seventh day of March, 2012, has issued this complaint against respondent.

By the Commission.

**Exhibit 1**

## Complaint

**Exhibit 2**

Complaint

**Exhibit 3**

close X



## Install TurboSaver™

and get college savings when you shop online.

By pressing install now, I agree to the [TurboSaver license agreement](#) and to download TurboSaver on to my computer.

**License Agreement**

Upromise TurboSaver™ End User License Agreement

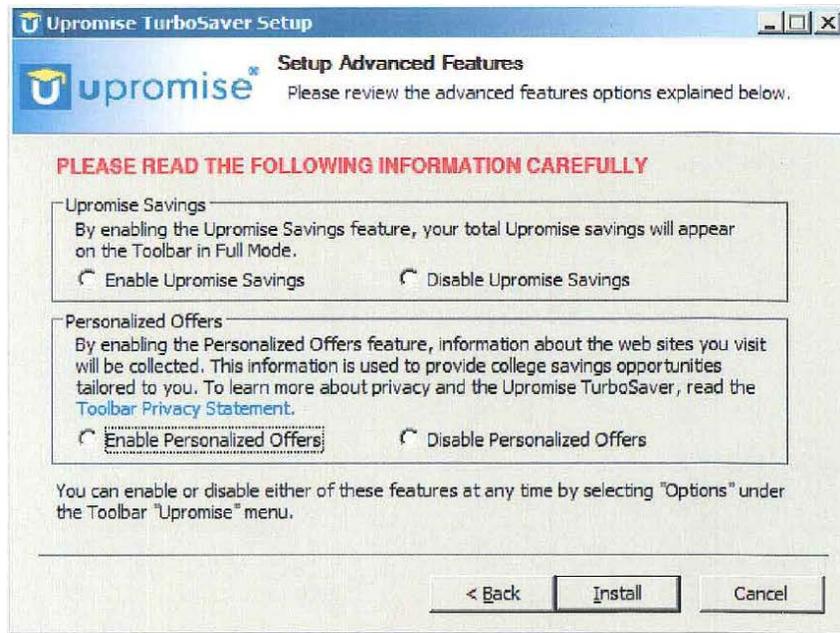
Thank you for using the Upromise TurboSaver™, a savings tool. BY DOWNLOADING, INSTALLING OR USING THIS SOFTWARE, INCLUDING ANY THIRD PARTY SOFTWARE MADE AVAILABLE IN CONJUNCTION WITH THIS SOFTWARE, YOU AGREE TO BE BOUND BY THE TERMS OF THIS AGREEMENT BETWEEN YOU AND UPROMISE, INC. THE TERM "SOFTWARE", AS USED IN THIS AGREEMENT, ALSO INCLUDES ANY

Enable Personalized Offers (optional)

By enabling the Personalized Offers feature, information about the web sites you visit will be collected. This information is used to provide college savings opportunities tailored to you.

install now »

Complaint

**Exhibit 4**

## Complaint

### Exhibit 5

#### Upromise TurboSaver™ Privacy Statement

##### Introduction

We understand and respect that you are concerned about your privacy. Protecting your privacy is a top priority at Upromise. We want you to know that if you choose to enable the Personalized Offers feature of the Upromise TurboSaver, information about the web sites you visit will automatically be forwarded to Upromise or our service provider. This Upromise TurboSaver Privacy Statement is intended to explain to you the type of information being collected and the way that information may be used or shared.

##### Your Choice

Information about the web sites you visit will only be collected if you make an explicit choice to enable the Personalized Offers feature of the Upromise TurboSaver. Enabling Personalized Offers mean that you'll occasionally see windows slide up your screen reminding you of relevant Upromise partners or programs. You are not signing up for any email or regular mail of any kind.

During the installation of the Upromise TurboSaver, you will be asked if you would like to enable or disable the Personalized Offers feature. After installation, you may choose to enable or disable the Personalized Offers feature at any time by selecting "Options" under the TurboSaver's "Upromise" menu.

##### Information Collected

When you enable the Personalized Offers feature, either we or our service provider collects what is known as "Click Stream Data." Click Stream Data is anonymous, and includes information such as your IP address URLs of web pages that you have viewed, and the date that you viewed the web pages.

Infrequently, the Click Stream Data collected may inadvertently contain personal information. Potentially, a name, address, email address, or similar information that you enter into a web page can become part of the Click Stream Data that is transmitted to and stored by our service provider. Our service provider makes every commercially viable effort to purge their databases of any personally identifiable information. Before the Click Stream Data is transmitted to and stored by our service provider a proprietary rules engine is used to search through the Click Stream Data and remove any personally identifiable information. Our service provider is contractually bound not to use the data collected through the Personalized Offers feature for any purpose other than to assist us in the operation of the Upromise Service or the limited use described below under "Sharing with Third Parties."

##### How Collected Information is Used

We may use the non-personally identifiable information collected through the Personalized Offers feature to help us better target college savings opportunities and other content to you in an effort to create a personally relevant experience. We may also use the non-personally identifiable information collected through the Personalized Offers feature to help us formulate and predict responses to various savings opportunities, and to deliver and help determine the effectiveness of various savings opportunities.

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We may also combine the information collected through the Personalized Offers feature with personally identifiable data, such as your transaction information, to assist with targeting savings opportunities to your preferences and to help us formulate, predict responses to, deliver and determine the effectiveness of various savings opportunities.

### Sharing with Third Parties

We may share the non-personally identifiable data collected through the Personalized Offers feature on an anonymous and aggregate basis with third parties, including our contributing companies, to formulate, predict responses to, deliver and determine the effectiveness of various savings opportunities. In addition, our service provider may use the non-personally identifiable data collected through the Personalized Offers feature on an anonymous and aggregate basis to provide online consumer research services for others. For more information view our service provider's [Privacy Policy](#).

### More Information

The Upromise TurboSaver will periodically contact servers at Upromise to download updated configuration files. These files control the advanced features of the tool, including the "Specials" menu and the feature that allows you to receive college savings when shopping online at most Upromise partners, even if you forgot to start your online shopping at Upromise.com.

In addition, the Upromise TurboSaver will periodically contact servers at our service provider to see if you are running the most current version. If necessary, you will automatically be provided with the latest update to the Upromise TurboSaver.

We hope that you find this privacy statement helpful and understand the benefits associated with your use of the Upromise TurboSaver's Personalized Offers feature. If you feel that the benefits of using the Personalized Offers feature do not outweigh the information that we collect, you should choose not to enable the Personalized Offers feature.

For more information about Upromise's full privacy policy, click [here](#).

## Complaint

**Exhibit 6****Upromise Privacy Statement**

Protecting your privacy is a top priority at Upromise. We want you to understand how we handle the personal information about you that we may obtain, and how we may and may not share it. This statement covers all of our information handling practices for Upromise, Inc. and its subsidiaries, including Upromise Investments, Inc. and Upromise Investment Advisors, LLC, for the benefit of current and past customers. Please also see our separate statement, [Privacy of Upromise Rewards Service](#), for additional information about our practices relating to our Rewards service.

**Information We May Obtain.**

As part of providing you products or services, we may obtain personal information from the following sources:

- **Information you provide to us** on applications and other forms, that you otherwise enter on our web site, or that you provide to us in writing or by telephone, such as when you contact our customer service staff. This information may include items such as your name, address, telephone number and social security number. In addition, please see **Use of Cookies and other Technologies** below for information we receive automatically when you visit our web site.
- **Information from your transactions** with us, our affiliates or nonaffiliated third parties such as account activity and your purchase information in our Rewards service.
- **Information from third parties**, including public sources, such as verification services and consumer reporting agencies (to comply with regulatory requirements, ensure the accuracy of data and prevent fraud, for example), or from other sources (such as from other institutions like a bank or broker you use to transfer funds into a Upromise account, or public sources).

We use the information we obtain in order to develop, offer and deliver our products and services, to offer products and services of our affiliates, participating companies, marketing partners and other companies, to process transactions in your accounts, and to fulfill legal and regulatory requirements.

Please note that information you voluntarily include in bulletin boards, chat rooms and other online forums, such as the Upromise Community, may be viewed and used by anyone with access to those forums. Upromise is unable to control any use of such information.

**Sharing Information With Our Affiliates**

As a subsidiary of SLM Corporation, commonly known as Sallie Mae, our affiliates are the family of companies controlled by SLM Corporation. Our affiliates include, among others, Sallie Mae, Inc., Upromise Investments, Inc., Upromise Investment Advisors, LLC, Student Loan Funding Resources, Nellie Mae Corporation, Southwest Student Services Corporation, Student Loan Finance Association, Academic Management Services Corp., SLM Financial Corporation, and Sallie Mae Bank. Our affiliates offer a broad range of products and services including education loans, private loans, mortgage loans, 529 college savings plan administrative services and debt collection services. By sharing your personal information with our affiliates, we and our affiliates can better understand and meet your college savings and other needs by letting you know about products, services and promotional offers in which you are most likely to be interested. For example, if you have a Rewards account that has accumulated sufficient funds, you may be interested in opening an account with the Upromise College Fund, or if you have a high school student, you may be interested in learning more about Sallie Mae student loans.

Unless you tell us not to, we may share with our affiliates all of the information we obtain about

## Complaint

you. If you prefer that we not share with our affiliates consumer report information about you that we may receive from third parties, you may direct us not to do so by sending us an email at [customercare@upromise.com](mailto:customercare@upromise.com) containing your name, address, account number and request, or by calling the following toll free number: 1-800-877-6647. Please be aware that we may continue to share any other information as permitted by law.

**Sharing Information With Nonaffiliated Third Parties**

Information about our customers is an important part of our business. We do not share your personal information with nonaffiliated third parties except as permitted or required by law, including as provided below:

- **Agents and Service Providers.** In order to provide our products and services, we may share personal information about you with agents and service providers to perform functions on our behalf, such as to send email and postal mail, analyze data, provide marketing services, process applications and credit card payments, and service accounts. We contractually obligate these service providers to access and use personal information only as needed to perform their functions and for no other purposes.
- **Financial Services Providers.** In order to make certain financial products available to you (for example, credit cards, loans or insurance), we sometimes enter into marketing agreements with nonaffiliated financial institutions that offer those products. We select the financial institutions we work with very carefully. Generally, we provide these entities with only customer contact information. For some products, we might also provide them limited additional information. These entities are permitted to use the information we give them only for the specific products being offered under our contract. If you prefer that we do not share your information with nonaffiliated financial institutions so that they may market their products and services directly to you, you may opt-out of that information sharing by sending us an email at [customercare@upromise.com](mailto:customercare@upromise.com) containing your name, address, account number and request, or by calling the following toll free number: 1-800-877-6647. You may also opt-out of that information sharing by updating your Upromise account member profile opt-out preferences on our website to opt-out of receiving communications from our participating companies.
- **Protection of Upromise and Others.** We may disclose personal information about you to third parties when we believe such disclosure is appropriate to comply with a legal requirement, such as a law, regulation, court order, subpoena or search warrant, or in the course of a legal proceeding. We may also disclose personal information as we believe appropriate to enforce or apply our rights under our agreements with customers, to protect the rights, property or safety of Upromise, our customers and others, including exchanging information for fraud protection and credit risk reduction.
- **Business Transfers.** If there is a change of control in Upromise's business (whether by merger, sale, or otherwise), its customer information could be sold as part of that transaction and your personally identifying information potentially could be used by the purchaser. Notice will be posted on the website so that you are aware of this change of control.

Upromise does not share member information with nonaffiliated, non-financial institutions to enable them to market their products and services directly to you. Occasionally, we engage third party service providers in the business of facilitating communications to send you information from certain participating companies, but only subject to strict confidentiality provisions that prohibit those third parties from providing your personal information to the participating companies. If we ever make the decision to share member information with nonaffiliated third parties other than financial institutions as described above so that they may market their products and services directly to you, we will notify you ahead of time, and you will have the opportunity to opt-out of that information sharing.

**Use of Cookies and other Technologies**

## Complaint

Our web servers place and read "cookies" on our site's visitors' web browser for a variety of purposes. Cookies are small data files that are stored on an Internet user's web browser by a web server. One important use of cookies is to help identify you while you are logged in to the Upromise site. Consequently, if your browser does not accept session cookies, you will be unable to enroll or log in to our service using our site. You will, however, be able to browse our site as a visitor. The information Upromise collects from cookies and web server logs is used to administer the web service and customize information you receive when visiting our site. Upromise may also use and share aggregate information from cookies and web server logs to analyze and improve our web service offerings. This information does not identify individual visitors or customers.

As is true of most web sites, we gather certain information automatically and store it in log files. This information includes the internet protocol (IP) addresses, browser type, internet service provider (ISP), referring/exit pages, operating system, date/time stamp, and clickstream data. We use this information to analyze trends, to administer our web site, to track users' movements around the web site and to gather demographic information about our user base as a whole. We, certain third parties who host portions of our web site, and certain advertising affiliates or others employ cookies and/or small pieces of code known as "web beacons" or "clear gifs" that, on an anonymous basis, count users that have visited a page that contains these web beacons. We use web beacons to help us better manage content on our site and to determine which content is effective. In addition, third party advertising affiliates and others may use web beacons to help us track the effectiveness of our advertisements placed on third party web sites. Web beacons on our site are not used to collect personally identifiable information about our customers. Finally, we use web beacons in our HTML-based emails to let us know which emails have been opened by recipients so that we may gauge the effectiveness of our communications. If you would like to opt-out of these emails, please see "Choices Regarding the Receipt of Marketing Messages."

If you have not opted-out of receiving marketing messages from us about our products and services, we may use information from our log files, cookies or web beacons to help us make those communications more useful or interesting to you.

One of our third party service providers that uses these technologies to assist us in tracking site usage is Coremetrics. As a result of your accessing our site, Coremetrics may on our behalf collect information about you. This service allows us to better provide our product or service to you. Coremetrics does not have the right to use the information they receive beyond what is necessary to assist us. For further information, including how to opt out, consult Coremetrics' privacy policies at: [www.coremetrics.com/info\\_eluminate2.html](http://www.coremetrics.com/info_eluminate2.html).

### Choices Regarding the Receipt of Marketing Messages

You may choose whether and to what extent you receive marketing messages from Upromise about products and services offered by Upromise or third parties. You may also choose whether and to what extent you receive marketing messages from our participating companies based on our information. If you do not wish to receive any of these marketing messages, you may opt out. And we offer you choices, so that you may elect to receive offers that are of interest to you in the ways you wish. If you do not wish to receive marketing messages, you may opt out by sending us an email at [customercare@upromise.com](mailto:customercare@upromise.com) containing your name, address, account number and request, or by contacting a customer service representative at 1-800-877-6647. You may also opt-out of receiving marketing emails from Upromise and marketing messages from our participating companies, by updating your Upromise account member profile opt-out preferences on our web site. We reserve the right to send you specific administrative notices that are required by law, regulation, or as needed to service your account. In addition, our participating companies reserve the right to contact you using information from sources other than Upromise.

### Security of Your Personal Information

Upromise is committed to earning and keeping your trust. We understand the need for our customers' personal information to remain secure and private, and we have implemented policies and procedures designed to safeguard your information. The only Upromise employees who are authorized to see your personal information are those who need it as part of their jobs.

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Please remember that you also play a valuable part in data security. You should never share your Upromise password with anyone. If you feel your password has been compromised, you should change it immediately. After you have finished using our site, you should log out of your Upromise account and exit your browser so that no unauthorized persons can use our site under your name and account information.

### Collection of Information from Children.

None of Upromise's products or services are intended for purchase by children. Accordingly, Upromise does not knowingly collect, either online or offline, personally identifiable information from children under the age of 13.

### State Laws

In addition to the rights described in this policy, please note that you may have additional rights under state law. For example, if your address on file with us is a California address, we will not share personal information about you with a financial institution with whom we have a joint marketing relationship unless we provide you the required notice under California law and you do not opt-out of that information sharing. In addition, if your address on file with us is a Vermont address, we will not share consumer report information about you with our affiliates unless you expressly consent to that information sharing.

### Changes to This Privacy Statement

If we materially change this statement or our information-handling practices as described in this statement, we will notify you by email and/or through a notice on our web site at least 30 days prior to their implementation.

## Privacy of Upromise Rewards Service

### What information does Upromise collect, and why?

**Enrollment Information.** To set up your membership with the Upromise Rewards service, you will need to provide certain contact information, such as your name, mailing address, email address, phone number, username, and password. This information will also allow us to contact you about new college savings opportunities, unless you opt out of receiving these messages.

**Purchase Information.** As a Rewards service member, you can save for college by shopping with our participating companies. We may require additional information in order to keep track of and collect your contributions. For example, if you use a credit card to make a purchase, we may use your credit card number to identify the transaction. A phone company might require your telephone number, while an airline might require your frequent flyer account number. To take part in our grocery service, you may need to provide a grocery loyalty card number. In order to keep track of and collect your contributions, Upromise collects from some participating companies, grocery retailers or third party processors details of your transactions such as the date and amount of your transaction.

**Rewards Account Information.** We will maintain records to keep track of the contributions you earn from your purchases with our participating companies. You can use our website to view your Rewards service account balances and recent account activities, update your account profile, establish college savings goals, add new future college students, or contact a customer service representative.

**Student Information.** In order to link an eligible investment account or student loan account to the Rewards service so that we may direct your savings from your Rewards service account to the investment or student loan account you will need to provide certain information about the students or future students for whom you are saving such as the name, date of birth and social security

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number of the student and the account number of the investment or loan account. You can also personalize your Rewards service account to reflect your progress toward achieving your personal college savings goals by providing additional information about your future college students, such as when they anticipate starting college and whether they plan to attend a public or private institution. We may use this information to contact you about college savings opportunities, unless you opt out of receiving these messages.

**Investment Account Information.** When you open an investment account, the investment manager is required by law and by industry regulations to obtain certain personal information before creating your investment account. We and our investment manager partners will share certain personal information (such as your or your student's social security number or address) and demographic data with one another to facilitate the application process and monthly processing, and to comply with applicable law. This sharing of information is required to manage your account. Additionally, we may use this demographic information (such as your future college student's date of birth) to contact you about relevant college savings opportunities, unless you opt out of receiving such messages.

**Family and Friends Network Information.** You may use our Tell-a-Friend service to notify your family and friends about Upromise by providing their names and email addresses. You can also increase your college savings through Upromise by creating a savings network of family and friends that directs a portion of its Upromise savings to your future college students.

Upromise will automatically send a one-time email inviting your family and friends to visit Upromise. We store the information for the purpose of sending these emails and to measure overall response rates to these services. Your family and friends may [contact us](#) to request that their information be removed.

Family and friends who contribute to your future college students' investment accounts will receive confirmation of the name and age of each future college student for whom they are saving.

### How does Upromise use my information?

**Management of Your Account.** When you become a member, we use your contact and transaction data to manage your account.

**Use of Third Parties for Fulfillment Purposes.** We may use certain third parties to provide marketing and administrative services, such as keeping track of your purchases, analyzing data or delivering special college saving offers to you on our behalf or on behalf of our participating companies. Third parties may also be used to help us administer our grocery, dining, travel and other rewards programs. In order to obtain these services, we may need to share certain personally identifiable information about our members. However, these third parties will be bound by legal agreements to not use or disclose the information we provide them for any purpose other than to perform the requested service.

On occasion, contests, sweepstakes or surveys on our web site may be co-sponsored by Upromise and another company, or may be sponsored by companies other than Upromise. Some or all of the data collected through these contests, sweepstakes or surveys may be shared with the sponsor(s) or companies indicated on the entry form or in the applicable rules.

**Notification About Products and Services.** We offer you the chance to maximize your Upromise membership through opportunities made available to you on our site and, unless you opt out of receiving them, through email, mail, and telephone messages. We may use information about you to provide you offers tailored to your interests. Sometimes, we send offers to selected groups of members on behalf of our participating companies and/or affiliates. Occasionally, we engage third parties in the business of facilitating communications to send you information from certain participating companies, but only subject to strict confidentiality provisions that prohibit those third parties from providing your personal information to the participating companies. In addition, unless you opt-out, we may share your information with nonaffiliated financial institutions with whom we have a marketing relationship so that those participating companies may market to you the specific products being offered under our contract with them. If you do not want to receive any of these marketing communications, you may opt out of receiving them.

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**Use of Information from Third Parties.** We may obtain information about you from our participating companies and other third parties in order to provide you with college savings opportunities tailored to your interests. You may opt out of receiving these offers by updating your account profile at any time on our website, or by contacting a customer service representative at 1-800-877-6647. We may also use information obtained from our participating companies and other third parties in conjunction with member account and enrollment information for analytical and audit purposes.

**Use of Non-Personally Identifiable Information.** We may also provide aggregated, non-personally identifiable information about our members and their future college students to third parties for audit, marketing and other purposes. Because aggregated data is not associated with any particular person, these third parties will not have access to any personally identifiable information about you or your future college students.

**What are my choices regarding the receipt of marketing messages?**

We reserve the right to send you specific administrative notices that are required by law, regulation, or as needed to service your account. You may choose whether or not to receive messages from Upromise and our participating companies that may better suit your interests based on your preferences and transaction history. If you do not wish to receive these messages from Upromise and/or our participating companies, you may opt out by sending us an email at [customercare@upromise.com](mailto:customercare@upromise.com) containing your name, address, account number and request, or by calling the following toll free number: 1-800-877-6647. You may also opt-out of receiving marketing emails from Upromise and marketing messages from our participating companies by updating your Upromise account member profile opt-out preferences on our web site. Our participating companies reserve the right to contact you using information from sources other than Upromise.

**How can I access and update my Upromise data?**

You may access and update information stored in your account profile by visiting the Upromise site. Please keep your contact, account, and preference information up-to-date. Doing so ensures that your contributions are properly tracked and received. It also helps us inform you of new participating companies who may help you boost your college savings.

**What about links to other sites and participating companies' use of information?**

Through our various online offerings, we may provide links to third-party websites, such as those of our participating companies or your investment manager. Each of these sites may have separate privacy and different data-collection practices from Upromise, and we are not responsible for the actions or practices of these third parties, nor for the content on these sites. We encourage you to review the privacy policies of their sites. In addition, our remindU service and the Personalized Offers feature of the Upromise Toolbar are provided by third parties, which also have separate privacy policies and data-collection practices which can be accessed when you down-load the remindU and Upromise Toolbar software. To learn more about privacy and the Upromise Toolbar, please read the Toolbar Privacy Statement. Finally, please remember that when you shop or do any other business with any of our participating companies, any information you provide to them is subject to their own privacy and data collection practices, for which Upromise is not responsible.

**What is TRUSTe and why is it so important?**

Upromise, a wholly-owned subsidiary of Sallie Mae, is a licensee of the TRUSTe Privacy Program. TRUSTe is an independent, non-profit organization whose mission is to build users' trust and confidence in the Internet by promoting the use of fair information practices. TRUSTe has agreed to review the practices of [www.upromise.com](http://www.upromise.com) because this website wants to demonstrate its commitment to your privacy. Please note that the TRUSTe program does not cover the privacy practices of Upromise, Inc. affiliates. Please also note that the TRUSTe program covers only information that is collected through this website, and does not cover information that may be collected through software downloaded from the site.

If you have questions or concerns regarding this statement, you should first contact Upromise (see below). If you do not receive acknowledgment of your inquiry or your inquiry has not been satisfactorily addressed, you should then contact TRUSTe. TRUSTe will then serve as a liaison with Upromise to resolve your concerns.

## Complaint

### **How do I contact Upromise about this Privacy Statement?**

If you have any questions about this privacy statement, our information-handling practices, or other aspects of privacy at Upromise, please [contact us](#) by email or at Upromise, Inc., Customer Care - Privacy Policy Issues, 95 Wells Avenue, Suite 160, Newton, MA 02459.

*Last Updated 6-12-08*

## Complaint

**Exhibit 7****Upromise Security Statement**

Our members' security and privacy are critically important issues for Upromise. We are proud of the innovations we have made to protect your data and personal identity throughout the Upromise service.

Upromise protects your data by:

- Monitoring for intrusion attempts - 24 hours a day, 7 days a week;
- SSL, Data, and Password encryption technology;
- Firewalls and systems monitoring;
- Security audits and inspections by leading security firms.

**How Does Upromise Protect Your Security?**

The security of your personal information, transactions and savings is our priority at Upromise. Using the Secure Sockets Layer protocol (SSL), Upromise automatically encrypts your sensitive information in transit from your computer to ours. Once your information reaches us, it resides on servers that are configured for maximum security and are continuously monitored for unauthorized changes. Upromise security architecture and security procedures are audited and inspected by industry leaders specializing in security processes and technologies.

**How Can You Help Upromise Protect Your Security?****Username and Password**

Choose a password that will be difficult for others to guess. Do not use obvious or easily accessed data such as your name, initials, Social Security number, mother's maiden name, phone number, address, family birthdays, family names, pets, or any combination of the previous. We emphasize the importance of choosing a unique and secure password to help ensure your protection. Upromise will never contact you to solicit your username or password. Never provide them to anyone.

**Close Your Browser When Finished**

After you have finished your session with Upromise, log out and close your browser to erase information that may have been stored on your computer during your session. Any information you entered during your session may be temporarily stored in the memory storage area of your computer until you close the browser. Logging off and closing your browser will clear this temporary storage area from your computer.

**Verify authenticity of emails**

Never click on a link in an email if you are unsure of its origins, especially if the email asks for personal or financial information. If you have any doubt about the authenticity of an email from Upromise, simply open a new Web browser, type in <http://www.upromise.com>, log in to your Upromise account safely and securely and then perform the requested activity.

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the Respondent named in the caption hereof, and the Respondent having been furnished thereafter with a copy of a draft of Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the Respondent with violation of the Federal Trade Commission Act; and

The Respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the Respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comment received from an interested person pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Upromise, Inc., is a Delaware corporation with its principal office at 95 Wells Avenue, Suite 160, Newton, Massachusetts 02459.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the

## Decision and Order

Respondent, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Affected Consumers” shall mean persons who, prior to the date of issuance of this order, downloaded and installed the TurboSaver Toolbar and had the Personalized Offers feature enabled.
- B. “Clearly and prominently” shall mean as follows:
  - 1. In textual communications (*e.g.*, printed publications or words displayed on the screen of a computer or a mobile device), the required disclosures are of a type, size, and location sufficiently noticeable for an ordinary consumer to read and comprehend them, in print that contrasts highly with the background on which they appear;
  - 2. In communications disseminated orally or through audible means (*e.g.*, radio or streaming audio), the required disclosures are delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend them;
  - 3. In communications disseminated through video means (*e.g.*, television or streaming video), the required disclosures are in writing in a form consistent with subparagraph (A) of this definition and shall appear on the screen for a duration sufficient for an ordinary consumer to read and comprehend them, and in the same language as the predominant language that is used in the communication;

## Decision and Order

4. In communications made through interactive media, such as the Internet, online services, and software, the required disclosures are unavoidable and presented in a form consistent with subparagraph (A) of this definition, in addition to any audio or video presentation of them; and
  5. In all instances, the required disclosures are presented in an understandable language and syntax, and with nothing contrary to, inconsistent with, or in mitigation of the disclosures used in any communication of them.
- C. “Collected Information” shall mean any information or data transmitted from a computer by the TurboSaver Toolbar as a result of the Personalized Offers feature being enabled prior to the date of issuance of this order to any computer server owned by, operated by, or operated for the benefit of respondent.
- D. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- E. “Computer” shall mean any desktop or laptop computer, handheld device, telephone, or other electronic product or device that has a platform on which to download, install, or run any software program, code, script, or other content and to play any digital audio, visual, or audiovisual content.
- F. “Covered Online Service” shall mean any product or service using or incorporating a Targeting Tool. Covered Online Service includes, but is not limited to, the TurboSaver Toolbar with the Personalized Offers feature enabled.
- G. “Personal information” shall mean individually identifiable information from or about an individual consumer including, but not limited to: (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an

## Decision and Order

email address or other online contact information, such as an instant messaging user identifier or a screen name; (d) a telephone number; (e) a Social Security number; (f) a driver's license number or other government-issued identification number; (g) prescription information, such as medication and dosage, and prescribing physician name, address, and telephone number, health insurer name, insurance account number, or insurance policy number; (h) a bank account, debit card, or credit card account number; (i) a persistent identifier, such as a customer number held in a "cookie" or processor serial number, that is combined with other available data that identifies an individual consumer; (j) a biometric record; or (k) any information that is combined with any of (a) through (j) above.

- H. "Personalized Offers feature" shall mean the component of the TurboSaver Toolbar that Upromise has offered under the name of "Personalized Offers."
- I. "Respondent" shall mean Upromise, Inc., and its successors and assigns, and its officers, agents, representatives, and employees.
- J. "Targeting Tool" shall mean any software program or application distributed by or on behalf of respondent that is installed on a consumer's computer, whether as a standalone product or as a feature of another product, and used by or on behalf of respondent to record or transmit information about any activity occurring on that computer involving the computer's interactions with websites, services, applications, or forms, unless (a) the activity involves transmission of information related to the configuration of the software program or application itself; (b) the activity involves a consumer's interactions with respondent's websites, services, applications, and/or forms; or (c) the activity involves a consumer's interactions with respondent's member merchants and that information is collected, retained, or used only as necessary for the purpose of

## Decision and Order

providing the consumer's reward service benefits for transactions involving those merchants.

The TurboSaver Toolbar when configured to collect consumer data, for example, with the Personalized Offers feature enabled, is a Targeting Tool.

- K. "Third party" shall mean any individual or entity other than respondent, except that a third party shall not include a service provider of respondent that:
1. only uses or receives personal information collected by or on behalf of respondent for and at the direction of the respondent and no other individual or entity,
  2. does not disclose the data, or any individually identifiable information derived from such data, to any individual or entity other than respondent, and
  3. does not use the data for any other purpose.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, website, or other device, in connection with the advertising, promotion, offering for sale, sale, or distribution of any Targeting Tool, in or affecting commerce, shall,

- A. Prior to the consumer enabling (by downloading, installing, or otherwise activating) any Targeting Tool:
1. Clearly and prominently, and prior to the display of and on a separate screen from, any "end user license agreement," "privacy policy," "terms of use" page, or similar document, disclose:
    - a. all the types of data that the Targeting Tool will collect, including but not limited to, if applicable, a statement that the data includes transactions or communications between the

## Decision and Order

consumer and third parties in secure sessions, interactions with shopping baskets, application forms, online accounts, web-based email accounts, or search engine pages, and if the information includes personal, financial or health information.

- b. how the data is used, including if the data is shared with a third party, other than as reasonably necessary: (i) to comply with applicable law, regulation, or legal process, (ii) to enforce respondent's terms of use, or (iii) to detect, prevent, or mitigate fraud or security vulnerabilities.
2. Obtain express affirmative consent from the consumer to the enabling (by downloading, installing, or otherwise activating) and to the collection of data.
- B. For those TurboSaver Toolbars installed by consumers before the date of issuance of this order, prior to (1) enabling data collection through any Targeting Tool or (2) otherwise making any material change from stated practices about collection or sharing of personal information through the TurboSaverToolbar, provide the notice and obtain the express consent described in subparts A(1) and (2) of this Part.

**II.**

**IT IS FURTHER ORDERED** that respondent shall:

- A. Notify Affected Consumers: a) that they have or had the Personalized Offers feature enabled, and that from 2005 through January 2010 use of this feature resulted in collection and transmission of data to or on behalf of respondent, listing the categories of personal information that were, or could have been, transmitted; and b) how to permanently disable the Personalized Offers feature and uninstall the TurboSaver Toolbar. Notification shall be by each of the following means:

## Decision and Order

1. Beginning within thirty (30) days after the date of service of this order and for two (2) years after the date of service of this order, posting of a clear and prominent notice on its website.
  2. Beginning within thirty (30) days after the date of service of this order and for three (3) years after the date of service of this order, informing Affected Consumers who complain or inquire about the privacy or security of the TurboSaver Toolbar.
  3. Within sixty (60) days after the date of service of this order, providing direct, clear and prominent notice to Affected Consumers who have the Personalized Offers feature enabled.
- B. Provide prompt, toll-free, telephonic and electronic mail support to help Affected Consumers disable the Personalized Offers feature and, if requested, uninstall the TurboSaver Toolbar.

**III.**

**IT IS FURTHER ORDERED** that respondent shall, within five (5) days after the date of service of this order, delete or destroy, or cause to be deleted or destroyed, all Collected Information in respondent's custody or control, unless otherwise directed by a representative of the Commission.

**IV.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, website, or other device, in connection with its advertising, marketing, promotion, or offering of any service or product in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, about the extent to which respondent maintains and protects the security, privacy, confidentiality, or integrity of any personal information collected from or about consumers, unless the representation is true, and non-misleading.

## Decision and Order

## V.

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, website, or other device, in connection with its advertising, marketing, promotion, or offering of any product or service, in or affecting commerce, shall maintain a comprehensive information security program that is reasonably designed to protect the security, privacy, confidentiality, and integrity of personal information collected from or about consumers. This section may be satisfied through the review and maintenance of an existing program so long as that program fulfills the requirements set forth herein. Such program, the content and implementation of which must be fully documented in writing, shall contain administrative, technical, and physical safeguards appropriate to respondent's size and complexity and the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers, including:

- A. The designation of an employee or employees to coordinate and be accountable for the information security program;
- B. The identification of material internal and external risks that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of personal information and an assessment of the sufficiency of any safeguards in place to control these risks. At a minimum, this risk assessment should include consideration of risks in each area of relevant operation, including, but not limited to: (1) employee training and management; (2) information systems, including network and software design, information processing, storage, transmission, and disposal; and (3) prevention, detection, and response to attacks, intrusions, account takeovers, or other systems failures;
- C. The design and implementation of reasonable safeguards to control the risks identified through risk assessment, and regular testing or monitoring of the

## Decision and Order

effectiveness of the safeguards' key controls, systems, and procedures;

- D. The development and use of reasonable steps to select and retain service providers capable of appropriately safeguarding personal information such service providers receive from respondent or obtain on respondent's behalf, and the requirement, by contract, that such service providers implement and maintain appropriate safeguards; and
- E. The evaluation and adjustment of respondent's information security program in light of the results of the testing and monitoring required by subpart C, any material changes to respondent's operations or business arrangements, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of its information security program.

**VI.**

**IT IS FURTHER ORDERED** that, in connection with its compliance with Part V of this order, for any Covered Online Service respondent shall obtain initial and biennial assessments and reports ("Assessments") from a qualified, objective, independent third-party professional, who uses procedures and standards generally accepted in the profession. Professionals qualified to prepare such Assessments shall be: a person qualified as a Certified Information System Security Professional (CISSP) or as a Certified Information Systems Auditor (CISA); a person holding Global Information Assurance Certification (GIAC) from the SysAdmin, Audit, Network, Security (SANS) Institute; or a similarly qualified person or organization approved by the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580. The reporting period for the Assessments shall cover: (1) the first one hundred and eighty (180) days after service of the order for the initial Assessment, and (2) each two (2) year period thereafter for twenty (20) years after service of the order for the biennial Assessments. Each Assessment shall:

## Decision and Order

- A. Set forth the specific administrative, technical, and physical safeguards that respondent has implemented and maintained during the reporting period;
- B. Explain how such safeguards are appropriate to respondent's size and complexity, and the nature and scope of respondent's activities, and the sensitivity of the personal information collected from or about consumers;
- C. Explain how the safeguards that have been implemented meet or exceed the protections required by Part V of this order; and
- D. Certify that respondent's security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of personal information is protected and has so operated throughout the reporting period.

Each Assessment shall be prepared and completed within sixty (60) days after the end of the reporting period to which the Assessment applies. Respondent shall provide the initial Assessment to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C. 20580, within ten (10) days after the Assessment has been prepared. All subsequent biennial Assessments shall be retained by respondent until the order is terminated and provided to the Associate Director of Enforcement within ten (10) days of request.

**VII.**

**IT IS FURTHER ORDERED** that respondent shall, for a period of five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging and promotional material containing the representation;

## Decision and Order

- B. All materials relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this order, obtained pursuant to Part IX.

Moreover, for a period of three (3) years after the date of preparation of each Assessment required under Part VI of this order, respondent shall maintain and upon request make available to the Commission for inspection and copying all materials relied upon to prepare the Assessment, whether prepared by or on behalf of the respondent, including but not limited to all plans, reports, studies, reviews, audits, audit trails, policies, training materials, and assessments, for the compliance period covered by such Assessment.

**VIII.**

**IT IS FURTHER ORDERED** that respondent shall, in connection with this action or any subsequent investigations related to or associated with the transactions or the occurrences that are the subject of the Commission's complaint, cooperate in good faith with the Commission and appear at such places and times as the Commission shall reasonably request, after written notice, for interviews, conferences, pretrial discovery, review of documents, and for such other matters as may be reasonably requested by the Commission. If requested in writing by the Commission, respondent shall appear and provide truthful testimony in any trial, deposition, or other proceeding related to or associated with the transactions or the occurrences that are the subject of the complaint, without the service of a subpoena.

## Decision and Order

**IX.**

**IT IS FURTHER ORDERED** that respondent shall deliver a copy of this order to: (1) all current and future principals, officers, and directors; and (2) all current and future managers who have responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order, with any electronic signatures complying with the requirements of the E-Sign Act, 15 U.S.C. § 7001 *et seq.* Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

**X.**

**IT IS FURTHER ORDERED** that respondent shall notify the Commission at least thirty (30) days prior to any change in respondent that may affect compliance obligations arising under this order, including but not limited to, a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor company; the creation or dissolution of a subsidiary (including an LLC), parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in respondent's name or address. *Provided, however,* that with respect to any proposed change about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge.

Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. Upromise. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of such notices is contemporaneously sent to the Commission at [Debrief@ftc.gov](mailto:Debrief@ftc.gov).

## Decision and Order

**XI.**

**IT IS FURTHER ORDERED** that respondent shall, within sixty (60) days after service of this order, and at such other times as the FTC may require, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form in which respondent has complied with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, respondent shall submit additional true and accurate written reports.

**XII.**

This order will terminate on December 31, 2031, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part of this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that this order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission.

Analysis to Aid Public Comment

## **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order applicable to Upromise, Inc.

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Upromise offers, among other things, a membership service through which consumers who join can receive cash rebates for making online purchases from merchants who participate in the Upromise program. To take part in the program, consumers download and install software, the Upromise TurboSaver Toolbar ("Toolbar"), from Upromise that modifies the consumers' Internet browser to highlight Upromise member merchants.

The Commission's complaint involves the advertising, marketing, and operation of an optional feature of that Toolbar, the "personalized offers" feature. That feature modified the Toolbar to provide targeted advertising to the consumer based upon the consumers' online behavior (the modified version is referred to here as the "Targeting Tool"). Upromise engaged a service provider to develop the Toolbar and the personalized offers feature.

According to the FTC complaint, while Upromise represented to consumers that the Targeting Tool collected information about the web sites consumers visited, its failure to disclose the full extent of data collected through the software was deceptive. The complaint alleges that the Targeting Tool collected the names of all websites visited; all links clicked; information that consumers entered into some web pages such as usernames, passwords, and search terms; and, from July 2009 through mid-January 2010, consumers' interactions with forms on secure web pages. The complaint further alleges that Upromise misrepresented its

## Analysis to Aid Public Comment

privacy and security practices, including misrepresenting that consumers' data would be encrypted. The complaint alleges that these claims were false and thus violate Section 5 of the FTC Act.

In addition, the FTC complaint alleges that Upromise engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for the personal information it collected and maintained. Among other things, Upromise: (1) transmitted sensitive information from secure web pages, such as financial account numbers and security codes, in clear readable text; (2) did not use readily available, low-cost measures to assess and address the risks to consumer information; (3) failed to ensure that employees responsible for the information collection program received adequate guidance and training; (4) failed to take adequate measures to ensure that its service provider employed reasonable and appropriate measures to protect consumer information.

The complaint alleges that Upromise's failure to employ reasonable and appropriate measures to protect consumer information – including credit card and financial account numbers, security codes and expiration dates, and Social Security numbers – was unfair. Tools for capturing data in transit, for example over unsecured wireless networks such as those often provided in coffee shops and other public spaces, are commonly available, making such clear-text data vulnerable to interception. The misuse of such information – particularly financial account information and Social Security numbers – can facilitate identity theft and related consumer harms.

The proposed order contains provisions designed to prevent Upromise from engaging in the future in practices similar to those alleged in the complaint.

Part I of the proposed order requires Upromise to disclose to consumers – before the download or installation of software that records or transmits information about any activity occurring on a computer involving the computer's interactions with websites, services, applications, or forms – the types of information collected and how the information will be used. The disclosure must be clear and prominent and separate from other notices. The company must also obtain consumers' express affirmative consent

## Analysis to Aid Public Comment

before the consumer downloads, installs, or otherwise activates such software. In addition, the company must provide this clear and prominent notice, and obtain express affirmative consent, before enabling data collection through any previously installed TurboSaver Toolbar and before making any material change from stated practices about collection or sharing of personal information through the Toolbar.

Part II of the proposed order requires Upromise to provide notice to consumers who, prior to the issuance of the order, had the Personalized Offers feature enabled. The notice must inform consumers about the categories of personal information that were, or could have been, transmitted by the feature, and how to disable the Personalized Offers feature and uninstall the Toolbar. Part III of the proposed order requires the company to destroy data it collected during the years covered by the complaint unless otherwise directed by the Commission.

Part IV of the proposed order prohibits the company from making any misrepresentations about the extent to which it maintains and protects the security, privacy, confidentiality, or integrity of any information collected from or about consumers. Part V of the proposed complaint requires Upromise to maintain a comprehensive information security program that is reasonably designed to protect the security, confidentiality, and integrity of such information (whether in paper or electronic format) about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to Upromise's size and complexity, the nature and scope of its activities, and the sensitivity of the information collected from or about consumers and employees. Specifically, the proposed order requires Upromise to:

- designate an employee or employees to coordinate and be accountable for the information security program;
- identify material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the

## Analysis to Aid Public Comment

sufficiency of any safeguards in place to control these risks;

- design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures;
- develop and use reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from Upromise or obtain on behalf of Upromise, and require service providers by contract to implement and maintain appropriate safeguards; and
- evaluate and adjust its information security programs in light of the results of testing and monitoring, any material changes to operations or business arrangements, or any other circumstances that it knows or has reason to know may have a material impact on its information security program.

Part VI of the proposed order requires Upromise to obtain within the first one hundred eighty (180) days after service of the order, and on a biennial basis thereafter for a period of twenty (20) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that: (1) it has in place a security program that provides protections that meet or exceed the protections required by the proposed order; and (2) its security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of sensitive consumer, employee, and job applicant information has been protected.

Parts VII, VIII, IX, X, XI, and XII of the proposed order are reporting and compliance provisions. Part VII requires Upromise to retain documents relating to its compliance with the order. For most records, the order requires that the documents be retained for a five-year period. For the third-party assessments and supporting documents, Upromise must retain the documents for a period of three years after the date that each assessment is prepared. Part VIII requires the company to cooperate with the FTC in

## Analysis to Aid Public Comment

connection with this action or any subsequent investigations related to or associated with the transactions or the occurrences that are the subject of the FTC complaint. Part IX requires dissemination of the order now and in the future to persons with responsibilities relating to the subject matter of the order. Part X ensures notification to the FTC of changes in corporate status. Part XI mandates that Upromise submit a compliance report to the FTC within 60 days, and periodically thereafter as requested. Part XII provides that the order will terminate after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

## Complaint

## IN THE MATTER OF

**LONG FENCE & HOME, LLLP**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4352; File No. 112 3005*  
*Complaint, April 5, 2012 – Decision, April 5, 2012*

This consent order addresses Long Fence & Home, LLLP's marketing and sale of replacement windows for use in residences. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating the representations that consumers who replace their windows with Long Windows' Quantum2 replacement windows with SuperPak Glass are likely to achieve residential energy savings of 50% or save 50% on residential heating and cooling costs. The consent order prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Participants*

For the *Commission: Robert Frisby, Zachary Hunter, Joshua Millard, and Sarah Waldrop.*

For the *Respondent: D.S. Berenson, Johanson Berenson LLP.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Long Fence & Home, LLLP ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Long Fence is a Maryland limited liability limited partnership with its principal office or place of business at 10236 Southard Drive, Beltsville, Maryland 20705. Respondent

## Complaint

does business under its own name and various trade names bearing the “Long” mark, including “Long Windows.”

2. Respondent advertises, offers for sale, sells, and/or distributes windows, including its “Long Windows” replacement window lines manufactured by Serious Energy, Inc., which formerly did business under the name Serious Materials, Inc. Respondent sells these windows through its own salespersons to consumers for residential use.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused the dissemination of advertising and promotional materials, including print advertising, advertising on its website, and brochures and other promotional materials provided to its salespersons, including but not necessarily limited to the attached Exhibits A through F. Respondent disseminated or caused the dissemination of these advertisements and promotional materials to consumers. The advertisements and promotional materials contain the following statements or depictions:

a. Long Windows Print Advertisement

**50%**  
**SAVINGS**  
**GUARANTEED**

**PLEASE READ!**

Our energy use dropped so much after installing your windows — Dominion Virginia Power thought our meter was broken! We look forward to using Long Fence and Home for many years to come!

Derek and Jennifer H.  
Springfield, Virginia

Exhibit A (Jan. 2010) (Washington Post, Red Plum).

Complaint

b. Long Windows Print Advertisement

**50%  
ENERGY  
SAVINGS  
GUARANTEED\***

**AMAZING RESULTS!**

Our energy use dropped so much after installing your windows — Dominion Virginia Power thought our meter was broken! We look forward to using Long Fence and Home for many years to come!

Derek and Jennifer H.  
Springfield, Virginia

....

\* 50% Energy Savings based on manufacturer’s one year savings guarantee. Many factors determine actual savings and results may vary. Call for further details on our written savings guarantee.

Exhibit B (Jan.-Nov. 2010)  
(Washington Post, Red Plum, Examiner).

c. Long Windows Print Advertisement

— **Save 50% on  
Energy Bills – or  
LONG® PAYS YOU!**

Exhibit C (Mar.-June 2009) (Washington Post, Red Plum, Examiner, Merchandiser).

## Complaint

## d. Long Windows Print Advertisement

**will save you more than other replacement windows.**

**Save More Money and Energy**

....

- 50% energy savings guarantee

Exhibit D (Sept. 2009) (Washington Post, Red Plum, Examiner, Merchandiser).

## e. Long Windows Internet Promotional Material

<p>50%</p> <p>SAVINGS</p> <p>GUARANTEE</p>	<p>We guarantee you'll save 50% on your heating and cooling costs - and cut your energy bills in half - when you install Long Windows throughout your home or we'll reimburse you the difference.[ ] Speak to your Long Windows consultant for full details.</p>
--	--

Exhibit E (Sept. 2010)

(<http://www.longwindows.com>).

## f. Long Windows Energy Saving Pledge:

*50% Energy Savings*

*Guarantee*

This pledges a savings of at least 50% of energy consumption for heating and cooling the residence listed below during the 12 month period beginning with the date of this pledge. In the event energy saving[s] are less than 50% of the previous 12 months['] energy consumption, the homeowner should

## Complaint

notify Long Fence and Home who will provide the homeowner with the necessary forms to file for benefits under this pledge. If energy savings are less than 50% of the previous 12 month[s'] energy consumption, the homeowner will be reimbursed the difference between the actual savings and 50% of the energy costs for the previous 12 months.

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this pledge only be effective if the homeowner, located at the address shown hereon, has purchased a complete installation of Quantum2 replacement windows with SuperPak Glass™ glazing, and is effective on the dates shown.

....

Exhibit F.

5. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with Long Windows replacement windows are not likely to achieve a 50% reduction in residential energy consumption or heating and cooling costs.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- a. Consumers who replace windows with Quantum2 replacement windows with SuperPak Glass are likely to achieve residential energy savings of 50%; or
- b. Consumers who replace windows with Quantum2 replacement windows with SuperPak Glass are likely to save 50% on residential heating and cooling costs.

7. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the

## Complaint

representation(s) set forth in Paragraph 6 at the time that the representation(s) were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time that the representation(s) were made. Therefore, the representation set forth in Paragraph 7 was false or misleading.

9. Respondent's practices, as alleged in this complaint, constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission, this fifth day of April 2012, has issued this complaint against respondent.

By the Commission.

Complaint

Exhibit A

**LONG KITCHENS**  
YOU CAN AFFORD YOUR DREAM KITCHEN!

**LONG SIDING**  
MAKE YOUR HOME LOOK LIKE NEW!

**LONG ATTIC MIRROR**  
NEW! ENERGY SAVING PRODUCT FOR 2010  
SAVE 20% ON UTILITY BILLS GUARANTEED!

**50% SAVINGS GUARANTEED**  
**PLEASE READ!**  
Our energy use dropped so much after installing your windows - Dominion Virginia Power thought our meter was broken! We look forward to using Long Fence and Home for many years to come!  
Derek and Jennifer H.  
Springfield, Virginia

**LONG WINDOWS**  
THE ULTIMATE WINDOW  
**LIFETIME WARRANTY**

**OVER 3X DOUBLE PANE PERFORMANCE**  
• Q-Foam® Insulation  
• Heat Mirror™ Technology  
• 5 Coats Low-e\*  
UP TO **\$1500 TAX CREDIT**

**LONG GUTTERS**  
Gutter Jacket™  
BEFORE NO CLOG GUARANTEE! AFTER

**LONG DOORS**  
BEAUTIFUL & ENERGY-EFFICIENT!

**CALL NOW!**  
**1-800-637-9014**  
**FREE ESTIMATES**  
www.longfenceandhome.com  
Improve your home. Improve your life.  
Affordable Financing

Licensed • Bonded • Insured  
MHIC# 51346 • DC# 6700678 • VM# 2705048183A

Complaint

Exhibit B

# LONG WINDOWS

## THE RESPONSIBLE & Beautiful SOLUTION

**LAST CHANCE! FEDERAL TAX CREDIT ENDING! HURRY!**

Engineered for maximum efficiency – Long Windows will help you burn less fuel, reduce carbon dioxide emissions and become more earth-friendly all while you save money and beautify your home!

**50% ENERGY SAVINGS GUARANTEED\***

**AMAZING RESULTS!**

*Our energy use dropped so much after installing your windows – Dominion Virginia Tower thought our meter was broken! We look forward to using Long Fence and Home for many years to come!*

*Deck and Jennifer H.  
Springfield, Virginia*

**1 DAY INSTALL!**

**LIFETIME WARRANTY**

**UP TO \$1500 TAX CREDIT**

- Clear Heat Mirror™ Technology dramatically reduces solar heat gain in summer and allows solar heat gain in winter
- Up to 5 layers of Low E Coating reflects damaging UV rays and increases R-value
- Patented Q Foam insulation stops air convection making frame/sash an incredible R-13!

*All above features are exclusive to Long Windows and allow for a 50% energy saving guarantee.*

**COUPON + FREE REPORT**

**UP TO \$3000 TAX CREDIT MATCH COUPON**

GO TO [LONGWINDOWS.COM](http://LONGWINDOWS.COM) TO DOWNLOAD

**Long® Windows Outperform All Major Brands**  
Fullframe R-value windows from R1.2 - R 6.25

Brand	R-Value
Andersen*	1.455 (U 0.22)
Pella*	1.385 (U 0.26)
Warner**	1.3 (U 0.28)
Millgard**	1.3 (U 0.3)
Double Pass	1.2 (U 0.49)
Singlo Pass	1.2 (U 0.84)

**Over 3x** the performance of Double Pass!

**FREE ESTIMATES CALL NOW!**

**1-800-637-9014**

[longwindows.com](http://longwindows.com)

Improve your home. Improve your life.

\* 50% Energy Savings based on manufacturer's one year savings guarantee. Many factors determine actual savings and results may vary. Call for further details on our written savings guarantee. † One day installation on most homes. See representative for details.

Licensed • Bonded • Insured  
MHIC# 51346 • DC# 6700678 • VA# 2705048183A

Complaint

**Exhibit C**

**Receive \$1500 Tax Credit from the Federal Government!**

**Save 50% on Energy Bills – or LONG® PAYS YOU!**

**BREAKING NEWS!!!**  
**Long® Windows will MATCH YOUR TAX CREDIT!\***

**FREE Estimates! Call Now!**  
**1-800-637-9014**  
**www.longwindows.com**

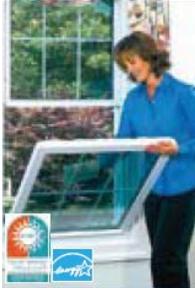
Licensed • Bonded • Insured • FINANCING AVAILABLE  
MHIC #51346 • DC# 6700678 • VA# 2705048183A

\* Minimum purchase 6 windows. Cannot be combined with other offers.

The advertisement features a blue background with a white window frame in the center. A red starburst graphic contains the 'BREAKING NEWS!!!' text. A circular seal in the top left corner shows the US Capitol and '\$1500 FEDERAL TAX CREDIT'. Two red checkmarks point to the top two promotional offers. The 'LONG WINDOWS' logo is prominently displayed above the window frame. At the bottom left, there are logos for 'Energy Star' and 'Energy Efficient Windows Alliance'. At the bottom right, there are logos for 'EXCELLENCE SINCE 1943' and various payment methods including Visa, MasterCard, American Express, and Discover.

Complaint

**Exhibit D**


## LONG<sup>®</sup> WINDOWS will save you more than other replacement windows.

**Save More Money and Energy**

- Up to \$3,000 in savings and tax credits
- 400% more energy-efficient than Energy Star-rated windows
- 50% energy savings guarantee
- Energy saving Heat Mirror™, recognized by *Popular Science* as a top 100 invention
- Lifetime warranty covering parts and labor

**Limited Time Only. Save Up to \$3,000!**  
**\$1,500 Federal Tax Credit**  
**+ \$1,500 match from Long<sup>®</sup> Windows**

Call or log on for a FREE report  
*"Is your home safe and energy-efficient?"*  
 Includes 10-point energy-efficiency test.

**1-800-637-9014**  
[www.longwindows.com](http://www.longwindows.com)

Affordable Financing & FREE In-Home Estimates  
Licensed • Bonded • Insured  
 MHIC# 51346 • DC# 6700678 • VA# 2705048183A



Long<sup>®</sup> Windows provides some of the best guaranteed, most durable and energy-efficient replacement windows.

**Long<sup>®</sup> Windows Outperform All Major Brands**  
Full frame double windows from R 5.0 - R 11.0

Brand	U-Factor
Long Windows	0.10 U-10
Brand A	0.20 U-20
Brand B	0.30 U-30
Brand C	0.40 U-40
Brand D	0.50 U-50
Brand E	0.60 U-60
Brand F	0.70 U-70
Brand G	0.80 U-80
Brand H	0.90 U-90
Brand I	1.00 U-100

4x  
ENERGY  
STAR

**Here's What They're Saying...**

"A month after we installed Long Windows, we received a call from Dominion Virginia Power about the sudden drop in our energy use. When we said we purchased Long Windows, the representative replied, 'That explains it!'"

*Derek & Jennifer H.*  
Derek and Jennifer H.  
 Springfield, VA

**LONG<sup>®</sup> WINDOWS**  
 Improve your home. Improve your life.



Complaint

- Jim Craig, Severna Park, MD

Yet another factor in energy-efficiency is the SHGC, which measures how well the window blocks solar heat coming inside the house. Again, the lower the value the greater the energy-efficiency of your window.

Long Windows have an industry-leading SHGC of 0.20. This surpasses the 2009 Energy Star Standards, which recognize a SHGC of 0.32 as acceptable.

The guidelines for the Federal Tax Credit require that your windows carry a SHGC of 0.30 or less. All Long Windows qualify; many Energy Star windows do not.

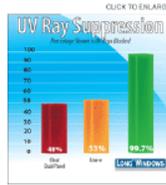


**UV Transmission**

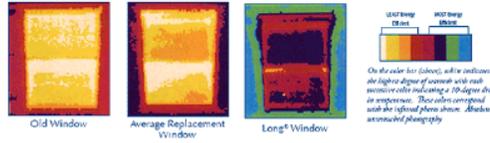
A final factor in energy-efficiency is the transmission of UV light. Long Windows utilize Heat Mirror™ Technology, recognized in Popular Science magazine as one of the top 100 inventions of the last 1,000 years.

Long Windows with Heat Mirror™ Technology only allow 0.3% of damaging UV rays into your home. Other windows on the market today allow roughly 50% of damaging UV rays into your home.

The difference is clear if you look at heat mapping photos of Long Windows versus competitors.



CLICK TO ENLARGE



**Request a free, no obligation in-home consultation and estimate today or call us at 1-800-417-LONG (5664).**

WINDOWS   KITCHENS   SIDING   GUTTERS   DOORS   ATTIC   MIRROR   INSULATION   ENERGY SOLUTIONS   ABOUT   CONTACT   PRIVACY   ESTIMATE  
REQUEST   SITE MAP

Long Fence and Home is a home improvement and remodeling company serving clients in Maryland, Virginia and Washington, DC. Contact us for a free estimate on your home improvement or remodeling project. Other areas we service

Long Fence and Home • 10236 Southard Drive • Beltsville, MD 20705 • 1-800-417-LONG (5664)  
© 2010 Long Fence and Home

Complaint

Exhibit F



50% Energy Savings Guarantee

This pledges a savings of at least 50% of energy consumption for heating and cooling the residence listed below during the 12 month period beginning with the date of this pledge. In the event energy saving are less than 50% of the previous 12 months energy consumption, the homeowner should notify Long Fence and Home who will provide the homeowner with the necessary forms to file for benefits under this pledge. If energy savings are less than 50% of the previous 12 month energy consumption, the homeowner will be reimbursed the difference between the actual savings and 50% of the energy costs for the previous 12 months.

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this pledge only be effective if the homeowner, located at the address shown hereon, has purchased a complete installation of Quantum2 replacement windows with SuperPak Glass™ glazing, and is effective on the dates shown.

THIS PLEDGE IS BASED UPON CONSUMPTION, NOT COST. IT IS SUBJECT TO THE FOLLOWING PROVISIONS:

- 1. This pledge only covers Quantum2 replacement windows with SuperPak Glass™ glazing.
2. Complete installation of Quantum2 replacement windows with SuperPak Glass™ glazing is defined as all windows in this residence except attic, basement, and porches.
3. This pledge covers only single family dwellings and townhomes.
4. Maximum payment under this pledge is \$500.00
5. Claims under this pledge must be filed in writing with supporting evidence within 30 days of 1st anniversary.
6. Homeowners must properly maintain heating and cooling systems.
7. Proper allowance shall be made for cost of operation of any utilities included in energy bill in adjusting a claim.
8. Proper allowance for abnormal weather conditions shall be made in adjusting a claim.

Homeowner Name: \_\_\_\_\_
Homeowner Address: \_\_\_\_\_
City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_
Date of Installation: \_\_\_\_\_

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Long Fence & Home, LLLP ("LF&H") is a Maryland limited liability limited partnership with its principal office or place of business at 10236 Southard Drive, Beltsville, Maryland 20705.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

## Decision and Order

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Clearly and prominently” means
1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
  2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen, and its location, for an ordinary consumer to notice, read and comprehend it; and
  3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language

## Decision and Order

and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.

- B. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.
- E. “Covered product or service” means any fenestration product, any component thereof, and any product or any service for which respondent makes any claim about energy savings, energy costs, energy consumption, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy.
- F. “Fenestration product” means any window, sliding glass door, or skylight.
- G. “K-value” is a measure of a material’s thermal conductivity.
- H. Unless otherwise specified, “respondent” shall mean Long Fence & Home, LLLP, its successors and assigns, and its officers, agents, representatives, and employees.

## Decision and Order

- I. “R-value” is a measure of a material’s resistance to heat flow.
- J. “SHGC” means solar heat gain coefficient, which is the fraction of incident solar radiation admitted through a window, both directly transmitted and absorbed and subsequently released inward.
- K. “U-factor” is a measure of the rate of heat loss.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names that:

- A. Consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or
- B. Respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Provided, however,* that if respondent represents that consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, or if respondent guarantees or pledges up to or a

## Decision and Order

specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, it must disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge and it must substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region).

**II.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names:

- A. That any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or
- B. About energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy of any covered product or service;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that such representation is true.

**III.**

**IT IS FURTHER ORDERED** that respondent LF&H, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order,

## Decision and Order

maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**IV.**

**IT IS FURTHER ORDERED** that respondent LF&H, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to such current personnel within thirty (30) days after the date of service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

**V.**

**IT IS FURTHER ORDERED** that respondent LF&H, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the partnership that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor; the creation or

## Decision and Order

dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the partnership name or address. *Provided, however*, that, with respect to any proposed change in the partnership about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: “Long Fence & Home, File No. 112 3005, Docket No. C-4352.”

**VI.**

**IT IS FURTHER ORDERED** that respondent LF&H, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

**VII.**

This order will terminate on April 5, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order’s application to any respondent that is not named as a defendant in such complaint; and

## Analysis to Aid Public Comment

- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further,* that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Long Fence & Home, LLLP, a partnership (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves respondent’s marketing and sale of replacement windows for use in residences. According to the FTC complaint, respondent represented that consumers who replace their windows with Long Windows’ Quantum2 replacement windows with SuperPak Glass are likely to achieve residential energy savings of 50% or save 50% on residential

## Analysis to Aid Public Comment

heating and cooling costs. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating these representations when it made them. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with LongWindows replacement windows are not likely to achieve a 50% reduction in residential energy consumption or heating and cooling costs. Thus, the complaint alleges that respondent engaged in unfair or deceptive practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains two provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I addresses the marketing of windows. It prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction. Further, if respondent represents, guarantees, or pledges that consumers achieve such energy savings or heating and cooling cost reductions under specified circumstances, it must: disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge; and substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region). The performance standard imposed under this Part constitutes fencing-in relief

## Analysis to Aid Public Comment

reasonably necessary to ensure that any future energy savings or reduction claims are not deceptive.

Part I of the order requires substantiation for representations including the words “up to” because the respondent may elect to make such representations in the future. The words “up to” do not effectively qualify representations regarding the energy savings or cost reductions likely to be achieved through replacement windows. Therefore, Part I requires the same level of substantiation regardless of whether the covered representation includes the words “up to.” The FTC’s proposed consent order should not be interpreted as a general statement of how the Commission may interpret or take other action concerning representations including the words “up to” for other products or services in the future.

Part II addresses any product or service for which respondent makes any energy-related efficacy representation. It prohibits respondent from making any representation: (A) that any specific number or percentage of consumers who replace their windows with respondent’s windows achieve energy savings or reduction in heating and cooling costs; or (B) about energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, solar heat gain coefficient, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy; unless the representation is non-misleading and substantiated by competent and reliable scientific evidence.

Parts III through VI require respondent to: keep copies of advertisements and materials relied upon in disseminating any representation covered by the order; provide copies of the order to certain personnel, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in its structure that might affect compliance obligations under the order; and file a compliance report with the Commission and respond to other requests from FTC staff. Part VII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official

*Analysis to Aid Public Comment*

interpretation of the complaint or the proposed order, or to modify the proposed order's terms in any way.

## Complaint

## IN THE MATTER OF

**CARPENTER TECHNOLOGY CORPORATION  
AND  
LATROBE SPECIALTY METALS, INC.****CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT**

*Docket No. C-4349; File No. 111 0207  
Complaint, February 28, 2012 – Decision, April 12, 2012*

This consent order addresses the \$410 million acquisition by Carpenter Technology Corporation of certain assets of Latrobe Specialty Metals, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act in the markets for each of the specialty alloys: (1) MP159 and (2) MP35N used in aerospace applications. The consent order requires Carpenter to divest assets related to the manufacture and sale of the MP Alloys to Eramet S.A.

*Participants*

For the *Commission: Marc Alvarez, Monica Castillo, Janet Kim, David Morris, Scott Reiter, Kristian Rogers, Danielle Sims, and David Von Nirschl.*

For the *Respondents: Barbara Sicalides, Pepper Hamilton LLPTom D. Smith, Jones Day.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Carpenter Technology Corporation (“Carpenter”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire Respondent Latrobe Specialty Metals, Inc. (“Latrobe”), a corporation subject to the jurisdiction of the Commission (collectively, “Respondents”), in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in

## Complaint

respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

**I. RESPONDENTS**

1. Respondent Carpenter is a Delaware corporation, headquartered at 2 Meridian Boulevard, Wyomissing, Pennsylvania 19610-3202.

2. Respondent Latrobe is a Delaware Corporation, headquartered at 2626 Ligonier Street, Latrobe, Pennsylvania 15650. HHEP-Latrobe, L.P., the ultimate parent entity of Latrobe Specialty Metals, Inc., has its headquarters at 100 Crescent Court, Suite 1200, Dallas, Texas 75201.

3. Respondents are corporations who are engaged in, among other activities, the production and sale of specialty alloys, including, but not limited to, multiphase nickel-cobalt alloys MP159, and MP35N used in aerospace applications (“Aerospace MP35N”).

4. Respondents are corporations and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and are corporations whose business is in, or affects commerce, as “commerce” is defined under Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**II. THE PROPOSED ACQUISITION**

5. Pursuant to the June 20, 2011 Agreement and Plan of Merger (“Merger Agreement”), Carpenter announced its intention to purchase all of Latrobe’s approximately 8.1 million voting securities for approximately \$410 million (“Acquisition”).

**III. THE RELEVANT MARKET**

6. For purposes of this Complaint, the relevant lines of commerce in which to analyze the Acquisition are: (1) MP159; and (2) Aerospace MP35N.

7. For purposes of this Complaint, the relevant geographic area in which to analyze the effects of the Acquisition on the

### Complaint

MP159 and Aerospace MP35N markets, respectively, is the United States plus foreign countries approved by the United States Congress to supply materials for military purposes under the Defense Federal Acquisition Regulation System (“DFARS”), as amended, 48 C.F.R. § 225-7012.

8. Foreign countries approved under DFARS are: Australia, Belgium, Canada, Denmark, Egypt, Federal Republic of Germany, France, Greece, Israel, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, and the United Kingdom of Great Britain and Northern Ireland. Under DFARS, companies manufacturing products in Austria and Finland may also supply materials for military purposes, provided that they receive waivers exempting their sale of materials from the Buy American Act and Balance of Payments programs.

### IV. MARKET STRUCTURE

9. The market for MP159 is highly concentrated, as measured by the Herfindahl-Hirschman Index (“HHI”). The Acquisition would consolidate the only MP159 manufacturers. Post-Acquisition, Respondents will have 100 percent market share. The post-Acquisition HHI will be 10,000, with a 4,668 HHI increase. This market concentration level far exceeds the *Horizontal Merger Guidelines* thresholds, and thus, supports the presumption that the Acquisition will create or enhance market power.

10. The market for Aerospace MP35N is highly concentrated, as measured by the HHI. The Acquisition would consolidate the only Aerospace MP35N manufacturers. Post-Acquisition, Respondents will have 100 percent market share. The post-Acquisition HHI will be 10,000, with a 4,928 HHI increase. This market concentration level far exceeds the *Horizontal Merger Guidelines* thresholds, and thus, supports the presumption that the Acquisition will create or enhance market power.

### V. ENTRY CONDITIONS

11. Entry into the market for MP159 or Aerospace MP35N, respectively, would not be timely, likely, or sufficient to deter the likely anticompetitive effects of the Acquisition. The time and

## Complaint

costs required to obtain the physical assets and expertise necessary for the manufacture of MP159 and Aerospace MP35N are substantial. Before supplying the alloys to customers, MP159 and Aerospace MP35N manufacturers must also invest significant amounts of time and money to receive customer and end-user qualifications. Finally, these two markets are small, which further deters firms from making the investments required to compete effectively in these markets.

**VI. EFFECTS OF THE ACQUISITION**

12. The effects of the Acquisition, if consummated, may be to substantially lessen competition, and to tend to create a monopoly, in the markets for MP159 and Aerospace MP35N, respectively, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. by eliminating actual, direct, and substantial competition between Respondents Carpenter and Latrobe; and
- b. by increasing the likelihood that Respondent Carpenter would unilaterally exercise market power in the MP159 and Aerospace MP35N markets.

**VII. VIOLATIONS CHARGED**

13. The allegations contained in Paragraphs 1 through 12 above are hereby incorporated by reference as though fully set forth here.

14. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

15. The Acquisition described in Paragraph 5, if consummated, would constitute a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

## Order to Maintain Assets

16. The Merger Agreement described in Paragraph 5 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this twenty-eighth day of February, 2012, issues its complaint against said Respondents.

By the Commission.

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Carpenter Technology Corporation (“Carpenter”) of 100 percent of the outstanding voting securities of Respondent Latrobe Specialty Metals, Inc. (“Latrobe”) from HHEP-Latrobe, L.P., and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

## Order to Maintain Assets

The Commission having thereafter considered the matter and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Carpenter Technology Corporation is a corporation organized, existing and doing business under and by virtue of the laws of State of Delaware, with its headquarters address located at 101 West Bern Street, Reading, Pennsylvania 19601.
2. Respondent Latrobe Specialty Metals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 2626 Ligonier Street, Latrobe, Pennsylvania 15650. HHEP-Latrobe, L.P., the ultimate parent entity of Latrobe Specialty Metals, Inc., has its headquarters address at 100 Crescent Court, Suite 1200, Dallas, Texas 75201. "Latrobe" also includes HHEP-Latrobe, L.P., the ultimate parent entity of Latrobe Specialty Metals, Inc.
3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final and effective, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

## Order to Maintain Assets

- A. “Carpenter” means Carpenter Technology Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Carpenter (including, but not limited to, Hawke Acquisition Corp.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Carpenter shall include Latrobe.
- B. “Latrobe” means Latrobe Specialty Metals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Latrobe, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” mean Carpenter and Latrobe, individually and collectively.
- D. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final Decision and Order by the Commission; and
  2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission.
- E. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- F. “Orders” means the Decision and Order and this Order to Maintain Assets.
- G. “Commission” means the Federal Trade Commission.

## Order to Maintain Assets

- H. “Specialty Metals Product Business(es)” means Respondent Latrobe’s business throughout the United States of America related to all of the Specialty Metals Products, including the research, Development, manufacture, distribution, marketing, and sale of each Specialty Metals Product and the assets related to such business, including, but not limited to, the Specialty Metals Product Assets.
- I. “Pre-Acquisition Marketing Plan” means any marketing or sales plan that was planned or implemented within the period immediately prior to the Acquisition and without consideration of the influence of the pending Acquisition for the Specialty Metals Product Business.

**II.**

**IT IS FURTHER ORDERED** that from the date this Order to Maintain Assets becomes final and effective:

- A. Until Respondents fully deliver the Specialty Metals Product Assets to the Acquirer, Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Specialty Metals Product Business, to minimize any risk of loss of competitive potential for the Specialty Metals Product Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Specialty Metals Product Business except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the Specialty Metals Product Assets (other than in the manner prescribed in the Decision and Order) nor take any action that lessens the full economic viability, marketability or competitiveness of the Specialty Metals Product Business.
- B. Prior to the Acquisition Date and as a condition precedent to the consummation of the Acquisition, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit

## Order to Maintain Assets

Respondents to divest the Specialty Metals Product Assets required to be divested pursuant to the Decision and Order to the Acquirer, and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Specialty Metals Products;

*provided, however,* Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- C. Until Respondents fully deliver the Specialty Metals Product Assets to the Acquirer, Respondents shall maintain the operations of the Specialty Metals Product Business in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the assets of such Business) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Specialty Metals Product Business and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors and distributors, including, but not limited to, the High Volume Accounts; customers; Agencies; employees; and others having business relations with the Specialty Metals Product Business. Respondents' responsibilities shall include, but are not limited to, the following:
1. Respondents shall provide the Specialty Metals Product Business with sufficient working capital to operate at least at current rates of operation, to meet all capital calls with respect to such Business and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Specialty Metals Product Business;
  2. Respondents shall continue, at least at their scheduled pace, any additional expenditures for the Specialty Metals Product Business authorized prior

## Order to Maintain Assets

to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, Development, manufacture, distribution, marketing and sales expenditures;

3. Respondents shall provide such resources as may be necessary to respond to competition against the Specialty Metals Products and/or to prevent any diminution in sales of the Specialty Metals Products during and after the Acquisition process and prior to divestiture of the related Specialty Metals Product Assets;
  4. Respondents shall provide such resources as may be necessary to maintain the competitive strength and positioning of the Specialty Metals Products at the High Volume Accounts;
  5. Respondents shall make available for use by the Specialty Metals Product Business funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the assets related to such business, including the Specialty Metals Product Assets;
  6. Respondents shall provide the Specialty Metals Product Business with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Specialty Metals Product Business; and
  7. Respondents shall provide such support services to the Specialty Metals Product Business as were being provided to these Business by Respondents as of the date the Consent Agreement was signed by Respondents.
- D. Until Respondents fully deliver the Specialty Metals Product Assets to the Acquirer, Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated

## Order to Maintain Assets

with the Specialty Metals Products for the relevant Specialty Metals Product's most recent Pre-Acquisition Marketing Plan.

- E. Respondents shall, during the Specialty Metals Product Employee Access Period, not interfere with the hiring or employing by the Acquirer of Specialty Metals Product Core Employees, and shall remove any impediments within the control of Respondents that may deter these employees from accepting employment with such Acquirer, including, but not limited to, any non-compete or non-disclosure provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by such Acquirer. In addition, Respondents shall not make any counteroffer to a Specialty Metals Product Core Employee who receives a written offer of employment from the Acquirer;

*provided, however,* subject to the conditions of continued employment prescribed in this Order, this Paragraph II.E. shall not prohibit Respondents from continuing to employ any Specialty Metals Product Core Employee under the terms of such employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer to such employee.

- F. Respondents shall adhere to and abide by the Remedial Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of the Orders, it being understood that nothing in the Orders shall be construed to reduce any obligations of Respondents under such agreement(s)), which are incorporated by reference into this Order to Maintain Assets and made a part hereof.
- G. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Specialty Metals Product Business through its full and complete delivery to the

## Order to Maintain Assets

Acquirer, to minimize any risk of loss of competitive potential for the Specialty Metals Product Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Specialty Metals Product Assets except for ordinary wear and tear.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint an Interim Monitor to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by the Orders and the Remedial Agreements. The Commission may appoint one or more Interim Monitors to assure Respondents' compliance with the requirements of the Orders, and the related Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Carpenter, which consent shall not be unreasonably withheld. If Respondent Carpenter has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Carpenter of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Orders in a manner consistent with the purposes of the Orders.

## Order to Maintain Assets

- D. If one or more Interim Monitors are appointed pursuant to this Paragraph or pursuant to the relevant provisions of the Decision and Order in this matter, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of each Interim Monitor:
1. The Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Orders, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Orders and in consultation with the Commission;
  2. The Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission; and
  3. The Interim Monitor shall serve until, the latter of:
    - a. the date of completion by Respondents of the divestiture of all Specialty Metal Product Assets and the delivery of the Manufacturing Technology and Product Intellectual Property in a manner that fully satisfies the requirements of this Order; and
    - b. with respect to each Specialty Metal Product, the date the Acquirer has obtained or achieved all Product Approvals and Specifications necessary to manufacture, market, import, export, and sell such Specialty Metal Product for use for aerospace applications and is able to manufacture such Specialty Metal Product in commercial quantities independently of Respondents;
- provided, however,* that the Interim Monitor's service shall not exceed five (5) years from the date the Decision and Order is issued;

## Order to Maintain Assets

*provided further*, that the Commission may shorten or extend this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Orders, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Orders.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondents on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of the Respondents, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

## Order to Maintain Assets

- H. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order to Maintain Assets and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Orders or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Orders; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph VI.B. of the Decision and Order, and every ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward:
1. obtaining all of the relevant Product Approvals and Specifications necessary to manufacture in commercial quantities, the Specialty Metals Products independently of Respondents and;
  2. to secure sources of supply of the raw materials, inputs and components for the Specialty Metals Products from entities other than Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement;
- provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate

## Order to Maintain Assets

confidentiality agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.

- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph or the relevant provisions of the Decision and Order in this matter.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Orders.
- M. The Interim Monitor appointed pursuant to this Order to Maintain Assets or the relevant provisions of the Decision and Order in this matter may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of the Decision and Order.

**IV.**

**IT IS FURTHER ORDERED** that within thirty (30) days after the date this Order to Maintain Assets is issued, and every thirty (30) days thereafter until Respondents have fully complied with their obligations under Paragraphs II.A., II.B., II.C. II.D., II.E., II.F. and II.H. of the Decision and Order, Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order to Maintain Assets and the Decision and Order; *provided, however*, that, after the Decision and Order becomes final and effective, the reports due under this Order to Maintain Assets shall be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondents pursuant to Paragraph V of the Decision and Order.

## Order to Maintain Assets

**V.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of any Respondent;
- B. any proposed acquisition, merger or consolidation of any Respondent; or
- C. any other change in any Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order to Maintain Assets.

**VI.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order to Maintain Assets, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

## Decision and Order

**VII.**

**IT IS FURTHER ORDERED** that this Order to Maintain Assets shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The latter of:
  - 1. the day after the divestiture of all of the Specialty Metals Product Assets, as required by and described in the Decision and Order, has been completed and each Interim Monitor, in consultation with Commission staff and the Acquirer, notifies the Commission that all assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions related to such divestitures are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated; or
  - 2. the day after the day the Decision and Order becomes final and effective.

By the Commission.

**DECISION AND ORDER**  
**[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Carpenter Technology Corporation (“Carpenter”) of 100 percent of the outstanding voting securities of Respondent Latrobe Specialty Metals, Inc. (“Latrobe”) from HHEP-Latrobe,

## Decision and Order

L.P., and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and that, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order ("Order"):

1. Respondent Carpenter Technology Corporation is a corporation organized, existing and doing business under and by virtue of the laws of State of Delaware, with its headquarters address located at 101 West Bern Street, Reading, Pennsylvania 19601.
2. Respondent Latrobe Specialty Metals, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 2626

## Decision and Order

Ligonier Street, Latrobe, Pennsylvania 15650. HHEP-Latrobe, L.P., the ultimate parent entity of Latrobe Specialty Metals, Inc., has its headquarters address at 100 Crescent Court, Suite 1200, Dallas, Texas 75201.

3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. “Carpenter” means Carpenter Technology Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Carpenter (including, but not limited to, Hawke Acquisition Corp.) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Carpenter shall include Latrobe.
- B. “Latrobe” means Latrobe Specialty Metals, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Latrobe, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. “Latrobe” also includes HHEP-Latrobe, L.P., the ultimate parent entity of Latrobe Specialty Metals, Inc.
- C. “Respondents” mean Carpenter and Latrobe, individually and collectively.
- D. “Commission” means the Federal Trade Commission.

## Decision and Order

- E. “Acquirer” means the following:
1. a Person specified by name in this Order to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order and that has been approved by the Commission to accomplish the requirements of this Order in connection with the Commission’s determination to make this Order final and effective; or
  2. a Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- F. “Acquisition” means Respondent Carpenter’s acquisition of fifty percent (50%) or more of the voting securities of Respondent Latrobe. The Acquisition is contemplated by the Agreement and Plan of Merger, as amended, by and among Latrobe Specialty Metals, Inc., Carpenter Technology Corporation, Hawke Acquisition Corp., HHEP-Latrobe, L.P., and Watermill-Toolrock Partners, L.P. dated as of June 20, 2011, submitted to the Commission, pursuant to which Carpenter plans to acquire 100% of the outstanding voting securities of Latrobe from HHEP-Latrobe, L.P., with the transaction to be structured as the merger of Hawke Acquisition Corp., a wholly-owned subsidiary of Carpenter, with and into Latrobe, with Latrobe as the surviving entity.
- G. “Acquisition Date” means the day on which the Acquisition occurs.
- H. “Agency(ies)” means any government regulatory authority or authorities in the world responsible for granting approval(s), specifications(s), clearance(s), qualification(s), license(s), or permit(s) for any aspect of the research, Development, manufacture, marketing,

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distribution, or sale of a Specialty Metals Product. The term “Agency” includes, with out limitation, the United States Department of Defense.

- I. “Closing Date” means the date on which Respondent(s) (or a Divestiture Trustee) consummates a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Specialty Metal Product Assets and grants the Specialty Metal Product License to an Acquirer pursuant to this Order.
- J. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent Latrobe that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, importation, exportation, cost, supply, sales, sales support, or use of the Specialty Metal Product(s). The term “Confidential Business Information” *excludes* (i) information that is protected by the attorney work product, attorney-client, joint defense or other privilege prepared in connection with the Acquisition and relating to any United States, state, or foreign antitrust or competition Laws and (ii) information relating to Respondent Latrobe’s general business strategies or practices relating to research, Development, manufacture, marketing or sales of products that does not discuss with particularity the Specialty Metal Product(s).
- K. “Contract Manufacture” means:
  - 1. to manufacture, or to cause to be manufactured, a Contract Manufacture Product on behalf of an Acquirer; and/or
  - 2. to provide, or to cause to be provided, any part of the manufacturing process of a Contract Manufacture Product on behalf of an Acquirer.
- L. “Contract Manufacture Product(s)” means all raw materials, inputs, and components of a Specialty Metal

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Product, and/or any finished goods that are provided for resale as Specialty Metal Products.

- M. “Copyrights” means rights to all original works of authorship of any kind directly related to the Specialty Metal Product(s) and any registrations and applications for registrations thereof, including, but not limited to, the following: all such rights with respect to all promotional, marketing and advertising materials, educational and training materials for the sales force, and sales forecasting models; copyrights in all process development data and reports relating to the research and Development of the Specialty Metal Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Specialty Metal Product(s), including copyrights in all raw data, statistical programs developed (or modified in a manner material to the use or function thereof (other than through user preferences)) to analyze research data, market research data, market intelligence reports and statistical programs (if any) used for marketing and sales research; all copyrights in customer information; all records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all copyrights in records, including customer lists, sales force call activity reports, vendor lists, sales data, manufacturing records, manufacturing processes, and supplier lists; all copyrights in data contained in laboratory notebooks relating to the Specialty Metal Product(s); all copyrights in analytical and quality control data; and all correspondence with Agencies.
- N. “Current Operating Condition” means that, as of the date of delivery to the Acquirer, the equipment meets or exceeds all current operational, functional, productive and manufacturing capabilities required to manufacture the Specialty Metals Product and meets or exceeds all current U.S. Agency-approved

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protective workplace safety standards for the operation of such equipment by workers.

- O. “Development” means all research and development activities, including, without limitation, the following: test method development; formulation, including without limitation, customized formulation for a particular customer(s); mechanical properties testing; performance testing; safety testing; composition measurements; process development; manufacturing scale-up; development-stage manufacturing; quality assurance/quality control development; statistical analysis and report writing; and conducting experiments and other activities for the purpose of obtaining or achieving any and all Product Approvals and Specifications. “Develop” means to engage in Development.
- P. “Direct Cost” means a cost not to exceed the cost of labor, material, travel and other expenditures to the extent the costs are directly incurred to provide the relevant assistance or service. “Direct Cost” to the Acquirer for its use of any of Respondents’ employees’ labor shall not exceed the average hourly wage rate for such employee; *provided, however*, in each instance where: (1) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Specialty Metal Product, “Direct Cost” means such cost as is provided in such Remedial Agreement for that Specialty Metal Product.
- Q. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- R. “Employee Information” means the following, for each Specialty Metal Product Core Employee, as and to the extent permitted by the Law:
1. a complete and accurate list containing the name of each relevant employee (including former

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employees who were employed by Respondent Latrobe within ninety (90) days of the execution date of any Remedial Agreement); and

2. with respect to each such employee, the following information:
  - a. the date of hire and effective service date;
  - b. job title or position held;
  - c. a specific description of the employee's responsibilities related to the relevant Specialty Metal Product;
  - d. the base salary or current wages;
  - e. the most recent bonus paid, aggregate annual compensation for Respondents' last fiscal year and current target or guaranteed bonus, if any;
  - f. employment status (*i.e.*, active or on leave or disability; full-time or part-time); and
  - g. any other material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees.
- S. "Eramet" means Eramet, S.A., a corporation organized, existing, and doing business under and by virtue of the laws of the French Republic, with its offices and principal place of business located at 33 avenue du Maine, 75015 Paris France. Eramet is a group of companies that includes Aubert & Duval, Erasteel Company, and Brown Europe.
- T. "Government Entity" means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.

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- U. “High Volume Account(s)” means any customer of Respondent Latrobe whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Specialty Metal Product from Respondent Latrobe was, is, or is projected to be, among the top ten highest of such purchase amounts by Respondent Latrobe’s customers on each of the following dates: (1) the end of the last quarter that immediately preceded the date of the public announcement of the proposed Acquisition, *i.e.*, June 20, 2011; (2) the end of the last year that immediately preceded the Acquisition Date; (3) the end of the last quarter that immediately preceded the Closing Date for the Specialty Metal Product Assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.
- V. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.
- W. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- X. “Manufacturing Employees” means all salaried or skilled-labor employees of Respondent Latrobe who have directly participated in the planning, design, implementation, use, or operational management of the Manufacturing Technology (irrespective of the portion of working time involved unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the five (5) year period immediately prior to the Closing Date; *provided, however*, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Specialty Metal Products, “Manufacturing Employees” means the specific individuals identified as “Manufacturing Employees” in such Remedial Agreement.

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- Y. “Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information (whether patented, patentable or otherwise) used at any time within the five (5) year period immediately preceding the Closing Date by Respondent Latrobe to manufacture each Specialty Metal Product, including, but not limited to, the following:
1. product specifications, including without limitation, the exact combination and proportion of metals, other agents, reactive diluents and other components that achieves a particular set of application and end-use characteristics (*e.g.*, shear strength, tensile strength, yield strength) in a final Specialty Metals Product;
  2. processes, including without limitation, aging, annealing, bump pressing, cold drawing, cutting, grinding, pickling, quenching, shot blasting, solutionizing, and swaging;
  3. standard operating procedures;
  4. product designs and design protocols;
  5. plans, ideas, and concepts;
  6. repair and performance records related to the Specialty Metal Product Equipment for the two (2) year period immediately preceding the Closing Date;
  7. records related to the protective workplace safety standards related to the Specialty Metal Product Equipment for the two (2) year period immediately preceding the Closing Date;
  8. safety procedures for handling of materials and substances;
  9. flow diagrams;
  10. quality assurance and control procedures;

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11. research records;
12. annual product reviews;
13. manuals and technical information provided to employees, customers, suppliers, agents or licensees including, without limitation, manufacturing, equipment, and engineering manuals and drawings;
14. audits of manufacturing methods for Specialty Metal Products conducted by all of the following:
  - a. applicable United States' Agencies;
  - b. non-governmental Persons that provide audits and certifications of management systems and/or manufacturing processes and product assessments and certifications related to the use of metals or metal alloys for applications in the aerospace industry (*e.g.*, National Aerospace and Defense Contractors Accreditation Program, Performance Review Institute, and American Society for Testing Materials);
  - c. direct purchasers of Specialty Metal Products that use the Specialty Metal Products to manufacture products (*e.g.*, aerospace fasteners) for aerospace applications; and
  - d. end-users of products for aerospace applications that are made from Specialty Metal Products (*e.g.*, manufacturers of United States' military aircraft and components, jet aircraft, jet aircraft landing gear, or jet engines);
15. control history;
16. labeling;
17. supplier lists;

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18. chemical descriptions and specifications of, all raw materials inputs, components, and ingredients related to the Specialty Metal Products; and
  19. all other information related to the manufacturing process.
- Z. “Marketing and Business Development Employees” means all management-level employees of Respondent Latrobe who directly have participated (irrespective of the portion of working time involved) in the marketing, contracting, pricing or promotion of the Specialty Metal Products to customers within the two (2) year period immediately prior to the Closing Date. These employees include, without limitation, all management-level employees having any responsibilities in the areas of sales management, brand management, sales training, market research, business development, and specialty metal alloy markets for use in Aerospace applications, but *excludes* administrative assistants; *provided, however*, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Specialty Metal Products, “Marketing and Business Development Employees” means the specific individuals identified as “Marketing and Business Development Employees” in such Remedial Agreement.
- AA. “Marketing Materials” means all marketing materials used specifically in the marketing or sale of a Specialty Metal Product(s) prior to and as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, sales call reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchases information to be provided on the basis of either

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dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, Website content and advertising and display materials, video masters and other similar materials related to the Specialty Metal Product(s). The term “Marketing Materials” *excludes* documents relating to the Respondents’ general business strategies or practices relating to the marketing or sales of specialty metal alloys, where such documents do not discuss with particularity the Specialty Metal Products.

- BB. “MP35N Product(s)” means an alloy with a nominal chemical composition of 35 percent Nickel, 35 percent Cobalt, 20 percent Chromium, and 10 percent Molybdenum and that meets the following Aerospace Materials Specifications: AMS 5758 (solution heat treated and centerless ground bars); AMS 5844 (solution heat treated and cold drawn bars); AMS 5845 (solution heat treated, cold drawn and aged bars); and/or, AMS 7468 (bolts, screws, forged head, roll threaded after aging).
- CC. “MP 159 Product(s)” means an alloy with a nominal chemical composition of 25.5 percent Nickel, 35.7 percent Cobalt, 19.0 percent Chromium, 9.0 percent Iron, 7.0 percent Molybdenum, 3.0 percent Titanium, 0.6 percent Columbium (Niobium), and 0.2 percent Aluminum and that meets the following Aerospace Materials Specifications: AMS 5841, AMS 5842; and/or AMS 5843.
- DD. “Order Date” means the date on which this Decision and Order becomes final and effective.
- EE. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- FF. “Patents” means all patents, patent applications, including provisional patent applications, invention

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disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date (*except* where this Order specifies a different time), and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any product of or owned by Respondents as of the Closing Date (*except* where this Order specifies a different time).

- GG. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- HH. “Product Approval(s) and Specification(s)” means the approvals, specifications, certifications, registrations, permits, licenses, consents, authorizations, and other approvals, and pending applications and requests therefor, related to the research, Development, manufacture, distribution, finishing, packaging, marketing, sale, storage or transport of the Specialty Metals Products that have been adopted or required as of the Closing Date by the following:
1. applicable Agencies;
  2. non-governmental Persons that provide audits and certifications of management systems and/or manufacturing processes and product assessments and certifications related to the use of metals or metal alloys for applications in the aerospace industry (*e.g.*, National Aerospace and Defense Contractors Accreditation Program, Performance Review Institute, and American Society for Testing Materials);

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3. direct purchasers of Specialty Metal Products that use the Specialty Metal Products to manufacture products (*e.g.*, aerospace fasteners) for aerospace applications; and
  4. end-users of products for aerospace applications that are made from Specialty Metal Products (*e.g.*, manufacturers of United States military aircraft and components, jet aircraft, jet aircraft landing gear, or jet engines).
- II. “Product Assumed Contracts” means all of the following contracts or agreements (copies of each such contract to be provided to the Acquirer on or before the Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):
1. that make specific reference to any Specialty Metal Product and pursuant to which any Third Party purchases, or has the option to purchase, any Specialty Metal Product from Respondent Latrobe;
  2. relating to any experiments, audits, or scientific studies involving any Specialty Metal Product;
  3. with universities or other research institutions for the use of any Specialty Metal Product in scientific research;
  4. relating to the particularized marketing of any Specialty Metal Product or educational matters relating solely to any Specialty Metal Product;
  5. pursuant to which a Third Party provides the Manufacturing Technology related to any Specialty Metal Product to Respondent Latrobe;
  6. pursuant to which a Third Party is licensed by Respondent Latrobe to use the Manufacturing Technology;

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7. constituting confidentiality agreements involving any Specialty Metal Product;
8. involving any royalty, licensing, or similar arrangement involving any Specialty Metal Product;
9. pursuant to which a Third Party provides any specialized services necessary to the research, Development, manufacture or distribution of the Specialty Metal Products to Respondent Latrobe including, but not limited to, consultation arrangements;
10. pursuant to which any Third Party collaborates with Respondent Latrobe in the performance of research, Development, marketing, distribution or selling of any Specialty Metal Product or the business associated with the Specialty Metal Products; and/or

*provided, however,* that where any such contract or agreement also relates to a Retained Product(s), Respondent Latrobe shall assign the Acquirer all such rights under the contract or agreement as are related to the Specialty Metal Product(s), but concurrently may retain similar rights for the purposes of the Retained Product(s).

- JJ. “Product Intellectual Property” means all of the following related to each Specialty Metal Product:
1. Patents;
  2. Copyrights;
  3. Software;
  4. trade secrets, know-how, utility models, design rights, techniques, data, inventions, practices, recipes, raw material specifications, process descriptions, quality control methods in process

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and in final Specialty Metal Products, protocols, methods and other confidential or proprietary technical, business, research, Development and other information, and all rights in any jurisdiction to limit the use or disclosure thereof;

5. rights to obtain and file for patents and copyrights and registrations thereof; and
6. rights to sue and recover damages or obtain injunctive relief for infringement, dilution, misappropriation, violation or breach of any of the foregoing;

*provided, however,* Product Intellectual Property expressly includes all customer specific product formulations for Specialty Metal Products that are owned, licensed, or in the possession of, Respondent Latrobe, licenses from customers related to the manufacture of products for that specific customer, and all proprietary and/or trade secret information related to a particular customer that are owned, licensed, or in the possession of, Respondent Latrobe;

*provided further, however,* “Product Intellectual Property” *excludes* Product Trademarks.

- KK. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefor (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Specialty Metal Product(s);

*provided, however,* “Product Trademark(s)” does not include the corporate names or corporate trade dress of “Carpenter” or “Latrobe” or the related corporate logos thereof, or the corporate names or corporate trade dress of any other corporations or companies owned or controlled by the Respondents or the related

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corporate logos thereof, or general registered images or symbols by which either Carpenter or Latrobe can be identified or defined.

- LL. “Proposed Acquirer” means an entity proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission to become the Acquirer of particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondents pursuant to this Order.
- MM. “Remedial Agreement(s)” means the following:
1. any agreement between Respondents and an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
  2. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents related to a Specialty Metal Product to the benefit of an Acquirer that is specifically referenced and attached to this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, that has been approved by the Commission to accomplish the requirements of the Order in connection with the Commission’s determination to make this Order final and effective;
  3. any agreement between Respondents and an Acquirer (or between a Divestiture Trustee and an Acquirer) that has been approved by the Commission to accomplish the requirements of this

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Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets or rights to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed, and that has been approved by the Commission to accomplish the requirements of this Order; and/or

4. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents related to a Specialty Metal Product to the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.

NN. “Research and Development Employees” means all salaried or skilled-labor employees of Respondent Latrobe who directly have participated in the research, Development, or process to obtain or achieve Product Approvals and Specifications for the Specialty Metal Products (irrespective of the portion of working time involved, unless such participation consisted solely of oversight of legal, accounting, tax or financial compliance) within the five (5) year period immediately prior to the Closing Date; *provided, however*, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Specialty Metal Products, “Research and Development Employees” means the specific individuals identified as “Research and Development Employees” in such Remedial Agreement.

OO. “Research and Development Records” means all research and development records relating to Specialty Metal Products including, but not limited to:

1. inventory of research and development records, research history, research efforts, research

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notebooks, research reports, technical service reports, testing methods, invention disclosures, and know how related to the Specialty Metal Products;

2. all correspondence, submissions, notifications, communications, registrations or other filings made to, received from or otherwise conducted with (i) Agencies and (ii) non-governmental Persons that provide audits and certifications of management systems and/or manufacturing processes and product assessments and certifications (e.g., National Aerospace and Defense Contractors Accreditation Program, Performance Review Institute, and American Society for Testing Materials) relating to Product Approval(s) and Specification(s) submitted by, on behalf of, or acquired by, Respondent Latrobe related to the Specialty Metal Products;
3. designs of experiments, and the results of successful and unsuccessful designs and experiments;
4. annual and periodic reports (both internal and external) related to the above-described Product Approval(s) and Specification(s);
5. currently used product usage instructions related to the Specialty Metal Products;
6. reports relating to the protection of human safety and health related to the manufacture or use of the Specialty Metal Products;
7. reports relating to the protection of the environment related to the manufacture or use of the Specialty Metal Products;
8. summary of performance reports, safety reports, and product complaints from customers related to the Specialty Metal Products; and

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9. product recall reports filed with any Agency related to the Specialty Metal Products.
- PP. “Retained Product(s)” means any product(s) that is not a Specialty Metals Product.
- QQ. “Sales Employee(s)” means all employees of Respondent Latrobe who directly have participated (irrespective of the portion of working time involved) in the marketing or promotion of the Specialty Metal Product(s) directly to customers within the three (3) year period immediately prior to the Closing Date. This includes employees trained to perform such sales activity for a Specialty Metal Product within the three (3) year period immediately prior to the Closing Date, *provided, however*, in each instance where: (i) an agreement to divest relevant assets is specifically referenced and attached to this Order, and (ii) such agreement becomes a Remedial Agreement for the Specialty Metal Products, “Sales Employees” means the specific individuals identified as “Sales Employees” in such Remedial Agreement.
- RR. “Software” means computer programs related to the Specialty Metal Product(s), including all software implementations of algorithms, models, and methodologies whether in source code or object code form, databases and compilations, including any and all data and collections of data, all documentation, including user manuals and training materials, related to any of the foregoing and the content and information contained on any Website; *provided, however*, that “Software” does not include software that is readily purchasable or licensable from sources other than the Respondents and which has not been modified in a manner material to the use or function thereof (other than through user preference settings).
- SS. “Specialty Metal Products” means the MP35N Products and the MP159 Products Developed, in Development, researched, manufactured, marketed or

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sold by Respondent Latrobe for use in aerospace applications at any time prior to the Acquisition.

TT. “Specialty Metal Product Assets” means all of Respondent Latrobe’s rights, title and interest in and to all assets related to Respondent Latrobe’s business within the United States of America related to each of the Specialty Metal Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of each Specialty Metal Product, including, without limitation, the following:

1. copies of all Research and Development Records;
2. at the Acquirer’s option, all Product Assumed Contracts related to the Specialty Metal Product(s) (copies to be provided to the Acquirer on or before the Closing Date);
3. a list of all customers and/or targeted customers for the Specialty Metal Product(s) and the net sales (in either units or dollars) of the Specialty Metal Products to such customers on either an annual, quarterly, or monthly basis including, but not limited to, a separate list specifying the above-described information for the High Volume Accounts and including the name of the employee(s) for each High Volume Account that is or has been responsible for the purchase of the Specialty Metal Products on behalf of the High Volume Account and his or her business contact information;
4. at the Acquirer’s option and to the extent approved by the Commission in the relevant Remedial Agreement, all inventory in existence as of the Closing Date, including, but not limited to, raw materials, supplies, operating materials, work-in-process, and finished goods, and other items of inventory related to the Specialty Metal Product(s);

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5. copies of all unfilled customer purchase orders for the Specialty Metal Product(s) as of the Closing Date, to be provided to the Acquirer not later than two (2) days after the Closing Date;
6. at the Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for the Specialty Metal Products;
7. the Specialty Metal Product Equipment; and
8. copies of all of the Respondent Latrobe's books and records, customer files, customer lists and records, vendor files, vendor lists and records, cost files and records, credit information, distribution records, business records and plans, studies, surveys, and files related to the foregoing or to the Specialty Metal Product(s);

*provided however*, "Specialty Metal Product Assets" *excludes* (1) documents relating to the Respondent Latrobe's general business strategies or practices relating to research, Development, manufacture, marketing or sales of specialty metal alloys, where such documents do not discuss with particularity the Specialty Metal Products; (2) administrative, financial, and accounting records; (3) quality control records that are determined not to be material to the manufacture of the Specialty Metal Products by the Interim Monitor or the Acquirer of the Specialty Metal Products; and (4) any real estate and the buildings and other permanent structures located on such real estate.

- UU. "Specialty Metal Product Core Employees" means the Manufacturing Employees, Marketing and Business Development Employees, the Research and Development Employees, and the Sales Employees.
- VV. "Specialty Metal Product Divestiture Agreements" means the following agreements:

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1. “Product Line Purchase Agreement” by and between Carpenter Technology Corporation, Latrobe Specialty Metals, and Eramet, S.A., dated as of February 16, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. “Supply Agreement” by and between Carpenter Technology Corporation, Latrobe Specialty Metals, and Eramet, S.A., dated as of February 16, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto; and
3. “Consulting Agreement” by and between Carpenter Technology Corporation, Latrobe Specialty Metals, and Eramet, S.A., dated as of February 16, 2012, and all amendments, exhibits, attachments, agreements, and schedules thereto;

each related to the Specialty Metal Product Assets that have been approved by the Commission to accomplish the requirements of this Order. The Specialty Metal Product Divestiture Agreements are attached to this Order and contained in non-public Appendix A.

- WW. “Specialty Metal Product Equipment” means all equipment listed as “Purchased Assets” in the “Specialty Metal Product Divestiture Agreements” in Non-Public Appendix A, including, without limitation, draw benches, dies and other ancillary finishing equipment.
- XX. “Specialty Metal Product License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all of Respondent Latrobe’s rights, title and interest in, the following:
1. all Product Intellectual Property related to the Specialty Metal Product(s);
  2. all Product Approvals and Specifications related to the Specialty Metal Product(s);

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3. all Manufacturing Technology related to the Specialty Metal Product(s);
4. all Marketing Materials related to the Specialty Metal Product(s); and
5. all Product Development Reports related to the Specialty Metal Product(s);

to the extent legally transferable by license, and, including, without limitation, rights to copies of all of the Respondent Latrobe's books and records related to the foregoing.

- YY. "Specialty Metal Product Releasee(s)" means the Acquirer or any entity controlled by or under common control with the Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of the Acquirer, or of the Acquirer-affiliated entities.
- ZZ. "Supply Cost" means a cost not to exceed the manufacturer's average direct per unit cost in United States dollars of manufacturing the Specialty Metal Product, or raw material or ingredients related to a Specialty Metal Product, for the twelve (12) month period immediately preceding the Acquisition Date. "Supply Cost" shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contract Manufacture is specifically referenced and attached to this Order, and (2) such agreement becomes a Remedial Agreement for a Specialty Metal Product, "Supply Cost" means the cost as specified in such Remedial Agreement for that Specialty Metal Product.
- AAA. "Third Party(ies)" means any non-governmental Person other than the following: the Respondent; or, the Acquirer of particular assets or rights pursuant to this Order.

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**II.****IT IS FURTHER ORDERED** that:

- A. Not later than the earlier of: (i) ten (10) days after the Acquisition Date or (ii) ten (10) days after the Order Date, Respondents shall divest the Specialty Metal Product Assets and grant the Specialty Metal Product License, absolutely and in good faith, to Eramet pursuant to, and in accordance with, the Specialty Metal Product Divestiture Agreements (which agreements shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that this Order shall not be construed to reduce any rights or benefits of Eramet or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Specialty Metal Product Assets, is incorporated by reference into this Order and made a part hereof;

*provided, however,* that if Respondents have divested the Specialty Metal Product Assets and granted the Specialty Metal Product License to Eramet prior to the Order Date, and if, at the time the Commission determines to make this Order final and effective, the Commission notifies Respondents that Eramet is not an acceptable purchaser of the Specialty Metal Product Assets then Respondents shall immediately rescind the transaction with Eramet, in whole or in part, as directed by the Commission, and shall divest the Specialty Metal Product Assets and grant the Specialty Metal Product License, within one hundred eighty (180) days from the Order Date, absolutely and in good faith, at no minimum price, to an Acquirer and only in a manner that receives the prior approval of the Commission;

*provided further,* that if Respondents have divested the Specialty Metal Product Assets and granted the Specialty Metal Product License to Eramet prior to the Order Date, and if, at the time the Commission

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determines to make this Order final and effective, the Commission notifies Respondents that the manner in which the divestiture or grant of license was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Specialty Metal Product Assets or grant of the Specialty Metal Product License to Eramet (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Acquisition Date, and as a condition precedent to the consummation of the Acquisition, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Specialty Metal Product Assets and grant the Specialty Metals Product License to the Acquirer, and/or to permit the Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Specialty Metal Products;

*provided, however,* Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- C. Respondents shall:
1. deliver the Specialty Metals Product Equipment to the Acquirer in Current Operating Condition; *provided however,* that, subject to the consent of the Acquirer on a piece-by-piece basis, Respondents, at Respondents' own expense, may substitute equipment in Current Operating Condition that:
    - a. is suitable for the same use as the particular piece of Specialty Metals Product Equipment

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that is the subject of the proposed substitution;  
and

- b. meets or exceeds the operational, functional, productive and manufacturing capabilities of the particular piece of the Specialty Metals Product Equipment that is the subject of the proposed substitution; and
  2. at the Acquirer's option, provide such technical assistance as is necessary to integrate the Specialty Metals Product Equipment (or any equipment substituted pursuant to Paragraph II.C.1) into the Acquirer's facility for use in the manufacture of Specialty Metals Products.
- D. Respondents shall provide the Manufacturing Technology to the Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondents shall, *inter alia*:
1. designate employees of Respondents knowledgeable with respect to such Manufacturing Technology to a committee for the purposes of communicating directly with the Acquirer and the Interim Monitor (if any has been appointed) for the purposes of effecting such delivery;
  2. prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the Specialty Metal Products, such protocols and acceptance criteria to be subject to the approval of the Acquirer;
  3. prepare and implement a detailed technological transfer plan that contains, *inter alia*, the delivery of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all Manufacturing Technology to the Acquirer; and

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4. upon reasonable written notice and request from the Acquirer to Respondents, provide in a timely manner, at no greater than Direct Cost, assistance and advice to enable the Acquirer to:
    - a. manufacture the Specialty Metal Products in the same quality achieved by Respondent Latrobe and in commercial quantities;
    - b. obtain or achieve any Product Approvals and Specifications necessary for the Acquirer to manufacture, sell, market or distribute the Specialty Metal Products; and
    - c. receive, integrate, and use such Manufacturing Technology.
- E. Respondents shall:
1. Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the Contract Manufacture Products at Respondents' Supply Cost, for a period of time sufficient to allow the Acquirer to:
    - a. obtain or achieve all of the relevant Product Approvals and Specifications necessary to manufacture and sell in commercial quantities, the Contract Manufacture Products independently of Respondents; and
    - b. to secure sources of supply of the raw materials, inputs and components for the Contract Manufacture Products from entities other than Respondents;
  2. make representations and warranties to the Acquirer that the Contract Manufacture Product(s) supplied through Contract Manufacture pursuant to a Remedial Agreement meets the relevant

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Aerospace Material Specifications and the relevant customer specifications for Aerospace use;

3. for the Contract Manufacture Products supplied by Respondents, Respondents shall agree to indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufacture Products supplied by Respondents to the Acquirer to meet all relevant Product Approvals and Specifications. This obligation may be made contingent upon the Acquirer giving Respondents prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement to Contract Manufacture shall be consistent with the obligations assumed by Respondents under this Order; *provided, however*, that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the Contract Manufacture Products in the manner required by this Order; *provided further*, that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the Acquirer that exceed the representations and warranties made by Respondents to the Acquirer;
4. make representations and warranties to the Acquirer that Respondents shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Contract Manufacture Products in a timely manner as required by the Remedial Agreement to Contract Manufacture unless Respondents can demonstrate that their failure was entirely beyond the control of Respondents and in

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no part the result of negligence or willful misconduct by Respondents;

5. during the term of the Remedial Agreement to Contract Manufacture, upon request of the Acquirer or Interim Monitor (if any has been appointed), make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture, storage, or transport of the Contract Manufacture Products that are generated or created after the Closing Date;
6. during the term of the Remedial Agreement to Contract Manufacture, maintain manufacturing facilities necessary to manufacture each of the Contract Manufacture Products; and
7. during the term of the Remedial Agreement to Contract Manufacture, provide consultation with knowledgeable employees of Respondents and training, at the request of the Acquirer and at a facility chosen by the Acquirer, for the purposes of enabling the Acquirer to obtain or achieve all Product Approvals and Specifications to manufacture Specialty Metal Products in the same quality achieved by the Respondent Latrobe and in commercial quantities, and in a manner consistent with the relevant customer specifications for Aerospace use, independently of Respondents, and sufficient to satisfy management of the Acquirer that its personnel are adequately trained in the manufacture of Specialty Metal Products.

The foregoing provisions, II.E.1. - 7., shall remain in effect with respect to each Contract Manufacture Product until the earliest of the following dates: (i) the date eighteen (18) months from the date that the Respondent completes delivery of all pieces of the Specialty Metals Product Equipment to the Acquirer in a manner consistent with this Order; or (ii) the date three (3) years from the Order Date.

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- F. Respondents shall:
1. submit to the Acquirer, at Respondents' expense, copies of all Confidential Business Information;
  2. deliver copies of the Confidential Business Information as follows:
    - a. in good faith;
    - b. in a timely manner, *i.e.*, as soon as practicable, avoiding any delays in transmission of the respective information; and
    - c. in a manner that ensures its completeness and accuracy and that fully preserves its usefulness; and
  3. pending complete delivery of copies of all Confidential Business Information to the Acquirer, provide the Acquirer and the Interim Monitor (if any has been appointed) with access to all such Confidential Business Information and employees who possess or are able to locate such information for the purposes of identifying the books, records, and files directly related to the Specialty Metal Products that contain such Confidential Business Information and facilitating the delivery in a manner consistent with this Order.
- G. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire the Manufacturing Technology, Product Intellectual Property or Product Trademarks, related to the relevant Specialty Metal Product(s) from the Third Party. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to such Manufacturing Technology or Product Intellectual Property.

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- H. Not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in Paragraph II.G. that allows the Third Party to provide the relevant Manufacturing Technology or Product Intellectual Property to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to the Acquirer for the relevant assets.
- I. Respondents shall:
1. for each Specialty Metal Product, for a period of at least eighteen (18) months from the Closing Date, provide the Acquirer with the opportunity to enter into employment contracts with the Specialty Metal Product Core Employees. Each of these periods is hereinafter referred to as the “Specialty Metal Product Core Employee Access Period(s)”;
  2. not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondents to provide the Product Employee Information; or (2) ten (10) days after the Closing Date, provide the Acquirer or the Proposed Acquirer with the Product Employee Information related to the Specialty Metal Product Core Employees. Failure by Respondents to provide the Product Employee Information for any Specialty Metal Product Core Employee within the time provided herein shall extend the Specialty Metal Product Core Employee Access Period(s) with respect to that employee in an amount equal to the delay; and
  3. during the Specialty Metal Product Core Employee Access Period(s), not interfere with the hiring or employing by the Acquirer of the Specialty Metal Product Core Employees related to the particular Specialty Metal Products and assets acquired by the Acquirer, and remove any impediments within the control of Respondents that may deter these

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employees from accepting employment with the Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Specialty Metal Product or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, Respondents shall not make any counteroffer to such a Specialty Metal Product Core Employee who has received a written offer of employment from the Acquirer;

*provided, however,* that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.I.3. shall not prohibit Respondents from continuing to employ any Specialty Metal Product Core Employee under the terms of such employee's employment with Respondents prior to the date of the written offer of employment from the Acquirer to such employee.

- J. Until Respondents complete the divestiture and grant of license required by Paragraph II.A., deliver the Specialty Metals Product Equipment to the Acquirer and provide the Manufacturing Technology to the Acquirer,
1. Respondents shall take such actions as are necessary to:
    - a. maintain the full economic viability and marketability of the businesses associated with each Specialty Metal Product;
    - b. minimize any risk of loss of competitive potential for such business;
    - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to each Specialty Metal Product;

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- d. ensure the Specialty Metal Product Assets are delivered to the Acquirer in a manner without disruption, delay, or impairment of the Product Approval and Specification processes related to the business associated with each Specialty Metal Product;
  - e. ensure the completeness of the delivery of the Manufacturing Technology; and
2. Respondents shall not sell, transfer, encumber or otherwise impair the Specialty Metal Product Assets (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the businesses associated with each Specialty Metal Product.
- K. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer or the Specialty Metal Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Specialty Metal Product(s) under the following:
1. any Patent owned or licensed by Respondents as of the Acquisition Date that claims a method of making, using, or a composition of matter, relating to a Specialty Metal Product;
  2. any Patent owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of a Specialty Metal Product, other than such Patents that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of a particular Specialty Metal Product; or (2) the use

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within, import into, export from, or the supply, distribution, or sale within, the United States of a particular Specialty Metal Product. Respondents shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the above-described Patents, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer or the related Specialty Metal Product Releasee(s) under such Patents, if the suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of a particular Specialty Metal Product; or (2) the use within, import into, export from, or the supply, distribution, or sale within, the United States of a particular Specialty Metal Product.

- L. Upon reasonable written notice and request from an Acquirer to Respondent, Respondent shall provide, in a timely manner, at no greater than Direct Cost, assistance of knowledgeable employees of Respondent to assist that Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Product Intellectual Property related to any of the Specialty Metal Products, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) the research, Development, or manufacture of the Specialty Metal Products; or (2) the use within, import into, export from, or the supply, distribution, or sale within the United States.
- M. Within eighteen (18) months of the Closing Date, Respondents shall either license or assign any and all intellectual property to the Acquirer that constitutes Product Intellectual Property that the Acquirer, with the concurrence of the Interim Monitor, identifies as being necessary to the conduct of the business associated with the Specialty Metal Product (as such business had been conducted by Respondent Latrobe prior to the Acquisition Date) and that was not listed

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and/or included in the intellectual property that was licensed or assigned to the Acquirer pursuant to the Remedial Agreements previously submitted by Respondents to the Commission.

- N. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Specialty Metal Products a decision the result of which would be inconsistent with the terms of this Order and/or the remedial purposes thereof.
- O. No provision of this Order shall be interpreted to restrict the Respondents' use of the Manufacturing Technology, Product Intellectual Property, or Confidential Business Information for the purposes of the research, Development, manufacture, marketing or sales of any of Respondents's own products, including MP 35N Products or MP 159 Products.
- P. The purpose of the divestiture of the Specialty Metal Product Assets, the grant of the Specialty Metals Product License, the provision of the Manufacturing Technology and the related obligations imposed on the Respondents by this Order is:
1. to ensure the continued use of the Specialty Metal Product Assets in the research, Development, manufacture, use, import, export, distribution, and sale of each of the respective Specialty Metal Products;
  2. to provide for the future use of the Specialty Metal Product Assets for the research, Development, manufacture, use, import, export, distribution, and sale of each of the respective Specialty Metal Products;
  3. to create a viable and effective competitor, who is independent of the Respondents in the research, Development, manufacture, use, import, export,

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distribution, or sale of each of the respective Specialty Metal Products; and

4. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondents sign the Consent Agreement in this matter, the Commission may appoint a monitor ("Interim Monitor") to assure that Respondents expeditiously comply with all of their obligations and perform all of their responsibilities as required by this Order, the Order to Maintain Assets, and the Remedial Agreements.
- B. The Commission shall select the Interim Monitor, subject to the consent of Respondent Carpenter, which consent shall not be unreasonably withheld. If Respondent Carpenter has not opposed, in writing, including the reasons for opposing, the selection of a proposed Interim Monitor within ten (10) days after notice by the staff of the Commission to Respondent Carpenter of the identity of any proposed Interim Monitor, Respondents shall be deemed to have consented to the selection of the proposed Interim Monitor.
- C. Not later than ten (10) days after the appointment of the Interim Monitor, Respondents shall execute an agreement that, subject to the prior approval of the Commission, confers on the Interim Monitor all the rights and powers necessary to permit the Interim Monitor to monitor Respondents' compliance with the relevant requirements of the Order in a manner consistent with the purposes of the Order.

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- D. If an Interim Monitor is appointed, Respondents shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:
1. the Interim Monitor shall have the power and authority to monitor Respondents' compliance with the divestiture and asset maintenance obligations and related requirements of the Order, and shall exercise such power and authority and carry out the duties and responsibilities of the Interim Monitor in a manner consistent with the purposes of the Order and in consultation with the Commission;
  2. the Interim Monitor shall act in a fiduciary capacity for the benefit of the Commission; and
  3. the Interim Monitor shall serve until, the latter of:
    - a. the date of completion by Respondents of the divestiture of all Specialty Metal Product Assets and the delivery of the Manufacturing Technology and Product Intellectual Property in a manner that fully satisfies the requirements of this Order; and
    - b. with respect to each Specialty Metal Product, the date the Acquirer has obtained or achieved all Product Approvals and Specifications necessary to manufacture, market, import, export, and sell such Specialty Metal Product for use for aerospace applications and able to manufacture such Specialty Metal Product in commercial quantities independently of Respondents;
- provided, however,* that the Interim Monitor's service shall not exceed five (5) years from the Order Date;

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*provided further*, that the Commission may shorten or extend this period as may be necessary or appropriate to accomplish the purposes of the Orders.

- E. Subject to any demonstrated legally recognized privilege, the Interim Monitor shall have full and complete access to Respondents' personnel, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as the Interim Monitor may reasonably request, related to Respondents' compliance with their obligations under the Order, including, but not limited to, their obligations related to the relevant assets. Respondents shall cooperate with any reasonable request of the Interim Monitor and shall take no action to interfere with or impede the Interim Monitor's ability to monitor Respondents' compliance with the Order.
- F. The Interim Monitor shall serve, without bond or other security, at the expense of Respondent, on such reasonable and customary terms and conditions as the Commission may set. The Interim Monitor shall have authority to employ, at the expense of Respondent, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Interim Monitor's duties and responsibilities.
- G. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Interim Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.

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- H. Respondent shall report to the Interim Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Interim Monitor shall evaluate the reports submitted to the Interim Monitor by Respondent, and any reports submitted by the Acquirer with respect to the performance of Respondent's obligations under the Order or the Remedial Agreement(s). Within thirty (30) days from the date the Interim Monitor receives these reports, the Interim Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order; *provided, however*, beginning ninety (90) days after Respondent has filed its final report pursuant to Paragraph V.B., and every ninety (90) days thereafter, the Interim Monitor shall report in writing to the Commission concerning progress by the Acquirer toward:
1. obtaining or achieved all of the relevant Product Approvals and Specifications necessary to manufacture in commercial quantities, the Specialty Metal Products independently of Respondents; and
  2. securing sources of supply of the raw materials, inputs and components for the Specialty Metal Products from entities other than Respondents.
- I. Respondents may require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, that such agreement shall not restrict the Interim Monitor from providing any information to the Commission.
- J. The Commission may, among other things, require the Interim Monitor and each of the Interim Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission

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materials and information received in connection with the performance of the Interim Monitor's duties.

- K. If the Commission determines that the Interim Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- L. The Commission may on its own initiative, or at the request of the Interim Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- M. The Interim Monitor appointed pursuant to this Order may be the same person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

**IV.****IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Specialty Metal Product Assets as required by this Order, the Commission may appoint a trustee ("Divestiture Trustee") to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief

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available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of the Respondents, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If the Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  - 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust

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agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.

3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.
4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than

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one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further, however*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.

5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondents, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondents, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of Respondents, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondents shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the

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preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Interim Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets in this matter.
  8. The Divestiture Trustee shall report in writing to Respondents and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
  9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.
- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

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**V.****IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition Date, Respondents shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Within thirty (30) days after the date this Order is issued, and every sixty (60) days thereafter until Respondents have fully complied with the following:
  - 1. Paragraphs II.A , II.B., II.C., II.D., II.E., II.F., and II.H.; and
  - 2. all of their responsibilities to render transitional services to the Acquirer as provided by this Order and the Remedial Agreement(s);

Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order. Respondents shall submit at the same time a copy of their report concerning compliance with this Order to the Interim Monitor, if any Interim Monitor has been appointed. Respondents shall include in their reports, among other things that are required from time to time, a full description of the efforts being made to comply with the relevant Paragraphs of the Order, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, including copies of all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- C. One (1) year after the date this Order is issued, annually for the next four (4) years on the anniversary of the date this Order is issued, and at other times as the Commission may require, Respondents shall file a verified written report with the Commission setting forth in detail the manner and form in which it has complied and is complying with the Order.

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**VI.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to:

- A. any proposed dissolution of Respondents;
- B. any proposed acquisition, merger or consolidation of Respondents; or
- C. any other change in Respondents, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**VII.**

**IT IS FURTHER ORDERED** that:

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by Respondents to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order.
- C. Respondents shall include in each Remedial Agreement related to each of the Specialty Metal Products a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondents' obligations to the Acquirer pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to obtain or achieve the Product Approvals and Specifications necessary to manufacture and sell, in commercial quantities, each such Specialty Metal Product and to have any such manufacture and sale to be independent of Respondents, all as soon as reasonably practicable.

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- E. Respondents shall not modify or amend any of the terms of any Remedial Agreement without the prior approval of the Commission.

**VIII.**

**IT IS FURTHER ORDERED** that, for purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. access, during business office hours of such Respondent and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondent related to compliance with this Order, which copying services shall be provided by such Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. to interview officers, directors, or employees of such Respondent, who may have counsel present, regarding such matters.

**IX.**

**IT IS FURTHER ORDERED** that this Order shall terminate on April 12, 2022.

By the Commission, Commissioner Ohlhausen not participating.

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX A**

**SPECIALTY METAL PRODUCT  
DIVESTITURE AGREEMENTS**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

**I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) with Carpenter Technology Corporation (“Carpenter”), Latrobe Specialty Metals, Inc. (“Latrobe”), and HHEP-Latrobe, L.P., which is designed to remedy the anticompetitive effects of Carpenter’s proposed acquisition of Latrobe.

Pursuant to an Agreement and Plan of Merger dated June 20, 2011, Carpenter intends to acquire all of Latrobe’s voting securities for approximately \$410 million. Carpenter and Latrobe compete in the sale of specialty alloys used in the aerospace, energy, and other industries. The proposed acquisition would result in a merger to monopoly in the market for two of these specialty alloys: (1) MP159 and (2) MP35N used in aerospace applications (“Aerospace MP35N,” and collectively, the “MP Alloys”). The Commission’s Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, in the markets for each of the MP Alloys.

The proposed Consent Agreement remedies the alleged violations by replacing the lost competition in the relevant

## Analysis to Aid Public Comment

markets that would result from the acquisition. Under the terms of the Consent Agreement, Carpenter is required to divest assets related to the manufacture and sale of the MP Alloys to Eramet S.A. (“Eramet”). The Consent Agreement requires Carpenter to provide Eramet with all of the relevant equipment, licenses, and technical information necessary for Eramet to replace Latrobe as a competitor in the markets for the MP alloys. In addition, the Consent Agreement requires Carpenter to contract manufacture the MP Alloys for Eramet at cost until Eramet is able to produce and commercially sell these products on its own.

The proposed Consent Agreement has been placed on the public record for thirty days, and comments from interested persons have been requested. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the accompanying Decision and Order.

**II. The Products and Structure of the Markets**

The MP Alloys have unique physical characteristics that make them well suited for use in aerospace applications, and especially in aerospace engine fasteners. Purchasers of the MP Alloys are generally willing to consider overseas suppliers, although to avoid the cost of dual inventories for commercial and military customers, they typically require that suppliers be located in countries approved by Congress to supply materials for military purposes. For these reasons, the relevant markets in which to analyze the competitive effects of the proposed acquisition are the markets for MP159 and Aerospace MP35N manufactured in the United States and in foreign countries approved to supply materials for military purposes under the Defense Federal Acquisition Regulation System (“DFARS”). In these markets, Carpenter and Latrobe are the only options for U.S. consumers, and the proposed transaction would create a monopoly in both relevant markets.

## Analysis to Aid Public Comment

**III. Entry**

Entry or expansion by other specialty alloy manufacturers is not likely to avert the anticompetitive impact of Carpenter's acquisition of Latrobe. The time and cost required to obtain the physical assets, expertise, and qualifications necessary to produce the MP Alloys are substantial, and far outweigh the potential profits from entry into these small markets.

**IV. Effects of the Acquisition**

The proposed acquisition likely would result in significant anticompetitive harm in the highly-concentrated relevant markets for each of the MP Alloys. Carpenter and Latrobe are the only competitors in these highly-concentrated markets. The acquisition will eliminate actual, direct, and substantial competition between Carpenter and Latrobe, and likely result in higher prices for both of the MP Alloys.

**V. The Consent Agreement**

The proposed Consent Agreement remedies the competitive concerns raised by the transaction by requiring the parties to divest assets related to the manufacture of the MP Alloys to Eramet. The terms required by the Consent Agreement will enable Eramet to effectively replace the competition in the MP Alloys markets lost as a result of the proposed acquisition.

Eramet is a global supplier of specialty alloys with an established sales and marketing network in the United States that will allow it to be immediately competitive in the relevant MP Alloys markets. Eramet is based in France, which is an approved foreign source country for U.S. military operations under DFARS. The proposed Consent Agreement requires Carpenter to provide Eramet with product licenses and the manufacturing technology necessary to manufacture the MP Alloys. This includes technical assistance from current Latrobe company designees, and confidential business information directly related to the manufacture of the MP Alloys. In addition, the Consent Agreement requires Carpenter to contract manufacture the MP Alloys for Eramet at cost until Eramet is able to produce and commercially sell these products on its own. The Commission

## Analysis to Aid Public Comment

has appointed James R. Bucci, who has over 35 years of experience in the specialty alloy industry, as the interim monitor to oversee the divestiture.

If after the public comment period the Commission determines that Eramet is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, Carpenter must unwind the divestiture and divest the assets within 180 days of the date the Order becomes final to another Commission-approved acquirer. If Carpenter fails to divest the assets within the 180 days, the Commission may appoint a trustee to divest the relevant assets.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

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## IN THE MATTER OF

**OSF HEALTHCARE SYSTEM  
AND  
ROCKFORD HEALTH SYSTEM****COMPLAINT AND FINAL ORDER IN REGARD TO ALLEGED  
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION  
ACT AND SECTION 7 OF THE CLAYTON ACT***Docket No. 9349; File No. 111 0102**Complaint, November 17, 2011 – Decision, April 13, 2012*

This case addresses the \$218.7 million acquisition by OSF Healthcare System of Rockford Health System. The complaint alleges that the acquisition, if consummated, would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by significantly reducing competition in the markets for general acute-care inpatient hospital services and primary care physician services in Winnebago and Boone counties and the northeast portion of Ogle County, Illinois. The order dismisses the Administrative Complaint without prejudice because Respondents have announced that they are abandoning the proposed affiliation, and have withdrawn the Hart-Scott-Rodino Notification and Report Forms filed for the proposed transaction.

*Participants*

For the *Commission*: *Katherine Ambrogi, Richard Cunningham, Ken Field, Jeremy Morrison, Paul Nolan, Nancy Park, Kaj Rozga, Samuel Sheinberg, and Sarah Swain.*

For the *Respondents*: *Alan Greene, Hinshaw & Culbertson LLP; Jeffrey Brennan and David Marx, McDermott, Will & Emery.*

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by the Act, the Federal Trade Commission (“Commission”), having reason to believe that Respondents OSF Healthcare System (“OSF”) and Rockford Health System (“RHS”), having executed an affiliation agreement (the “Acquisition”) which if consummated would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and it appearing to the Commission that a proceeding by it in

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respect thereof would be in the public interest, hereby issues its complaint pursuant to Section 11(b) of the Clayton Act, 15 U.S.C. § 21(b), stating its charges as follows:

**I.****NATURE OF THE CASE**

1. OSF's acquisition of RHS's assets (the "Acquisition") would substantially lessen competition for critical health care services in the Rockford, Illinois area. By ending decades of competition between OSF and RHS that has benefitted the community, the Acquisition threatens to increase total health care costs and reduce the quality of care and range of health care choices for employers and residents in the Rockford region.

2. The Acquisition, by Respondents' own admission, is a merger to duopoly for general acute-care inpatient hospital services in the Rockford region. The Acquisition will eliminate vigorous competition between OSF and RHS, and leave the Rockford region with only one other competitor for general acute-care inpatient hospital services: SwedishAmerican Health System ("SwedishAmerican").

3. The Acquisition also will eliminate important competition for primary care physician services in the Rockford region by combining two of the three largest physician groups, and will leave SwedishAmerican as the only other large hospital-employed physician group competitor in Rockford.

4. The Acquisition will create a single dominant health system in the Rockford region, with the combined OSF/RHS controlling 64% of the general acute-care inpatient hospital services market and over 37% of the market for primary care physician services. The Acquisition will leave just two firms, OSF and SwedishAmerican, controlling 99.5% of the general acute-care inpatient hospital services market and 58% of the market for primary care physician services.

5. The Acquisition is presumptively unlawful under the relevant case law and the U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines ("Merger

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Guidelines”) because of the extraordinarily high post-acquisition market shares and concentration levels in the market for general acute-care inpatient hospital services in the Rockford region. The likelihood of anticompetitive effects arising from the Acquisition, including increased reimbursement rates stemming from the creation of a dominant health system, is independently supported and confirmed by evidence from sources including health plans, local employers and physicians, third party hospitals, and the merging parties themselves.

6. Rockford region employers and their employees would bear the costs – either directly or through higher health insurance premiums, co-pays, and other out-of-pocket health care expenses – of the rate increases likely to result from the Acquisition. Such health care cost increases force employers to reduce or eliminate health insurance benefits, force families to drop their health insurance altogether, and force some patients to delay or forego medical care that they can no longer afford.

7. The Acquisition also would diminish the quality of care, range of health care choices, patient experience, and access to care for Rockford region residents by ending decades of important non-price competition between OSF and RHS, and by reducing the incentive for OSF and SwedishAmerican to compete aggressively post-acquisition.

8. The price and non-price competition eliminated by the Acquisition would not be replaced by other providers. SwedishAmerican is the only other hospital that meaningfully competes for Rockford region patients, and significant barriers to entry and expansion, including regulatory requirements and substantial up-front costs, prevent new hospitals from entering the market.

9. The fact that the merged entity would still face at least some competition from one meaningful competitor, SwedishAmerican, is not sufficient to render the Acquisition lawful under Section 7. This conclusion is compelled by the antitrust laws – which condemn more than just mergers to monopoly – and also by the market realities in the Rockford region. Specifically, after the Acquisition, the merged system will be a virtual “must-have” for health plans seeking to offer

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insurance to Rockford employers and employees. This fact – and the greater leverage the merged firm will enjoy as a result – stems from the inability of commercial health plans after the Acquisition to offer an attractive provider network without contracting with the combined system.

10. Health plans must offer at least two of the Rockford hospitals to be marketable to local residents. As a result, every major health plan network in the Rockford region includes two, but not all three, of the Rockford hospitals. After the Acquisition, no health plan could continue to offer a multi-hospital network in Rockford without facing the substantially higher rates that will be demanded by the merged OSF and RHS.

11. The Acquisition also increases the incentive and ability for the only remaining competitors in Rockford, SwedishAmerican and OSF, to engage in anticompetitive coordinated behavior. Such coordination could include directly or indirectly sharing sensitive information related to commercial health plan contracts and negotiations, or it could involve deferring competitive initiatives that otherwise would benefit the Rockford community.

12. Unless prevented, the Acquisition will substantially lessen competition and greatly enhance Respondents' market power. The Acquisition's likely anticompetitive effects will directly increase health care costs for Rockford residents, as well as lower the quality of care that they receive. Respondents' speculative efficiency and quality-of-care claims are insufficient to offset the significant anticompetitive harm likely to result from the Acquisition.

**II.****BACKGROUND****A.****Jurisdiction**

13. OSF and RHS are, and at all relevant times have been, engaged in commerce or in activities affecting commerce, within

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the meaning of the Clayton Act. The Acquisition constitutes an acquisition under Section 7 of the Clayton Act.

### B.

#### Respondents

14. Respondent OSF is a not-for-profit health care system incorporated under and by virtue of the laws of Illinois. OSF is headquartered in Peoria, Illinois. OSF owns and operates six acute care hospitals in Illinois, and a seventh hospital in northwestern Michigan. In Rockford, OSF operates St. Anthony Medical Center (“OSF St. Anthony”), which has 254 licensed beds and serves the Rockford region. OSF also owns and operates OSF St. Anthony’s employed physician group, OSF Medical Group (“OSFMG”), which employs approximately physicians in the Rockford region. During fiscal year 2010, OSF generated \_\_\_\_\_ in operating revenue, with OSF St. Anthony generating approximately \_\_\_\_\_ of that total.

15. Respondent RHS is a not-for-profit health care system incorporated under and by virtue of the laws of Illinois. RHS is headquartered in Rockford, Illinois. RHS owns and operates one acute care hospital, Rockford Memorial Hospital (“Rockford Memorial”), which is located in Rockford, Illinois and serves the Rockford region. Rockford Memorial has 396 licensed beds. RHS also owns and operates Rockford Health Physicians (“RHPH”), which employs approximately \_\_\_\_\_ physicians in the Rockford region. During fiscal year 2010, RHS generated \_\_\_\_\_ in operating revenue.

### C.

#### Employers and Health Plans

16. Competition between hospitals occurs in two “stages.” In the first stage, hospitals compete to be selected as in-network providers by health plans. To become an in-network provider, a hospital engages in bilateral negotiations with the health plan. Hospitals benefit from in-network status by gaining access to the health plan’s members as patients. Health plans seek to create provider networks with geographic coverage and a scope of

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services sufficient to attract and satisfy employers and their employees. One of the critical terms that a hospital and a health plan agree upon during a negotiation is the reimbursement rates that the health plan will pay to the hospital when the health plan's members obtain care at the hospital's facilities or from its employed physicians.

17. Fully-insured employers and their employees pay premiums, co-pays, and deductibles in exchange for access to a health plan's provider network and for insurance against the cost of future care. The costs to employers and health plan members are inextricably linked to the reimbursement rates that health plans negotiate with each health care provider in their provider network. Self-insured employers have access to their health plan's network and negotiated reimbursement rates but assume all risk for the costs of care provided to their employees. Self-insured employers must pay the entirety of their employees' health care claims and, as a result, they immediately and fully incur any hospital rate increases. Therefore, regardless of whether an employer is fully-insured or self-insured, its health plan acts as its agent – and by extension acts on behalf of its employees – in creating provider networks that offer convenience, high quality of care, and negotiated reimbursement rates.

18. In the second stage of competition, hospitals and their employed physicians compete with other in-network providers to attract patients. Health plans typically offer multiple in-network hospitals with similar out-of-pocket costs and those hospitals compete in this second stage to attract patients by offering better services, amenities, convenience, quality of care, and patient satisfaction than their competitors offer.

**D.****The Acquisition**

19. Under the terms of the affiliation agreement signed on January 31, 2011, OSF will acquire all operating assets of RHS and become the sole corporate member of RHS. OSF will hold reserve powers over the governance and operations of RHS. OSF's reserve powers will grant it control and ultimate authority over all significant business decisions of RHS, including strategic

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planning, operating and capital budgets, large capital expenditures, and significant borrowing and contracting.

**E.****Prior Holding by District Court of Illinois and Seventh Circuit Court of Appeals that Merger of Two Rockford Hospitals Would Violate the Antitrust Laws**

20. The United States District Court for the Northern District of Illinois, Western Division (“District Court”) found in 1989 that the proposed merger of Rockford Memorial and SwedishAmerican violated Section 7 of the Clayton Act. After holding a full trial on the merits, the District Court issued a permanent injunction to stop the merger and the U.S. Court of Appeals for the Seventh Circuit, in a decision written by Judge Posner, affirmed the District Court’s finding of liability and upheld the permanent injunction.

21. In the 1989 case, the District Court defined a relevant geographic market identical to the market alleged in this Complaint. The District Court also defined a relevant product market – general acute-care hospital inpatient services – identical to a market alleged in this Complaint. In fact, the District Court described a market structure, levels of market concentration, and entry conditions in the earlier case that are strikingly similar to those alleged in this Complaint and, on that basis, concluded that the merger of two Rockford hospitals would “produce a firm controlling an undue percentage share of the relevant market, thus increasing the likelihood of market dominance by the merged entity or collusion.”

22. Following a full hearing on the merits, and on facts very similar to the facts alleged in this case, the District Court issued a permanent injunction blocking the merger of two of the three Rockford hospitals. Given that the only meaningful difference between the 1989 merger and the Acquisition is the re-shuffling of the parties to the transaction, the District Court’s ruling in 1989 informs this Court’s assessment under Section 7 of the Clayton Act of this proposed merger of two of the three Rockford hospitals.

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**III.****THE RELEVANT SERVICE MARKETS****A.****General Acute-Care Inpatient Services Market**

23. The Acquisition threatens substantial harm to competition in the market for general acute-care inpatient hospital services sold to commercial health plans (“general acute-care services”). General acute-care services encompass a broad cluster of medical and surgical diagnostic and treatment services that include an overnight hospital stay, including, but not limited to, many emergency services, internal medicine services, and surgical procedures. It is appropriate to evaluate the Acquisition’s likely effects across this entire cluster of services, rather than analyzing each inpatient service independently, because the group of services is offered to Rockford region residents by the same set of competitors and under similar competitive conditions.

24. The general acute-care services market does not include outpatient services (those not requiring an overnight hospital stay) because such services are offered by a different set of competitors under different competitive conditions. Further, health plans and patients could not substitute outpatient services for inpatient services in response to a price increase. Similarly, the most complex and specialized tertiary and quaternary services, such as certain major surgeries and organ transplants, also are not part of the relevant cluster of services because they generally are not available in the Rockford region, are offered by a different set of suppliers under different competitive circumstances, and are not substitutes for general acute-care services.

25. The District Court defined the same general acute-care services market in its 1989 opinion, which was upheld by the Seventh Circuit.

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**B.****Primary Care Physician Services**

26. The Acquisition also threatens substantial competitive harm in the market for primary care physician services provided to commercially-insured adults. This market encompasses services offered by physicians practicing in internal medicine, family practice, and general practice. This relevant market does not include physician services provided by pediatricians because they typically treat only patients eighteen years old and younger. This relevant market also excludes physician services provided by obstetricians and gynecologists (“OB/GYN”) because those services generally complement, rather than substitute for, general primary care physician services.

**IV.****THE RELEVANT GEOGRAPHIC MARKET**

27. The relevant geographic market in which to analyze the effects of the Acquisition in the general acute-care inpatient hospital services market is no broader than the geographic market defined by the District Court in its 1989 opinion: an area encompassing all of Winnebago County, essentially all of Boone County, the northeast portion of Ogle county, and single zip codes in McHenry, DeKalb, and Stephenson counties (referred to by the District Court as the “Winnebago-Ogle-Boone” market). Today, as was the case in 1989, this relevant geographic market accounts for 87% of the inpatient admissions of the merging parties. Notably, and in contrast to other previous hospital mergers, the precise contours of the relevant geographic market do not alter in any meaningful way the number of competitors, the market share statistics, or the ultimate conclusion that the Acquisition is likely to lead to competitive harm.

28. The appropriate geographic market is determined by examining the geographic boundaries within which a hypothetical monopolist for the services at issue could profitably raise prices by a small but significant amount.

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29. Rockford region residents have a clear preference for obtaining hospital care and primary care physician services locally. As a result, health plans must include hospitals and primary care physicians from the Rockford region in their provider networks in order to meet their members' needs. Patients do not and would not go to hospitals or primary care physicians outside of the Rockford region in response to rate increases within the region. Thus, a hypothetical monopolist that controlled all of the hospitals or all of the primary care physicians in the Rockford region could profitably increase rates by at least a small but significant amount.

30. In the ordinary course, OSF and RHS treat only their Rockford counterparts as meaningful competitors, and both hospitals focus their competitive efforts on providers located in Rockford. OSF and RHS define their primary service areas Patient draw data maintained in the ordinary course by both OSF and RHS indicates that nearly all of their inpatients originate from the Winnebago-Ogle-Boone area.

31. The relevant geographic market in which to analyze the market for primary care physician services provided to commercially-insured adults is similarly no broader than the Winnebago-Ogle-Boone area defined by the District Court in 1989, and may be significantly more narrow. Patients are no more willing to travel to obtain primary care services than they are to obtain acute-care inpatient hospital services. Indeed, because patients generally obtain primary care services much more frequently than acute inpatient hospital services, their preference for access to local providers is significantly stronger.

Complaint

V.

**MARKET STRUCTURE AND THE ACQUISITION'S  
PRESUMPTIVE ILLEGALITY**

A.

**General Acute-Care Inpatient Services Market**

32. The Acquisition will reduce the number of general acute-care hospital competitors in the Rockford region from three to two, creating a duopoly of OSF and SwedishAmerican.<sup>1</sup>

33. The Acquisition is presumptively unlawful by a wide margin under the relevant case law and the Merger Guidelines because it would significantly increase concentration in the already highly concentrated market for general acute-care services in the Rockford region.

34. OSF's post-Acquisition market share in the general acute-care services market will be 64% (as measured by patient days), easily surpassing levels held to be presumptively unlawful by the Supreme Court. Moreover, the Acquisition would leave just two hospitals, OSF and SwedishAmerican, in control of 99.5% of the Rockford region market for general acute-care services.

35. As described in the Merger Guidelines, the standard for measuring market concentration is the Herfindahl-Hirschman Index ("HHI"). A merger or acquisition is likely to create or enhance market power, and is presumed illegal, when the post-acquisition HHI exceeds 2500 points and the acquisition would increase the HHI by more than 200 points. Here, the general acute-care services market concentration levels drastically exceed

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<sup>1</sup> The only other provider within the relevant geographic market, Rochelle Community Hospital ("Rochelle"), is located in Rochelle, Illinois, a small community 30 miles (over 40 minutes driving time) south of Rockford. As the District Court held previously, and the evidence continues to show, Rochelle is not competitively relevant to Rockford and its three hospitals. Rochelle's market share in the Rockford region is less than one half of one percent. It is a 25-bed critical access facility that offers a very limited range of services, is prohibited by the state from expanding its capacity, and serves its immediate community almost exclusively.

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these thresholds. The Acquisition would, as shown below, increase the HHI from 3319 to 5351, a change of 2032 points.

36. In its 1989 decision, the District Court found that the merger of two Rockford hospitals resulting in concentration figures similar to those resulting from this Acquisition “would produce a firm controlling an undue percentage share of the relevant market, thus increasing the likelihood of market dominance by the merged entity or collusion.” Notably, the Rockford region is even more concentrated today than it was in 1989, due to the lack of new hospital entry, the closure of one hospital, and the acquisition of another by SwedishAmerican.

<b>GENERAL ACUTE-CARE INPATIENT SERVICES</b>		
<b>Hospital/System</b>	<b>Pre-Acquisition Market Share</b>	<b>Post-Acquisition Market Share</b>
SwedishAmerican	35.6%	35.6%
RHS	34.3%	
OSF	29.6%	63.9%
Rochelle	0.5%	0.5%
<b>Pre-Acquisition HHI</b>		3319
<b>Post-Acquisition HHI</b>		5351
<b>HHI Increase</b>		2032

**B.****Primary Care Physician Services Market**

37. The Acquisition will reduce the number of hospital-employed physician groups from three to two in the Rockford region, and leave the remainder of the market highly fragmented with small independent physician practices. Under the relevant case law and the Merger Guidelines, the Acquisition raises

## Complaint

significant competitive concerns in the primary care physician services market.

38. The Acquisition will result in a concentrated primary care physician services market with few significant competitors. Based on the best currently-available data, OSF's post-Acquisition market share will exceed 37%. Post-Acquisition, the two remaining hospitals, OSF and SwedishAmerican, will control 58% of the primary care physician services market in the Rockford region.

39. Under the Merger Guidelines, a merger or acquisition potentially raises significant competitive concerns that warrant scrutiny when the post-merger HHI exceeds 1500 points and the merger or acquisition increases the HHI by more than 100 points. Here, the post-Acquisition HHI in the primary care physician services market exceeds these levels by a wide margin, with an increase of 696 points to 1925. The HHI figures for the primary care physician services market are summarized in the table below.

<b>PRIMARY CARE PHYSICIAN SERVICES*</b>		
<b>Hospital/System</b>	<b>Pre-Acquisition Market Share</b>	<b>Post-Acquisition Market Share</b>
SwedishAmerican	20.4%	20.4%
OSFMG	19.9%	37.4%
RPH	17.5%	
University of Illinois	7.3%	7.3%
Others**	4.0%	4.0%
Independent***	30.9%	30.9%
<b>Pre-Acquisition HHI</b>		1229
<b>Post-Acquisition HHI</b>		1925
<b>HHI Increase</b>		696

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\* Due to limitations in the preliminarily-available data, the primary care physician market shares and HHIs have been calculated on the basis of full-time-equivalent physicians practicing in a geographic market comprising Winnebago, Boone, and Ogle counties, which has a slightly different scope than the geographic market defined by the District Court in 1989.

\*\* includes several small and mid-size physician groups

\*\*\* all independent physicians are treated as individual providers in HHI calculations

**VI.****ANTICOMPETITIVE EFFECTS****A.****Loss of Price Competition And the Increased Bargaining Leverage of OSF**

40. The Acquisition will end decades of significant competition between Respondents and will increase Respondents' ability and incentive to unilaterally demand higher reimbursement rates from commercial health plans.

41. Today, the three Rockford hospitals are close and vigorous competitors in the markets for general acute-care services and primary care physician services. There is nearly complete overlap in the service areas of OSF, RHS, and SwedishAmerican. Rockford region residents and, by extension, the health plans that represent them, consider all three Rockford hospitals as close substitutes for one another due to their proximity and similar scope of services. Residents benefit from the competition between the three hospitals.

42. Rockford residents strongly prefer to have a choice of where they receive their health care services. As a result, every major health plan serving the Rockford region features a provider network with two of the three local hospitals as preferred providers. While health plans and their members might prefer to have access to all three Rockford hospitals, the hospitals

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43. Currently, the three Rockford hospitals must compete vigorously – often through a competitive bidding process – to be included in each health plan’s provider network. Due to the similarity and close substitutability of the three Rockford hospitals, health plans today believe

As a result, the three Rockford hospitals compete for just two spots in each health plan’s network, each hospital being forced to provide competitive rates or else risk exclusion from a health plan’s network.

44. Nothing about the Acquisition will change the high value and importance that Rockford residents place on being able to choose their doctors and hospitals. Residents will continue to demand health plan provider networks that include at least two of the three Rockford hospitals, as they have for decades.

45. After the Acquisition, no health plan will be able to offer its members access to more than one of the Rockford hospitals without first agreeing to whatever terms the merged OSF and RHS may demand. As a result, the merged system will become even more important to health plans serving the Rockford region and thus become a virtual “must have.” Health plans will no longer be able to play the three Rockford hospitals against one another. They will have to choose between contracting only with SwedishAmerican, which would restrict their members’ choices and options, or accepting significantly higher reimbursement rates demanded by the newly dominant OSF.

46. Any increase in rates ultimately will be borne by the employers and residents of Rockford through increased insurance premiums and health care costs. The majority of commercially insured patients in the Rockford region are covered by health plans that are self-insured by their employers. Self-insured employers pay the full cost of their employees’ health care claims and, as a result, they immediately and directly bear the full burden of higher rates charged by hospitals or physicians. Fully-insured employers also are inevitably harmed by higher rates, because health plans pass on at least a portion of hospital rate increases to these customers.

## Complaint

47. Employers, in turn, will pass on their increased health care costs to their employees, in whole or in part. Employees will bear these costs in the form of higher premiums, higher co-pays, reduced coverage, or restricted services. Some Rockford region residents will forgo or delay necessary health care services because of the higher costs, and others may drop their insurance coverage altogether.

48. OSF could also exercise its newly acquired market power after the Acquisition by preventing health plans from including SwedishAmerican in their provider networks. The effect would be to eliminate entirely the ability of Rockford residents who want access to either OSF or RHS from also utilizing SwedishAmerican without incurring higher out-of-network costs. In Peoria, a market south of Rockford where OSF is already a self-acclaimed [REDACTED] OSF has successfully leveraged its market position to

49. Respondents' documents created in the ordinary course of business indicate that the managed care strategies of the parties encourage [REDACTED] with the ultimate goal to [REDACTED] and become a [REDACTED] system to health plans. Party executives concede that one motivation for the Acquisition was

50. Although SwedishAmerican will continue to act as a meaningful competitor in the Rockford region, the presence of SwedishAmerican will not prevent a post-Acquisition exercise of market power by OSF – whether it is in the form of a rate increase or exclusionary conduct. Because Rockford residents demand health plan networks that offer at least two Rockford hospitals, a network comprised exclusively of SwedishAmerican would be highly undesirable to employers and thus unlikely to have commercial success. Recent history confirms this: virtually every attempt by a health plan to market a provider network consisting of just one Rockford hospital – including one exclusive to SwedishAmerican – has failed.

51. The Acquisition also will significantly increase OSF's ability to unilaterally increase rates for primary care physician

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services. Hospitals and health plans engage in bilateral negotiations to create networks of physicians much like they do to create networks of hospitals. Similar competitive factors dictate the outcomes of negotiations over physician services as dictate the outcomes of negotiations over hospital services. As is the case with the three Rockford hospitals, Rockford residents consider the primary care physician groups of the three local hospitals as close substitutes for each other. Therefore, the Acquisition will strengthen OSF's bargaining leverage against health plans when it is negotiating the terms of including OSFMG and RHPH physicians in the health plans' provider networks.

**B.****The Acquisition will Reduce Competition Over Quality, Service, and Access**

52. Residents of the Rockford region have benefitted from decades of competition between OSF and RHS to improve the quality of care, increase the scope of services, and expand access to care in the Rockford region. The Acquisition would end this important non-price competition between OSF and RHS and reduce the quality, convenience, and breadth of services local residents would otherwise enjoy.

53. After decades of Respondents' self-described all three Rockford hospitals today offer convenient access to a broad range of high quality clinical services. And despite the costs incurred to invest in new technologies and improve the quality of care over the years, all three Rockford hospitals have been, and continue to be, financially stable organizations with positive operating performances and substantial cash reserves.

54. RHS, described as a \_\_\_\_\_ and \_\_\_\_\_ when it comes to expanding its services or improving its technology, repeatedly spurred OSF and SwedishAmerican to respond by upgrading their own offerings. The Acquisition would eliminate RHS as an independent competitor in the Rockford region and would thereby eliminate a competitive force behind much of the innovation and expansion that has benefitted local residents over the years.

## Complaint

**C.****The Acquisition Will Increase the Incentive and Ability to Coordinate**

55. The Acquisition also will diminish competition by enabling and encouraging OSF and its sole remaining competitor in the Rockford region, SwedishAmerican, to engage in coordinated interaction.

56. As the Seventh Circuit held in affirming the Commission's divestiture order in a prior hospital merger matter: "[t]he fewer the independent competitors in a hospital market, the easier they will find it, by presenting an unbroken phalanx of representations and requests, to frustrate efforts to control hospital costs."

57. According to the Merger Guidelines, coordination need not rise to the level of explicit agreement. It may involve a "common understanding that is not explicitly negotiated[.]" or even merely "parallel accommodating conduct not pursuant to a prior understanding."

58. The market structure and competitive dynamics in the Rockford region today are materially unchanged since the District Court found in 1989 that a merger of two of the Rockford hospitals would facilitate the likelihood of collusion among the two remaining hospital competitors. The acquisition of RHS by OSF, the latest proposed merger to duopoly in the Rockford region, is no less likely to result in coordinated interaction.

59. OSF and SwedishAmerican would have the incentive and ability to coordinate their managed care contracting strategies post-Acquisition, for example, by communicating confidential information related to health plan negotiations, either by directly contacting each other or by otherwise signaling their intentions. The two remaining hospitals could also defer competitive initiatives, such as adding amenities or expanding services, which would otherwise benefit Rockford residents. Indeed, Respondents' ordinary course documents suggest that

## Complaint

**VII.****ENTRY BARRIERS**

60. Neither hospital entry nor expansion by the sole remaining hospital competitor will deter or counteract the Acquisition's likely harm to competition in the relevant service markets.

61. New hospital entry or significant expansion in the Rockford region is unlikely to occur because Illinois' Certificate of Need ("CON") statute requires an extensive application process in order to construct a hospital, add acute care beds or new clinical services to an existing hospital, or to purchase medical equipment above a capital threshold. The CON approval process is focused on the number of hospital beds per capita; the process does not contemplate or permit consideration of antitrust or competition concerns. Based on the most recent findings of the Illinois Health Facilities and Services Review Board responsible for reviewing CON applications, any request to construct a new acute care hospital in the Rockford region is likely to be denied because the board does not believe Rockford needs any additional beds.

62. Even if new hospital entry did occur in the Rockford region, such entry would not be timely because it would take at least two to five years from the planning stages to opening doors to patients. New entry is also unlikely to be sufficient to deter or counteract the anticompetitive effects of the Acquisition because a new hospital would need to be able to replicate and offer a broad cluster of general acute-care inpatient services comparable to those offered by OSF and SwedishAmerican.

63. New primary care physician entry is unlikely because most physicians in Rockford are already employed by one of the three hospitals. Further, the number of independent primary care physicians is declining because hospitals offer stability and generous benefits, while self-managing a private physician practice is costly and time-consuming. As a result, there has been very little to no entry of independent primary care physicians into the Rockford region in the last several years.

## Complaint

64. New competition from currently-employed Rockford physicians who leave to open a private practice is unlikely to occur, and in any event would not be timely to deter or prevent competitive harm, in part because all three Rockford hospitals require their employed physicians to [REDACTED]

**VIII.****EFFICIENCIES**

65. Respondents' alleged benefits of the Acquisition fall well short of the substantial, merger-specific, well-founded, and competition-enhancing efficiencies that would be necessary to outweigh the Acquisition's significant harm to competition in Rockford. No court ever has found, without being reversed, that efficiencies rescue an otherwise illegal transaction. Relevant case law indicates that "extraordinary" efficiencies are required to justify an acquisition, such as this one, with vast potential to harm competition.

66. The alleged efficiencies are unfounded and unreliable. Respondents have refused to answer questions or reveal underlying data and analysis in support of their claims on the grounds that such material was prepared under the direction of antitrust counsel in anticipation of litigation, and thus constitutes attorney work product. The made-for-litigation efficiency claims, therefore, were unambiguously "generated outside of the usual business planning process." Even an analysis based on the information available to date reveals that Respondents' efficiency claims are speculative, exaggerated, and contradicted by the testimony of party executives.

67. Many of the alleged efficiencies also are not merger-specific because they could be accomplished unilaterally without any merger or acquisition, or through an affiliation with an alternative purchaser. The same litigation consultants who generated the estimates of the savings that may result from the Acquisition produced two separate reports detailing that RHS and OSF could accomplish on their own.

## Complaint

68. Any claim that the Acquisition is necessary for the parties to survive or continue to compete as full-service independent hospitals is speculative and unsupported by market realities. In fact, RHS and SwedishAmerican made similar claims to the District Court in 1989, and

Despite their repeated dire predictions, OSF, RHS, and SwedishAmerican have continued to compete successfully over the course of the last two decades and, today, each remains a financially stable, full-service hospital providing high-quality care to the community.

**IX.****VIOLATION****COUNT I - ILLEGAL ACQUISITION**

69. The allegations of Paragraphs 1 through 68 above are incorporated by reference as though fully set forth.

70. The Acquisition, if consummated, would substantially lessen competition in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

**NOTICE**

Notice is hereby given to the Respondents that the seventeenth day of April, 2012, at 10 a.m. is hereby fixed as the time, and Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580 as the place, when and where an evidentiary hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act and the Clayton Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14<sup>th</sup>) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain

## Complaint

a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under Rule 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions, and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after the answer is filed by the Respondents. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the pre-hearing scheduling conference (but in any event no later than five (5) days after the answer is filed by the Respondents). Rule 3.31(b) obligates counsel for each party, within five (5) days of receiving the Respondents' answer, to make certain initial disclosures without awaiting a discovery request.

## Complaint

**NOTICE OF CONTEMPLATED RELIEF**

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that the Acquisition challenged in this proceeding violates Section 7 of the Clayton Act, as amended, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. If the Acquisition is consummated, divestiture or reconstitution of all associated and necessary assets, in a manner that restores two or more distinct and separate, viable and independent businesses in the relevant markets, with the ability to offer such products and services as OSF and RHS were offering and planning to offer prior to the Acquisition.
2. A prohibition against any transaction between OSF and RHS that combines their businesses in the relevant markets, except as may be approved by the Commission.
3. A requirement that, for a period of time, OSF and RHS provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of their businesses in the relevant markets with any other company operating in the relevant markets.
4. A requirement to file periodic compliance reports with the Commission.
5. Any other relief appropriate to correct or remedy the anticompetitive effects of the transaction or to restore RHS as a viable, independent competitor in the relevant markets.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by its Secretary and its official seal to be hereto affixed, at Washington, D.C., this 17<sup>th</sup> day of November, 2011.

By the Commission.

Final Order

**ORDER DISMISSING COMPLAINT**

On November 17, 2011, the Federal Trade Commission issued the Administrative Complaint in this matter, having reason to believe that Respondents OSF Healthcare System (“OSF”) and Rockford Health System (“RHS”) had executed an affiliation agreement which, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Complaint Counsel and Respondents have now filed a Joint Motion to Dismiss Complaint, which states that the Respondents are abandoning the proposed affiliation, and have withdrawn the Hart-Scott-Rodino Notification and Report Forms they filed for the proposed transaction.<sup>1</sup>

The Commission has determined to dismiss the Administrative Complaint without prejudice, as the most important elements of the relief set out in the Notice of Contemplated Relief in the Administrative Complaint have been accomplished without the need for further administrative litigation.<sup>2</sup> In particular, Respondents have announced that they are abandoning the proposed affiliation, and have withdrawn the Hart-Scott-Rodino Notification and Report Forms filed for the proposed transaction. As a consequence, the Respondents would not be able to effect the proposed transaction without filing new Hart-Scott-Rodino Notification and Report Forms.

For the foregoing reasons, the Commission has determined that the public interest warrants dismissal of the Administrative Complaint in this matter. The Commission has determined to do so without prejudice, however, because it is not reaching a decision on the merits. Accordingly,

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<sup>1</sup> See Joint Motion To Dismiss Complaint (April 12, 2012), at <http://www.ftc.gov/os/adjpro/d9349/index.shtm>.

<sup>2</sup> See, e.g., *In the Matter of Omnicare, Inc.*, Docket No. 9352, Order Dismissing Complaint (Feb. 22, 2012), at <http://www.ftc.gov/os/adjpro/d9352/120223omnicareorder.pdf>; *In the Matter of Thoratec Corporation and HeartWare International, Inc.*, Docket No. 9339, Order Dismissing Complaint (August 11, 2009), at <http://www.ftc.gov/os/adjpro/d933.90811thoatecorder.pdf>; *In the Matter of CSL Limited and Cerberus-Plasma Holdings, LLC*, Docket No. 9337, Order Dismissing Complaint (June 22, 2009), at <http://www.ftc.gov/os/adjpro/d9337/090622commorderdismisscomplaint.pdf>.

Final Order

**IT IS ORDERED THAT** the Administrative Complaint in this matter be, and it hereby is, dismissed without prejudice.

By the Commission.

## Complaint

## IN THE MATTER OF

**FRANK MYERS AUTOMAXX, LLC**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4353; File No. 112 3206*  
*Complaint, April 19, 2012 – Decision, April 19, 2012*

This consent order addresses Frank Myers AutoMaxx, LLC's advertising of the purchase, financing, and leasing of its motor vehicles. The complaint alleges that respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan, but does not. The consent order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan and any other material fact relating to the financing or leasing of a motor vehicle.

*Participants*

For the *Commission*: Gregory A. Ashe and Robin Thurston.

For the *Respondent*: Matthew Bryant and Casey Otis,  
Hendrick Bryant Nerhood & Otis, LLP.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Frank Myers AutoMaxx, LLC, a limited liability corporation ("Respondent"), has violated provisions of the Federal Trade Commission Act ("FTC Act"), and, it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Frank Myers AutoMaxx, LLC, is a North Carolina limited liability corporation with its principal place of business at 4200 N. Patterson Ave., Winston Salem, NC, 27105. Respondent offers automobiles for sale.

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

## Complaint

3. Since at least September 2009, Respondent has disseminated or caused to be disseminated advertisements regarding the purchasing and financing of its automobiles.

4. Respondent's advertisements include, but are not necessarily limited to, video advertisements posted on the website YouTube.com, copies of which are attached as Exhibits A through E. These advertisements include the following statements:

- a. "We'll pay off your trade no matter what you owe!" (Exhibit A (DVD containing 7/6/11 capture of YouTube advertisement "Winston-Salem Car Dealer Wants You To Have A Nicer, Newer Car" at 0:18-0:23)).
- b. "You're driving a car you hate, but you owe more than it's worth; no problem. When you buy any certified car, we'll pay of your trade, regardless of what you owe." (Exhibit B (DVD containing 7/14/11 capture of YouTube advertisement "'Common Sense Ain't So Common' says Tracy Myers of Frank Myers Auto Maxx" at 0:11-0:19)).
- c. "We'll pay off your current loan no matter how much you owe." (Exhibit C (DVD containing 7/6/11 capture of YouTube Advertisement "Frank Myers Auto - Biz Is Booming Trade-In Event in Winston-Salem, NC 27105" at 0:13-0:16)).
- d. "Uncle Frank wants to pay [your trade] off in full, no matter how much you owe!" (Exhibit D (DVD containing 7/6/11 capture of YouTube Advertisement "HATE Your Car? STOP Making Payments - Frank Myers Auto in Winston-Salem, NC 27105" at 0:06-0:10)).
- e. "We'll pay off your lease or loan, in full, no matter how much you owe." (Exhibit E (DVD containing 7/6/11 capture of YouTube Advertisement "'Snow Blows!' exclaims a Winston-Salem, NC used car dealer" at 0:14-0:18)).

## Complaint

**VIOLATION OF THE FEDERAL TRADE COMMISSION  
ACT****Count I: Misrepresentation of Financing Terms**

5. Through the means described in Paragraph 4, Respondent has represented expressly or by implication that, when a consumer trades in a used vehicle in order to purchase another vehicle, Respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan.

6. In truth and in fact, in numerous instances, when a consumer trades in a used vehicle with a loan balance that exceeds the vehicle's value (*i.e.* the trade-in has negative equity) in order to purchase another vehicle, Respondent will not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, Respondent sometimes requires the consumer to pay the amount of the negative equity at the time of the sale.

7. Therefore, the representation set forth in Paragraph 5 of this Complaint was, and is, false or misleading.

8. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act.

**THEREFORE**, the Federal Trade Commission, this nineteenth day of April, 2012, has issued this complaint against Respondent.

By the Commission.

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of Respondent named in the caption hereof, and Respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violation of the Federal Trade Commission Act; and

Respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Frank Myers AutoMaxx, LLC, is a North Carolina limited liability corporation with its principal office or place of business at 4200 N. Patterson Ave., Winston Salem, North Carolina, 27105.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

Decision and Order

**ORDER****DEFINITIONS**

For the purposes of this order, the following definitions shall apply:

- A. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- B. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- C. “Motor vehicle” shall mean
  1. any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
  2. recreational boats and marine equipment;
  3. motorcycles;
  4. motor homes, recreational vehicle trailers, and slide-in campers; and
  5. other vehicles that are titled and sold through dealers.

**I.**

**IT IS ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with any advertisement to promote, directly or indirectly, the purchase, financing, or leasing of automobiles, in or affecting commerce, shall not, in any manner, expressly or by implication

- A. Misrepresent that when a consumer trades in a used motor vehicle (“trade-in vehicle”) in order to purchase another motor vehicle (“newly purchased vehicle”), Respondent will pay any remaining loan balance on the trade-in vehicle such that the consumer will have

## Decision and Order

no remaining obligation for any amount of that loan;  
or

- B. Misrepresent any material fact regarding the cost and terms of financing or leasing any newly purchased vehicle.

**II.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**III.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

## Decision and Order

**IV.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC, 20580. The subject line must begin: FTC v. Frank Myers AutoMaxx.

**V.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

**VI.**

This order will terminate on April 19, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any

## Analysis to Aid Public Comment

violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint;
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen not participating.

### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission ("FTC") has accepted, subject to final approval, an agreement containing a consent order from Frank Myers AutoMaxx, LLC. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

## Analysis to Aid Public Comment

The respondent is a motor vehicle dealer. The matter involves its advertising of the purchase, financing, and leasing of its motor vehicles. According to the FTC complaint, respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. The complaint alleges that in fact, when a consumer trades in a used vehicle with negative equity (*i.e.* the loan balance on the vehicle exceeds the vehicle's value) in order to purchase another vehicle, respondent does not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, the respondent may require the consumer to pay for the negative equity in cash at the time of sale. The complaint alleges therefore that the representation is false or misleading in violation of Section 5 of the FTC Act.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I of the proposed order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan. It also prohibits misrepresenting any other material fact relating to the financing or leasing of a motor vehicle.

Part II of the proposed order requires respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements. Part III requires that respondent provide copies of the order to certain of its personnel. Part IV requires notification of the Commission regarding changes in corporate structure that might affect compliance obligations under the order. Part V requires the respondent to file compliance reports with the Commission. Finally, Part VI is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

## Complaint

## IN THE MATTER OF

**RAMEY MOTORS, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, THE TRUTH IN LENDING ACT, AND REGULATION Z

*Docket No. C-4354; File No. 112 3207  
Complaint, April 19, 2012 – Decision, April 19, 2012*

This consent order addresses Ramey Motors, Inc.'s advertising of the purchase and financing of its motor vehicles. The complaint alleges that respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan, but does not. In addition, the complaint alleges violations of the Truth in Lending Act and Regulation Z for failing to disclose certain costs and terms when advertising credit. The consent order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan or any other material fact relating to the financing or leasing of a motor vehicle.

*Participants*

For the *Commission*: Gregory A. Ashe and Robin Thurston.

For the *Respondent*: Johnnie E. Brown, Pullin, Fowler, Flanagan, Brown & Poe, PLLC.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Ramey Motors, Inc., a corporation ("Respondent"), has violated provisions of the Federal Trade Commission Act ("FTC Act") and the Truth in Lending Act ("TILA"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a West Virginia corporation with its principal place of business at Route 460 East, Princeton, WV, 24720. Respondent offers automobiles for sale.

## Complaint

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. Since at least July 2010, Respondent has disseminated or has caused to be disseminated advertisements promoting the purchase, financing, and leasing of its automobiles.

4. Respondent’s advertisements include, but are not necessarily limited to, advertisements posted on the website YouTube.com, copies of which are attached as Exhibits A through C. These advertisements include the following statements:

- a. “Ramey will pay off your trade no matter what you owe. . . . Even if you’re upside down, Ramey will pay off your trade.” (Exhibit A (DVD containing 7/6/11 capture of YouTube Advertisement “2010 Toyota of Princeton Pay Off Trade Event Princeton West Virginia” at 0:08-0:12)).
- b. “Even if you’re upside down, Ramey will pay off your trade.” (Exhibit B (DVD containing 7/14/11 capture of YouTube advertisement “2010 Ramey Chrysler Jeep Dodge Pay Off Trade Event Princeton WV” at 0:19-0:23)).
- c. “Ramey will pay off your trade no matter what you owe.” (Exhibit C (DVD containing 7/14/11 capture of YouTube advertisement “2010 Ramey Chevrolet Pay Off Trade Event Princeton WV” at 0:07-0:11)).

The advertisements are accompanied by small, typically illegible text. In one of the advertisements, the text appears to state that the negative equity will be included in any new loan. In at least one of the advertisements, the text is completely illegible. To the extent there are any disclosures, they appear in small, illegible print for a short period of time.

5. Respondent also has disseminated or has caused to be disseminated advertisements promoting credit sales and other extensions of closed-end credit in consumer credit transactions, as

## Complaint

the terms “advertisement,” “closed-end credit,” “credit sale,” and “consumer credit” are defined in Section 226.2 of Regulation Z, 12 C.F.R. § 226.2, as amended, on the website YouTube.com, copies of which is attached as Exhibits B and D. These advertisements include the following statements:

- a. “New 2010 Dodge Caliber . . . \$249 per mo” (Exhibit B at 0:14-0:15).
- b. “New 2010 Ram 1500 . . . \$283 per mo” (*id.* at 0:19-0:20).
- c. “0% financing available” (Exhibit D (DVD containing 8/12/11 capture of YouTube advertisement “Labor Day Sales Event Ramey Auto Group Princeton WV” at 0:16-0:18)).

The disclosures required by Regulation Z, if provided, are not clear and conspicuous because they appear in small, blurred print for a short period of time.

**VIOLATION OF THE FEDERAL TRADE COMMISSION  
ACT**

**Misrepresentation of Financing Terms**

6. Through the means described in Paragraph 4, Respondent has represented expressly or by implication that, when a consumer trades in a used vehicle in order to purchase another vehicle, Respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan.

7. In truth and in fact, in many instances, when a consumer trades in a used vehicle with a loan balance that exceeds the vehicle’s value (*i.e.* the trade-in has negative equity) in order to purchase another vehicle, Respondent will not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, Respondent includes the amount of the negative equity in the loan for the newly purchased vehicle.

## Complaint

8. Therefore, the representation set forth in Paragraph 6 of this Complaint was, and is, false or misleading in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**VIOLATIONS OF THE TRUTH IN LENDING ACT AND  
REGULATION Z**

9. Under Section 144 of the TILA and Section 226.24(d) of Regulation Z, advertisements promoting closed-end credit in consumer credit transactions are required to make certain disclosures if they state any of several terms, such as the monthly payment (“TILA triggering terms”). In addition, the rate of the finance charge must be stated as an “annual percentage rate” using that term or the abbreviation “APR.” 15 U.S.C. § 1664; 12 C.F.R. § 226.24(c).

10. Respondent’s advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, are subject to the requirements of the TILA and Regulation Z.

**Failure to Disclose or Disclose Clearly and Conspicuously  
Required Credit Information**

11. Respondent’s advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, have included TILA triggering terms, but have failed to disclose or disclose clearly and conspicuously, additional terms required by the TILA and Regulation Z, including one or more of the following:

- a. The amount or percentage of the downpayment.
- b. The terms of repayment, which reflect the repayment obligations over the full term of the loan, including any balloon payment.
- c. The “annual percentage rate,” using that term, and, if the rate may be increased after consummation, that fact.

## Decision and Order

12. Therefore, the practices set forth in Paragraph 11 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. § 1664, and Section 226.24(d) of Regulation Z, 12 C.F.R. § 226.24(d), as amended.

**Failure to State Rate of Finance Charge as Annual Percentage Rate**

13. Respondent's advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, have stated a rate of finance charge without stating that rate as an "annual percentage rate" using that term or the abbreviation "APR."

14. Therefore, the practices set forth in Paragraph 13 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. § 1664, and Section 226.24(c) of Regulation Z, 12 C.F.R. § 226.24(c).

15. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act and violations of the Truth in Lending Act and Regulation Z.

**THEREFORE**, the Federal Trade Commission, this nineteenth day of April, 2012, has issued this complaint against Respondent.

By the Commission.

**DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of Respondent named in the caption hereof, and Respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for

## Decision and Order

its consideration and which, if issued by the Commission, would charge Respondent with violation of the Federal Trade Commission Act (“FTC Act”) and the Truth in Lending Act (“TILA”); and

Respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the FTC Act and the TILA, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent, Ramey Motors, Inc., is a West Virginia corporation with its principal place of business at Route 460 East, Princeton, WV, 24720.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

## Decision and Order

**ORDER****DEFINITIONS**

For the purposes of this order, the following definitions shall apply:

- A. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- B. “Clearly and conspicuously” shall mean as follows:
  - 1. In a print advertisement, the disclosure shall be in a type size, location, and in print that contrasts with the background against which it appears, sufficient for an ordinary consumer to notice, read, and comprehend it.
  - 2. In an electronic medium, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade and appear on the screen for a duration and in a location sufficient for an ordinary consumer to read and comprehend it.
  - 3. In a television or video advertisement, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade, and appear on the screen for a duration, and in a location, sufficient for an ordinary consumer to read and comprehend it.
  - 4. In a radio advertisement, the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
  - 5. In all advertisements, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of

## Decision and Order

the disclosure shall be used in any advertisement or promotion.

- C. “Consumer credit” shall mean credit offered or extended to a consumer primarily for personal, family, or household purposes.
- D. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- E. “Motor vehicle” shall mean
  1. any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
  2. recreational boats and marine equipment;
  3. motorcycles;
  4. motor homes, recreational vehicle trailers, and slide-in campers; and
  5. other vehicles that are titled and sold through dealers.

**I.**

**IT IS ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with any advertisement to promote, directly or indirectly, the purchase, financing, or leasing of automobiles, in or affecting commerce, shall not, in any manner, expressly or by implication:

- A. Misrepresent that when a consumer trades in a used motor vehicle (“trade-in vehicle”) in order to purchase another motor vehicle (“newly purchased vehicle”), Respondent will pay any remaining loan balance on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan; or

## Decision and Order

- B. Misrepresent any material fact regarding the cost and terms of financing or leasing any newly purchased vehicle.

**II.**

**IT IS FURTHER ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with an advertisement to promote, directly or indirectly, any extension of consumer credit, in or affecting commerce, shall not in any manner, expressly or by implication:

- A. State the amount or percentage of any down payment, the number of payments or period of repayment, the amount of any payment, or the amount of any finance charge, without disclosing clearly and conspicuously all of the following terms:
1. The amount or percentage of the down payment;
  2. The terms of repayment; and
  3. The annual percentage rate, using the term “annual percentage rate” or the abbreviation “APR.” If the annual percentage rate may be increased after consummation of the credit transaction, that fact must also be disclosed; or
- B. State a rate of finance charge without stating the rate as an “annual percentage rate” or the abbreviation “APR,” using that term.
- C. Fail to comply in any respect with Regulation Z, 12 C.F.R. § 226, as amended, and the Truth in Lending Act, as amended, 15 U.S.C. §§ 1601-1667.

**III.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

## Decision and Order

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**IV.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

**V.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place,

## Decision and Order

Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC, 20580. The subject line must begin: FTC v. Ramey Motors.

**VI.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns, within ninety (90) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within thirty (30) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

**VII.**

This order will terminate on April 19, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint;
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as

## Analysis to Aid Public Comment

though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen not participating.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission (“FTC”) has accepted, subject to final approval, an agreement containing a consent order from Ramey Motors, Inc. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

The respondent is a motor vehicle dealer. The matter involves its advertising of the purchase and financing of its motor vehicles. According to the FTC complaint, respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. The complaint alleges that in fact, when a consumer trades in a used vehicle with negative equity (*i.e.* the loan balance on the vehicle exceeds the vehicle’s value) in order to purchase another vehicle, respondent does not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, the respondent includes the amount of the negative equity in the loan for the newly purchased vehicle. The complaint alleges therefore that the representation is false or

## Analysis to Aid Public Comment

misleading in violation of Section 5 of the FTC Act. In addition, the complaint alleges violations of the Truth in Lending Act (“TILA”) and Regulation Z for failing to disclose certain costs and terms when advertising credit.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I of the proposed order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer’s trade-in vehicle such that the consumer will have no obligation for any amount of that loan. It also prohibits misrepresenting any other material fact relating to the financing or leasing of a motor vehicle.

Part II of the proposed order addresses the TILA allegations. It requires clear and conspicuous TILA/Regulation Z disclosures when advertising any of the relevant triggering terms with regard to issuing consumer credit. It also requires that if any finance charge is advertised, the rate be stated as an “annual percentage rate” using that term or the abbreviation “APR.” In addition, Part II prohibits any other violation of TILA or Regulation Z.

Part III of the proposed order requires respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements. Part IV requires that respondent provide copies of the order to certain of its personnel. Part V requires notification of the Commission regarding changes in corporate structure that might affect compliance obligations under the order. Part VI requires the respondent to file compliance reports with the Commission. Finally, Part VII is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

Complaint

IN THE MATTER OF

**BILLION AUTO, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, THE TRUTH IN LENDING ACT, THE CONSUMER LEASING ACT, REGULATION Z, AND REGULATION M

*Docket No. C-4356; File No. 112 3209  
Complaint, May 1, 2012 – Decision, May 1, 2012*

This consent order addresses Billion Auto, Inc.'s advertising of the purchase, financing, and leasing of its motor vehicles. The complaint alleges that respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan, but does not. In addition, the complaint alleges violations of the Truth in Lending Act and Regulation Z for failing to disclose certain costs and terms when advertising credit. The complaint also alleges a violation of the Consumer Leasing Act and Regulation M for failing to disclose the costs and terms of certain leases offered. The consent order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan or any other material fact relating to the financing or leasing of a motor vehicle.

*Participants*

For the *Commission*: Gregory A. Ashe and Robin Thurston.

For the *Respondent*: Jim McMahan, solo practitioner.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Billion Auto, Inc., a corporation ("Respondent"), has violated provisions of the Federal Trade Commission Act ("FTC Act"), the Truth in Lending Act ("TILA"), and the Consumer Leasing Act ("CLA"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a South Dakota corporation with its principal office or place of business at 3401 West 41st Street,

## Complaint

Sioux Falls, SD, 57106. Respondent offers automobiles for sale and lease.

2. The acts or practices of Respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

3. Since at least May 2011, Respondent has disseminated or has caused to be disseminated advertisements promoting the purchase, financing, and leasing of its automobiles.

4. Respondent’s advertisements include, but are not necessarily limited to, an advertisement on its website [www.billionpayoff.com](http://www.billionpayoff.com), a copy of which is attached as Exhibit A (DVD containing 7/6/11 capture of [www.billionpayoff.com](http://www.billionpayoff.com)). This advertisement includes the following statements and depictions:

- a. **“We will pay off your trade NO MATTER how much you owe!”**
- b. “Credit upside down? Need a new car? Go to Billionpayoff.com. We want to pay off your car.” The advertisement depicts a car driving, inverts the video to depict the car upside down, and then depicts the car right-side up again.

5. Respondent also has disseminated or has caused to be disseminated advertisements promoting credit sales and other extensions of closed-end credit in consumer credit transactions, as the terms “advertisement,” “closed-end credit,” “credit sale,” and “consumer credit” are defined in Section 226.2 of Regulation Z, 12 C.F.R. § 226.2, as amended, on one of its websites, a copy of which is attached as Exhibit B (copy of 7/6/11 capture of <http://www.billionauto.com>). This advertisement includes the following statements:

- a. **“New Buicks starting at \$249 Mo.”**
- b. **“0% 72 Mo. Toyota Certified”**
- c. **“Toyota 2.9% Financing”**

## Complaint

d. **“2.9% Financing GMC”**

No additional information regarding the cost or terms of financing a vehicle appears on this website.

6. Respondent also has disseminated or has caused to be disseminated advertisements promoting consumer leases, as the terms “advertisement” and “consumer lease” are defined in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended, copies of which are attached as Exhibits C and D (online newspaper advertisements). Respondent’s advertisements promoting consumer leases contain the following statement:

**\$199** lease  
/mo.

The term “lease” appears in fine print. No additional information regarding the cost or terms of leasing a vehicle appears in these advertisements.

**VIOLATION OF THE FEDERAL TRADE COMMISSION  
ACT****Misrepresentation of Financing Terms**

7. Through the means described in Paragraph 4, Respondent has represented expressly or by implication that, when a consumer trades in a used vehicle in order to purchase another vehicle, Respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan.

8. In truth and in fact, in many instances, when a consumer trades in a used vehicle with a loan balance that exceeds the vehicle’s value (*i.e.* the trade-in has negative equity) in order to purchase another vehicle, Respondent will not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, Respondent includes the amount of the negative equity in the loan for the newly purchased vehicle.

## Complaint

9. Therefore, the representation set forth in Paragraph 7 of this Complaint was, and is, false or misleading in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**VIOLATIONS OF THE TRUTH IN LENDING ACT AND  
REGULATION Z**

10. Under Section 144 of the TILA and Section 226.24(d) of Regulation Z, advertisements promoting closed-end credit in consumer credit transactions are required to make certain disclosures if they state any of several terms, such as the monthly payment (“TILA triggering terms”). In addition, the rate of the finance charge must be stated as an “annual percentage rate” using that term or the abbreviation “APR.” 15 U.S.C. § 1664; 12 C.F.R. § 226.24(c).

11. Respondent’s advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, are subject to the requirements of the TILA and Regulation Z.

**Failure to Disclose or Disclose Clearly and Conspicuously  
Required Credit Information**

12. Respondent’s advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, have included TILA triggering terms, but have failed to disclose or disclose clearly and conspicuously, additional terms required by the TILA and Regulation Z, including one or more of the following:

- a. The amount or percentage of the downpayment.
- b. The terms of repayment, which reflect the repayment obligations over the full term of the loan, including any balloon payment.
- c. The “annual percentage rate,” using that term, and, if the rate may be increased after consummation, that fact.

## Complaint

13. Therefore, the practices set forth in Paragraph 12 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. § 1664, and Section 226.24(d) of Regulation Z, 12 C.F.R. § 226.24(d), as amended.

**Failure to State Rate of Finance Charge as Annual Percentage Rate**

14. Respondent's advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 5, have stated a rate of finance charge without stating that rate as an "annual percentage rate" using that term or the abbreviation "APR."

15. Therefore, the practices set forth in Paragraph 14 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. § 1664, and Section 226.24(c) of Regulation Z, 12 C.F.R. § 226.24(c).

**VIOLATION OF THE CONSUMER LEASING ACT AND REGULATION M**

16. Under Section 184 of the CLA and Section 213.7 of Regulation M, advertisements promoting consumer leases are required to make certain disclosures if they state any of several terms, such as the amount of any payment ("CLA triggering terms"). 15 U.S.C. § 1667c, 12 C.F.R. § 213.7.

17. Respondent's advertisements promoting consumer leases, including but not necessarily limited to those described in Paragraph 6, are subject to the requirements of the CLA and Regulation M.

**Failure to Disclose or Disclose Clearly and Conspicuously Required Lease Information**

18. Respondent's advertisements promoting consumer leases, including but not necessarily limited to those described in Paragraph 6, have included CLA triggering terms, but have failed to disclose or disclose clearly and conspicuously additional terms required by the CLA and Regulation M, including one or more of the following:

## Decision and Order

- a. That the transaction advertised is a lease.
- b. The total amount of any initial payments required on or before consummation of the lease or delivery of the property, whichever is later.
- c. Whether or not a security deposit is required.
- d. The number, amount, and timing of scheduled payments.
- e. With respect to a lease in which the liability of the consumer at the end of the lease term is based on the anticipated residual value of the property, that an extra charge may be imposed at the end of the lease term.

19. Therefore, the practices set forth in Paragraph 18 of this Complaint have violated Section 184 of the CLA, 15 U.S.C. § 1667c, and Section 213.7 of Regulation M, 12 C.F.R. § 213.7.

20. The acts and practices of Respondent as alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, violations of the Truth in Lending Act and Regulation Z, and violations of the Consumer Leasing Act and Regulation M.

**THEREFORE**, the Federal Trade Commission, this first day of May 2012, has issued this complaint against Respondent.

By the Commission.

**DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of Respondent named in the caption hereof, and Respondent having been furnished thereafter with a copy of a draft complaint which the Bureau of

## Decision and Order

Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violation of the Federal Trade Commission Act (“FTC Act”), the Truth in Lending Act (“TILA”), and the Consumer Leasing Act (“CLA”); and

Respondent, its attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the FTC Act, the TILA, and the CLA, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent, Billion Auto, Inc., is a South Dakota corporation with its principal office or place of business at 3401 West 41st Street, Sioux Falls, South Dakota, 57106.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent, and the proceeding is in the public interest.

## Decision and Order

**ORDER****DEFINITIONS**

For the purposes of this order, the following definitions shall apply:

- A. “Advertisement” shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.
- B. “Clearly and conspicuously” shall mean as follows:
  - 1. In a print advertisement, the disclosure shall be in a type size, location, and in print that contrasts with the background against which it appears, sufficient for an ordinary consumer to notice, read, and comprehend it.
  - 2. In an electronic medium, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade and appear on the screen for a duration and in a location sufficient for an ordinary consumer to read and comprehend it.
  - 3. In a television or video advertisement, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade, and appear on the screen for a duration, and in a location, sufficient for an ordinary consumer to read and comprehend it.
  - 4. In a radio advertisement, the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
  - 5. In all advertisements, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of

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the disclosure shall be used in any advertisement or promotion.

- C. “Consumer credit” shall mean credit offered or extended to a consumer primarily for personal, family, or household purposes.
- D. “Consumer lease” shall have the same meaning as that term is defined in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended.
- E. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- F. “Motor vehicle” shall mean
  - 1. any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
  - 2. recreational boats and marine equipment;
  - 3. motorcycles;
  - 4. motor homes, recreational vehicle trailers, and slide-in campers; and
  - 5. other vehicles that are titled and sold through dealers.

**I.**

**IT IS HEREBY ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with any advertisement to promote, directly or indirectly, the purchase, financing, or leasing of automobiles, in or affecting commerce, shall not, in any manner, expressly or by implication:

- A. Misrepresent that when a consumer trades in a used motor vehicle (“trade-in vehicle”) in order to purchase another motor vehicle (“newly purchased vehicle”), Respondent will pay any remaining loan balance on

## Decision and Order

the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan; or

- B. Misrepresent any material fact regarding the cost and terms of financing or leasing any newly purchased vehicle.

**II.**

**IT IS FURTHER ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with an advertisement to promote, directly or indirectly, any extension of consumer credit, in or affecting commerce, shall not in any manner, expressly or by implication:

- A. State the amount or percentage of any down payment, the number of payments or period of repayment, the amount of any payment, or the amount of any finance charge, without disclosing clearly and conspicuously all of the following terms:
  - 1. The amount or percentage of the down payment;
  - 2. The terms of repayment; and
  - 3. The annual percentage rate, using the term “annual percentage rate” or the abbreviation “APR.” If the annual percentage rate may be increased after consummation of the credit transaction, that fact must also be disclosed; or
- B. State a rate of finance charge without stating the rate as an “annual percentage rate” or the abbreviation “APR,” using that term.
- C. Fail to comply in any respect with Regulation Z, 12 C.F.R. § 226, as amended, and the Truth in Lending Act, as amended, 15 U.S.C. §§ 1601-1667.

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**III.**

**IT IS FURTHER ORDERED** that Respondent, directly or through any corporation, subsidiary, division, or other device, in connection with an advertisement to promote, directly or indirectly, any consumer lease, in or affecting commerce, shall not, in any manner, expressly or by implication:

- A. State the amount of any payment or that any or no initial payment is required at lease signing or delivery, if delivery occurs after consummation, without disclosing clearly and conspicuously the following terms:
1. That the transaction advertised is a lease;
  2. The total amount due at lease signing or delivery;
  3. Whether or not a security deposit is required;
  4. The number, amounts, and timing of scheduled payments; and
  5. That an extra charge may be imposed at the end of the lease term in a lease in which the liability of the consumer at the end of the lease term is based on the anticipated residual value of the vehicle; or
- B. Fail to comply in any respect with Regulation M, 12 C.F.R. § 213, as amended, and the Consumer Leasing Act, 15 U.S.C. §§ 1667-1667f, as amended.

**IV.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

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- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**V.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

**VI.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondent learns less than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required

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by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC, 20580. The subject line must begin: FTC v. Billion Auto.

**VII.**

**IT IS FURTHER ORDERED** that Respondent and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

**VIII.**

This order will terminate on May 1, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any Respondent that is not named as a defendant in such complaint;
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the

## Analysis to Aid Public Comment

later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen not participating.

### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC”) has accepted, subject to final approval, an agreement containing a consent order from Billion Auto, Inc. The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

The respondent is a motor vehicle dealer. The matter involves its advertising of the purchase, financing, and leasing of its motor vehicles. According to the FTC complaint, respondent has represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondent will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. The complaint alleges that in fact, when a consumer trades in a used vehicle with negative equity (*i.e.* the loan balance on the vehicle exceeds the vehicle’s value) in order to purchase another vehicle, respondent does not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, the respondent includes the amount of the negative equity in the loan for the newly purchased vehicle. The complaint alleges therefore that the representation is false or misleading in violation of Section 5 of the FTC Act. In addition, the complaint alleges violations of the Truth in Lending

## Analysis to Aid Public Comment

Act (“TILA”) and Regulation Z for failing to disclose certain costs and terms when advertising credit. The complaint also alleges a violation of the Consumer Leasing Act (“CLA”) and Regulation M for failing to disclose the costs and terms of certain leases offered.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I of the proposed order prohibits the respondent from misrepresenting that it will pay the remaining loan balance on a consumer’s trade-in vehicle such that the consumer will have no obligation for any amount of that loan. It also prohibits misrepresenting any other material fact relating to the financing or leasing of a motor vehicle.

Part II of the proposed order addresses the TILA allegations. It requires clear and conspicuous TILA/Regulation Z disclosures when advertising any of the relevant triggering terms with regard to issuing consumer credit. It also requires that if any finance charge is advertised, the rate be stated as an “annual percentage rate” using that term or the abbreviation “APR.” In addition, Part II prohibits any other violation of TILA or Regulation Z.

Part III of the proposed order addresses the CLA allegation. It requires that the respondent clearly and conspicuously make all of the disclosures required by CLA and Regulation M if it states relevant triggering terms, including the monthly lease payment. In addition, Part III prohibits any other violation of CLA and Regulation M.

Part IV of the proposed order requires respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements. Part V requires that respondent provide copies of the order to certain of its personnel. Part VI requires notification of the Commission regarding changes in corporate structure that might affect compliance obligations under the order. Part VII requires the respondent to file compliance reports with the Commission. Finally, Part VIII is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

*Analysis to Aid Public Comment*

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

## Complaint

## IN THE MATTER OF

**CVS CAREMARK CORPORATION**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4357; File No. 112 3210*  
*Complaint, May 3, 2012 – Decision, May 3, 2012*

This consent order addresses CVS Caremark Corporation's ("CVSC") marketing and sales of Medicare drug plans and Medicare Part D drugs. The complaint alleges that respondent, through its subsidiary RxAmerica, violated Section 5 of the FTC Act by representing that the prices of covered Medicare Part D prescription drugs, as posted on Plan Finder and on the websites of RxAmerica and other third parties from approximately 2007 until the end of 2008, were accurate estimates of the prices that beneficiaries would pay for those drugs at CVS and Walgreens, when the prices charged to RxAmerica beneficiaries who purchased their covered Part D generic drugs from CVS Pharmacy or Walgreens during the relevant time period were significantly higher – in some cases as much as ten times higher – than the prices posted on those websites. The consent order prohibits CVSC from misrepresenting the price or cost of Medicare Part D prescription drugs, or other prices or costs associated with Medicare Part D prescription drug plans.

*Participants*

For the *Commission: Malcolm Catt, Philip Eisenstat, Andrew Kushner, Ryan Mehm, Lisa Schifferle and Meredyth Smith Andrus.*

For the *Respondent: Robert Kidwell and Bruce Sokler, Mintz Levin; and Seth Silber, Wilson Sonsini.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that CVS Caremark Corporation (hereinafter, "CVSC" or "Respondent"), through its subsidiary RxAmerica, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent is a Delaware corporation with its principal office or place of business at One CVS Drive, Woonsocket,

### Complaint

Rhode Island 02895. Respondent acquired Longs Drug Store Corporation (“Longs”) on October 30, 2008. Prior to October 30, 2008, RxAmerica LLC (“RxAmerica”) was a subsidiary entity of Longs.

2. The acts and practices of Respondent as alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

3. Respondent advertises, markets, promotes, offers to sell, sells and distributes its products and services throughout the United States, including Medicare drug plans (as approved in accordance with the Medicare Prescription Drug Improvement and Modernization Act, 42 U.S.C. § 1395w *et seq.*) and covered Medicare Part D drugs (as defined in 42 U.S.C. § 1395w-102(e)).

## **FACTS**

### **Background**

4. Medicare Part D is a prescription drug benefit for consumers with Medicare coverage, primarily senior citizens and persons with disabilities (“beneficiaries”). To obtain Part D benefits, beneficiaries must enroll in a Medicare drug plan administered by an insurer or other private company approved by the Centers for Medicare & Medicaid Services (“CMS”). Each such insurer or other private company is responsible for creating a network of pharmacies where beneficiaries can fill their prescriptions.

5. Respondent currently owns subsidiaries, including RxAmerica, offering multiple Medicare drug plans.

6. Beneficiaries initially sign up for a Medicare drug plan when they first become eligible for Medicare by age or disability. Every year during a period known as “open enrollment,” beneficiaries have an opportunity to enroll in a new Medicare drug plan or remain in the same plan for the following calendar year.

7. Medicare drug plans differ in cost and offer a variety of benefits. Beneficiaries generally have cost sharing obligations

## Complaint

until the total cost of their drugs reaches what is known as the coverage gap or “donut hole,” at which point the beneficiary pays the full cost of the drugs. If the beneficiary’s spending reaches a certain level, he exits the donut hole and enters a phase known as catastrophic coverage in which he is only responsible for paying a small copayment or coinsurance amount for each drug. Beneficiaries with low incomes are eligible for extra subsidies in the form of lower or no premiums, lower copayments or coinsurance, and coverage in the donut hole. 42 U.S.C. § 1395w-114.

8. Beneficiaries can shop for a Medicare drug plan by looking up plan benefits and drug costs on a provider’s website, by going onto CMS’ Medicare website and using the web-based tool known as Plan Finder, or by visiting other third-party websites where such information is posted. Every two weeks, Medicare drug plans are required by law to send their drug prices to CMS for posting on Plan Finder and to attest to the accuracy of those prices. Beneficiaries enter on Plan Finder the drugs they take and the pharmacy they use, and Plan Finder identifies potential Medicare drug plans based on information supplied to CMS by each Medicare drug plan.

9. Beneficiaries rely on the information posted on Plan Finder when selecting a Medicare drug plan because Plan Finder calculates the beneficiary’s estimated costs for any given plan and projects which plan will keep the beneficiary out of the donut hole the longest and which plan will have the lowest overall cost.

**RxAmerica Incident**

10. In 2007, RxAmerica owed money to CVS Pharmacy (a subsidiary of CVSC) and Walgreens. Rather than pay the pharmacies directly, RxAmerica instead decided to increase the reimbursement rate to those pharmacies for generic drugs purchased by plan beneficiaries. RxAmerica started reimbursing CVS and Walgreens at rates sometimes ten times as much as it was reimbursing other pharmacies for the same drugs. Because the total cost of a drug is comprised of the beneficiary’s copayment plus the pharmacy’s reimbursement rate, beneficiaries were adversely affected by this reimbursement structure, as described below.

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11. The higher reimbursement rates were not reflected in the pricing data RxAmerica sent to CMS for posting on Plan Finder, nor were they included in the prices RxAmerica posted on its website or sent to third-party websites. Therefore, beneficiaries seeking a Medicare drug plan through Plan Finder (or on RxAmerica's website or third-party websites) during this period saw a set of estimates for prices of drugs at CVS and Walgreens that had no bearing on the actual prices charged at these pharmacies.

12. For example, during 2008, RxAmerica represented to beneficiaries through prices posted on Plan Finder, on its website, and on third-party websites, that the price of gabapentin 600mg, a generic drug used to treat epileptic seizures, at CVS was \$26.83. In reality, RxAmerica was paying CVS \$257.70, almost ten times that amount. Similarly, RxAmerica represented on its website, on third-party websites, and on Plan Finder, that the price of megestrol, a generic drug used to relieve breast cancer symptoms, at CVS was \$55.68, whereas RxAmerica actually was paying CVS \$305.89, more than five times that amount. In another example, during 2008, RxAmerica represented the price of omeprazole 20mg, a drug used to treat ulcers and gastroesophageal reflux disease, at Walgreens was \$22.04, whereas RxAmerica actually was paying Walgreens \$162.00, more than seven times that amount.

13. As a result of this reimbursement structure, many beneficiaries using CVS and Walgreens stores ran through their benefits coverage at faster rates than they would have based on the posted prices. Many beneficiaries, therefore, unexpectedly entered the donut hole and became responsible for the total cost of their prescription drugs, with no opportunity to change plans until the next calendar year. Further, when most beneficiaries filled a prescription at a CVS or Walgreens store, they would have paid only a copayment at the point of sale and may not have been aware of the pharmacy's reimbursement rate until they reached the donut hole.

14. In late 2007 and early 2008, RxAmerica beneficiaries harmed by this conduct began to complain to RxAmerica about the discrepancies between the prices listed on Plan Finder (as well

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as on RxAmerica's website and third-party websites) and the prices at CVS and Walgreens stores.

15. RxAmerica became aware no later than January 2008 that its reimbursement methods were forcing some beneficiaries prematurely into the donut hole. Nonetheless, the discrepancy between the prices posted online and the actual reimbursement rates to CVS and Walgreens continued until at least November 2008.

16. Respondent's conduct injured many beneficiaries.

**VIOLATIONS OF THE FTC ACT**

17. Through the means described in Paragraphs 10 through 16, Respondent has represented, directly or indirectly, expressly or by implication, that the prices of covered Medicare Part D drugs at various pharmacies as posted on Plan Finder and on the websites of RxAmerica and other third parties, were accurate estimates of the prices that beneficiaries would pay for those drugs in those pharmacies.

18. In truth and in fact, the prices of covered Medicare Part D prescription drugs in various pharmacies as posted on Plan Finder and on the websites of RxAmerica and other third parties, were not accurate estimates of the prices that consumers would pay for those drugs in those pharmacies. Rather, the prices charged to consumers who purchased their covered Part D drugs from CVS or Walgreens, were significantly higher than the prices posted on those websites.

19. Therefore, the representations set forth in Paragraph 17 of this Complaint were, and are, false or misleading, and the making of such representations constitutes a deceptive act or practice in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C. § 45(a).

**THEREFORE**, the Federal Trade Commission this third day of May, 2012, has issued this Complaint against Respondent.

By the Commission.

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondent named in the caption hereof, and the Respondent having been furnished thereafter with a copy of a draft Complaint that the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondent with violation of the Federal Trade Commission Act, 15 U.S.C. § 41 et seq.;

The Respondent, its attorney, and counsel for the Commission having thereafter executed an Agreement Containing Consent Order (“Consent Agreement”), an admission by the Respondent of all the jurisdictional facts set forth in the aforesaid draft Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by the Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waives and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it has reason to believe that the Respondent has violated the said Act, and that a Complaint should issue stating its charges in that respect, and having thereupon accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and enters the following Order:

1. Respondent CVS Caremark Corporation is a Delaware corporation with its principal office or place of business at One CVS Drive, Woonsocket, Rhode Island 02895.

## Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. Unless otherwise specified, “Respondent” or “CVSC” means CVS Caremark Corporation, a corporation, its successors and assigns and its officers, agents, representatives, and employees.
- B. “Medicare Part D prescription drug” means a covered Part D drug, as defined in 42 U.S.C. § 1395w-102(e), that can only be obtained by means of a physician’s or other authorized health practitioner’s prescription and that is dispensed under a Medicare Part D prescription drug plan, as defined below.
- C. “Medicare Part D prescription drug plan” means Medicare Part D prescription drug coverage that is offered pursuant to a contract between the Centers for Medicare and Medicaid Services (CMS) and Respondent.
- D. “Medicare Part D” means “qualified prescription drug coverage” administered by the United States federal government pursuant to the Medicare Prescription Drug Improvement and Modernization Act (“MMA”), 42 U.S.C. § 1395w *et seq.*
- E. “Medicare Part D coverage gap” means the gap that occurs after a Medicare Part D beneficiary passes the initial coverage limit at which point the prescription drug plan does not cover any cost of prescription drugs until the beneficiary’s out of pocket costs reach a statutory threshold, pursuant to the MMA, 42 U.S.C. §

## Decision and Order

1395w-102(b). The gap is often referred to as the “donut hole.”

- F. “Plan Finder” means CMS’ online tool (available at [www.medicare.gov/find-a-plan](http://www.medicare.gov/find-a-plan)) used by beneficiaries to compare and select from among available Medicare Part D prescription drug plans in their area.
- G. “Beneficiary” means any Part D eligible individual as defined in 42 U.S.C. § 1395w-151(a)(4).
- H. “Enrollee” means any beneficiary enrolled in the RxAmerica prescription drug plans who was not eligible for a full low-income subsidy as set forth in 42 U.S.C. § 1395w-114(a)(1).
- I. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- J. The terms “and” and “or” in this order shall be construed conjunctively or disjunctively respectively as necessary, to make the applicable sentence or phrase inclusive rather than exclusive.

**I.**

**IT IS ORDERED** that Respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, and those persons in active concert or participation with them who receive actual notice of this order by personal service or otherwise, in connection with the marketing, advertising, promotion, distribution, offer for sale, sale or administration of Medicare Part D prescription drugs and Medicare Part D prescription drug plans, in or affecting commerce, shall not misrepresent, or assist others in misrepresenting, in any manner, expressly or by implication, the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans.

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**II.**

**IT IS FURTHER ORDERED** that Respondent shall pay to the Federal Trade Commission the sum of \$5 million. This payment shall be made in the following manner:

- A. This payment shall be made by wire transfer made payable to the Federal Trade Commission, the payment to be made no later than five (5) days after the date that this order becomes final.
- B. In the event of default on any obligation to make payment under this order, interest, computed pursuant to 28 U.S.C. § 1961(a), shall accrue from the date of default to the date of payment.
- C. All funds paid to the Commission pursuant to this order shall be deposited into an account administered by the Commission or its agents to be used for equitable relief, including but not limited to consumer redress, and any attendant expenses for the administration of such equitable relief. In the event that direct redress to consumers is wholly or partially impracticable or funds remain after the redress is completed, the Commission may apply any remaining funds for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Respondent's practices alleged in the Complaint. Any funds not used for such equitable relief shall be deposited to the United States Treasury as disgorgement. Respondent shall have no right to challenge the Commission's choice of remedies under this Section. Respondent shall have no right to contest the manner of distribution chosen by the Commission. No portion of any payment under the judgment herein shall be deemed a payment of any fine, penalty, or punitive assessment.
- D. Respondent relinquishes all dominion, control, and title to the funds paid to the fullest extent permitted by law. Respondent shall make no claim to or demand

## Decision and Order

return of the funds, directly or indirectly, through counsel or otherwise.

- E. Respondent agrees that the facts as alleged in the Complaint filed in this action shall be taken as true without further proof in any bankruptcy case or subsequent civil litigation pursued by the Commission to enforce its rights to any payment or money judgment pursuant to this final order, including but not limited to a nondischargeability complaint in any bankruptcy case. Respondent further stipulates and agrees that the facts alleged in the Complaint establish all elements necessary to sustain an action pursuant to, and that this order shall have collateral estoppel effect for purposes of, Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A).
- F. In accordance with 31 U.S.C. § 7701, Respondent is hereby required, unless it has done so already, to furnish to the Commission its taxpayer identifying numbers, which shall be used for the purposes of collecting and reporting on any delinquent amount arising out of Respondent's relationship with the government.
- G. Proceedings instituted under this Section are in addition to, and not in lieu of, any other civil or criminal remedies that may be provided by law, including any other proceedings the Commission may initiate to enforce this order. Nothing in this order shall have precedential or preclusive effect as to any claim or issue asserted by any third party in any other proceeding.

### III.

**IT IS FURTHER ORDERED** that Respondent shall, no later than thirty (30) days after the date of entry of this order, deliver to the Commission a list in the form of a declaration submitted under penalty of perjury in accordance with 28 U.S.C. § 1746, of (1) all RxAmerica Medicare Part D enrollees who purchased at least one

## Decision and Order

Medicare Part D generic prescription drug from Walgreens or CVS pharmacies, between June 1, 2007 and December 31, 2008.

- A. Respondent shall produce the list electronically in Excel, Access, or SQL and formatted to include (if available) in separate fields for each enrollee the following: (1) First Name, Middle Name, Last Name, Alias-Surname; (2) last known mailing address recorded as Address 1, Address 2, City, State, Zip Code and Country; (3) using a reasonable methodology provided to the Commission the total amount paid by the enrollee for prescription drugs, including but not limited to copayments, coinsurance, deductibles, and Medicare Part D coverage gap expenses; (4) the total amount the enrollee would have paid if his or her generic prescription drug purchases at CVS Pharmacy or Walgreens had been adjudicated at the RxAmerica MAC price applicable for the day the claim adjudicated instead of at the actual adjudicated price; this amount shall include but not be limited to copayments, coinsurance, deductibles, and Medicare Part D coverage gap expenses; (5) the difference between Subsection (3) and Subsection (4) in enrollee cost sharing amounts, including but not limited to copayments, coinsurance, deductibles, and Medicare Part D coverage gap expenses; and (6) if available, the enrollee's last known Telephone Number(s) and Email address(es). The list shall include identifying row header columns or any other identifying codes along with the supporting code key.
- B. In compiling the information required by Section IIIA, Respondent shall conduct a diligent search of records in its possession, custody, or control, including but not limited to computer files, sales records, invoices, complaints and correspondence. Respondent shall produce the list in an encrypted and secure fashion as directed by the Commission. Along with the list, Respondent shall specify the version of the software program used to create the list and Respondent must declare under penalty of perjury to its best knowledge, information and belief, that the list is true, accurate,

## Decision and Order

and complete. If Commission counsel requests further related information in writing, Respondent shall provide it within fourteen (14) days from the date of the request.

**IV.**

**IT IS FURTHER ORDERED** that Respondent shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All submissions to the Centers for Medicare & Medicaid Services containing representations regarding the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans;
- B. All representations regarding the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans;
- C. All Medicare Part D prescription drug plan pricing data compiled in accordance with CMS requirements and internal policies and procedures that was relied upon in disseminating representations set forth in Sections IV(A) and IV(B) regarding the price or cost of Medicare Part D prescription drugs or other prices or costs associated with Medicare Part D prescription drug plans;
- D. All pricing data for adjudicated claims and all complaints and any other communications with consumers or with governmental or consumer protection organizations that contradict, qualify, or call into question the representations set forth in Sections IV(A)-IV(C) of this order, or the basis relied upon for such representations; and
- E. All acknowledgments of receipt of this order obtained pursuant to Section V.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that Respondent shall deliver copies of the order as directed below:

- A. Respondent shall deliver a copy of this order to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities relating to the subject matter of this order. Respondent shall deliver this order to such current subsidiaries and personnel within thirty (30) days after service of this order, and to such future subsidiaries and personnel within thirty (30) days after respondent acquires the subsidiary or the person assumes such position or responsibilities.
- B. Respondent must secure a signed and dated statement acknowledging receipt of this order, within thirty (30) days of delivery, from all persons receiving a copy of the order pursuant to this Section.

**VI.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including, but not limited to: a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation(s) about which Respondent learns fewer than thirty (30) days prior to the date such action is to take place, Respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier (not the U.S. Postal Service) to the Associate Director of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington,

## Decision and Order

D.C. 20580, with the subject line *In the Matter of CVS Caremark Corp., FTC File No. 112 3210, Docket No. C-4357. Provided, however,* that in lieu of overnight courier, notices may be sent by first-class mail, but only if an electronic version of any such notice is contemporaneously sent to the Commission at [Debrief@ftc.gov](mailto:Debrief@ftc.gov).

**VII.**

**IT IS FURTHER ORDERED** that Respondent within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit an additional true and accurate written report.

**VIII.**

This order will terminate on May 3, 2032, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however,* that the filing of such a complaint will not affect the duration of:

- A. any Section in this order that terminates in fewer than twenty (20) years;
- B. this order's application to any respondent that is not named as a defendant in such complaint; and
- C. this order if such complaint is filed after the order has terminated pursuant to this Section.

*Provided, further,* that if such complaint is dismissed or a federal court rules that Respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order as to Respondent will terminate according to this Section as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing

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such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen not participating.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission has accepted, subject to final approval, a consent agreement from CVS Caremark Corporation (“CVSC”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement’s proposed order.

CVSC is a pharmacy services company that, among other things, markets and sells Medicare drug plans and Medicare Part D drugs. CVSC currently owns multiple subsidiaries, including RxAmerica, that offer Medicare Part D prescription drug plans. Medicare Part D is a prescription drug benefit for consumers with Medicare coverage, primarily seniors and persons with disabilities. To obtain Part D benefits, beneficiaries must enroll in a Medicare drug plan administered by an insurer or other private company approved by the Centers for Medicare & Medicaid Services (“CMS”). Beneficiaries can shop for a Medicare drug plan by looking up plan benefits and drug costs on a provider’s website, by going onto CMS’ Medicare website and using the web-based tool known as Plan Finder, or by visiting other third-party websites where such information is posted. Once enrolled, beneficiaries generally have cost sharing obligations until the total cost of their drugs reaches what is known as the coverage gap or

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“donut hole,” at which point the beneficiary pays the full cost of the drugs.

The Commission’s complaint alleges that CVSC, through its subsidiary RxAmerica, violated Section 5 of the FTC Act by misrepresenting that the prices of covered Medicare Part D prescription drugs, as posted on Plan Finder and on the websites of RxAmerica and other third parties from approximately 2007 until the end of 2008, were accurate estimates of the prices that beneficiaries would pay for those drugs at CVS and Walgreens. Rather, the prices charged to RxAmerica beneficiaries who purchased their covered Part D generic drugs from CVS Pharmacy or Walgreens during the relevant time period were significantly higher – in some cases as much as ten times higher – than the prices posted on those websites. As a result of this pricing discrepancy, many RxAmerica beneficiaries using CVS Pharmacy and Walgreens stores ran through their benefits coverage at faster rates than they would have based on the posted prices. Many beneficiaries, therefore, unexpectedly entered the donut hole and became responsible for the total cost of their prescription drugs, with no opportunity to change plans until the next calendar year.

To remedy the violations charged and to prevent CVSC from engaging in the future in practices similar to those alleged in the complaint, the proposed order contains injunctive provisions and a consumer redress program.

Section I of the proposed order prohibits CVSC from misrepresenting the price or cost of Medicare Part D prescription drugs, or other prices or costs associated with Medicare Part D prescription drug plans.

Section II of the proposed order requires CVSC, within five (5) days of the date the order becomes final, to pay the Commission \$5 million for consumer redress and administrative costs. This provision specifies that the Commission may apply any remaining funds after redress is completed for such other equitable relief as it determines to be reasonably related to CVSC’s practices alleged in the complaint. Any remaining funds not used for such equitable relief shall be deposited into the United States Treasury as disgorgement. Section III of the

## Analysis to Aid Public Comment

proposed consent order requires CVSC to produce certain information necessary for the Commission to administer consumer redress.

Sections IV through VIII of the proposed order are reporting and compliance provisions. Section IV requires CVSC to retain documents relating to its compliance with the order for a five (5) year period. Section V requires dissemination of the order now and in the future to all current and future subsidiaries, current and future principals, officers, directors, and managers, and to persons with responsibilities relating to the subject matter of the order. It also requires CVSC to secure a signed and dated statement acknowledging receipt of the order from all persons who receive a copy of the order pursuant to Section V. Section VI ensures notification to the Commission of changes in corporate status. Section VII mandates that CVSC submit a compliance report to the Commission within sixty (60) days, and periodically thereafter as requested. Section VIII is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify the proposed order’s terms in any way.

## Complaint

## IN THE MATTER OF

**KEY HYUNDAI OF MANCHESTER, LLC  
AND  
HYUNDAI OF MILFORD, LLC**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT, THE TRUTH IN LENDING ACT, THE CONSUMER LEASING ACT, REGULATION Z, AND REGULATION M

*Docket No. C-4358; File No. 112 3204  
Complaint, May 4, 2012 – Decision, May 4, 2012*

This consent order addresses Key Hyundai of Manchester, LLC, and Hyundai of Milford, LLC's advertising of the purchase, financing, and leasing of their motor vehicles. The complaint alleges that respondents have represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondents will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan, but do not. In addition, the complaint alleges violations of the Truth in Lending Act and Regulation Z for failing to disclose certain costs and terms when advertising credit and a violation of the Consumer Leasing Act and Regulation M for failing to disclose the costs and terms of certain leases offered. The consent order prohibits the respondents from misrepresenting that they will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan or any other material fact relating to the financing or leasing of a motor vehicle.

*Participants*

For the *Commission*: *Gregory A. Ashe* and *Robin Thurston*.

For the *Respondents*: *Robert C. Byerts*, *Bass Sox Mercer*.

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Key Hyundai of Manchester, LLC, and Hyundai of Milford, LLC, corporations ("Respondents"), have violated provisions of the Federal Trade Commission Act ("FTC Act"), the Truth in Lending Act ("TILA"), and the Consumer Leasing Act ("CLA"), and it appearing to the Commission that this proceeding is in the public interest, alleges:

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1. Respondent Key Hyundai of Manchester, LLC, (“Manchester”) is a Connecticut limited liability corporation with its principal office or place of business at 21 Hartford Turnpike, Vernon, CT, 06066. Manchester offers automobiles for sale and lease.

2. Respondent Hyundai of Milford, LLC, (“Milford”) is a Connecticut limited liability corporation with its principal office or place of business at 566 Bridgeport Ave., Milford, CT, 06460. Milford offers automobiles for sale or lease.

3. Respondents advertise their automobiles for sale or lease jointly. Both Respondents are responsible for disseminating or causing to be disseminated the advertisements referenced herein.

4. The acts or practices of Respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

5. Since at least March 2010, Respondents have disseminated or have caused to be disseminated advertisements promoting the purchase, financing, and leasing of their automobiles.

6. Respondents’ advertisements include, but are not necessarily limited to, advertisements posted on the website YouTube.com, copies of which are attached as Exhibits A through C. These advertisements include the following statements:

- a. “I want your trade no matter how much you owe or what you’re driving. In fact I’ll pay off your trade when you upgrade to a nicer, newer vehicle.” (Exhibit A (DVD containing 5/27/11 capture of You Tube advertisement “Pay off Your Trade Sales Event at Key Hyundai of Manchester CT and Key Hyundai of Milford CT” at 0:08-0:11)).
- b. “We’ll pay off your lease or loan no matter how much you owe.” (*Id.* at 0:25-0:30).
- c. “[W]e will pay off your trade no matter what you owe.” (Exhibit B (Print-out of text accompanying You

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Tube advertisement “Pay off Your Trade Sales Event at Key Hyundai of Manchester CT and Key Hyundai of Milford CT”).

- d. “I’ll pay off your loan no matter what you owe.” (Exhibit C (DVD containing 7/14/11 capture of You Tube advertisement “Key Hyundai Drive Lucky March Sales” at 1:08-1:11)).

7. Respondents also have disseminated or have caused to be disseminated advertisements promoting credit sales and other extensions of closed-end credit in consumer credit transactions, as the terms “advertisement,” “closed-end credit,” “credit sale,” and “consumer credit” are defined in Section 226.2 of Regulation Z, 12 C.F.R. § 226.2, as amended, on the website YouTube.com, copies of which are attached as Exhibits B and D. These advertisements include the following statements:

- a. “We will get you into the car of your dreams, like a 2010 Hyundai Sonata with 0% financing for 72 months. For more information, visit us on the web at <http://keycars.com>.” (Exhibit B).
- b. “**2011 Hyundai Sonata \$199 Per Mo**” (Exhibit D (DVD containing 7/14/11 capture of You Tube advertisement “Key Hyundai April Sales Promotion” at 0:32-0:35)).
- c. “**2011 Hyundai Elantra \$149 Per Mo**” (*Id.* at 0:36-0:39).

No additional information regarding the cost or terms of financing a vehicle appears on this website.

8. Respondents also have disseminated or have caused to be disseminated at least one advertisement promoting consumer leases, as the terms “advertisement” and “consumer lease” are defined in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended, on their website, a copy of which is attached as Exhibit E (printout of 5/16/11 capture of web advertisement at 1). This advertisement includes the following statement:

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**“Lease for only \$159 / MO\*”**

No additional information regarding the cost or terms of leasing a vehicle appears in this advertisement.

**VIOLATION OF THE FEDERAL TRADE COMMISSION  
ACT****Misrepresentation of Financing Terms**

9. Through the means described in Paragraph 6, Respondents have represented expressly or by implication that, when a consumer trades in a used vehicle in order to purchase another vehicle, Respondents will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan.

10. In truth and in fact, in many instances, when a consumer trades in a used vehicle with a loan balance that exceeds the vehicle's value (*i.e.* the trade-in has negative equity) in order to purchase another vehicle, Respondents will not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, Respondents include some or all of the negative equity in the loan for the newly purchased vehicle.

11. Therefore, the representation set forth in Paragraph 9 of this Complaint was, and is, false or misleading, in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

**VIOLATIONS OF THE TRUTH IN LENDING ACT AND  
REGULATION Z**

12. Under Section 144 of the TILA and Section 226.24(d) of Regulation Z, advertisements promoting closed-end credit in consumer credit transactions are required to make certain disclosures if they state any of several terms, such as the monthly payment (“TILA triggering terms”). In addition, the rate of the finance charge must be stated as an “annual percentage rate” using that term or the abbreviation “APR.” 15 U.S.C. § 1664; 12 C.F.R. § 226.24(c).

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13. Respondents' advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 7, are subject to the requirements of the TILA and Regulation Z.

**Failure to Disclose or Disclose Clearly and Conspicuously  
Required Credit Information**

14. Respondents' advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 7, have included TILA triggering terms, but have failed to disclose or disclose clearly and conspicuously, additional terms required by the TILA and Regulation Z, including one or more of the following:

- a. The amount or percentage of the downpayment.
- b. The terms of repayment, which reflect the repayment obligations over the full term of the loan, including any balloon payment.
- c. The "annual percentage rate," using that term, and, if the rate may be increased after consummation, that fact.

15. Therefore, the practices set forth in Paragraph 14 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. § 1664, and Section 226.24(d) of Regulation Z, 12 C.F.R. § 226.24(d), as amended.

**Failure to State Rate of Finance Charge as Annual Percentage  
Rate**

16. Respondents' advertisements promoting closed-end credit, including but not necessarily limited to those described in Paragraph 7, have stated a rate of finance charge without stating that rate as an "annual percentage rate" using that term or the abbreviation "APR."

17. Therefore, the practices set forth in Paragraph 16 of this Complaint have violated Section 144 of the TILA, 15 U.S.C. §

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1664, and Section 226.24(c) of Regulation Z, 12 C.F.R. § 226.24(c).

**VIOLATION OF THE CONSUMER LEASING ACT AND  
REGULATION M**

18. Under Section 184 of the CLA and Section 213.7 of Regulation M, advertisements promoting consumer leases are required to make certain disclosures if they state any of several terms, such as the amount of any payment (“CLA triggering terms”). 15 U.S.C. § 1667c, 12 C.F.R. § 213.7.

19. Respondents’ advertisements promoting consumer leases, including but not necessarily limited to those described in Paragraph 8, are subject to the requirements of the CLA and Regulation M.

**Failure to Disclose or Disclose Clearly and Conspicuously  
Required Lease Information**

20. Respondents’ advertisements promoting consumer leases, including but not necessarily limited to those described in Paragraph 8, have included CLA triggering terms, but have failed to disclose or disclose clearly and conspicuously additional terms required by the CLA and Regulation M, including one or more of the following:

- a. The total amount of any initial payments required on or before consummation of the lease or delivery of the property, whichever is later.
- b. Whether or not a security deposit is required.
- c. The number, amount, and timing of scheduled payments.
- d. With respect to a lease in which the liability of the consumer at the end of the lease term is based on the anticipated residual value of the property, that an extra charge may be imposed at the end of the lease term.

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21. Therefore, the practices set forth in Paragraph 20 of this Complaint have violated Section 184 of the CLA, 15 U.S.C. § 1667c, and Section 213.7 of Regulation M, 12 C.F.R. § 213.7.

22. The acts and practices of Respondents as alleged in this complaint constitute deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the FTC Act, violations of the Truth in Lending Act and Regulation Z, and violations of the Consumer Leasing Act and Regulation M.

**THEREFORE**, the Federal Trade Commission, this fourth day of May, 2012, has issued this complaint against Respondents.

By the Commission, Commissioner Ohlhausen not participating.

**DECISION AND ORDER**

The Federal Trade Commission having initiated an investigation of certain acts and practices of Respondents named in the caption hereof, and Respondents having been furnished thereafter with a copy of a draft complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violation of the Federal Trade Commission Act (“FTC Act”), the Truth in Lending Act (“TILA”), and the Consumer Leasing Act (“CLA”); and

Respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order (“consent agreement”), an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other

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than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the FTC Act, the TILA, and the CLA, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such consent agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to section 2.34 of its Rules, now in further conformity with the procedure prescribed in § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Key Hyundai of Manchester, LLC, is a Connecticut limited liability corporation with its principal office or place of business at 21 Hartford Turnpike, Vernon, Connecticut, 06066.
2. Respondent Hyundai of Milford, LLC, is a Connecticut limited liability corporation with its principal office or place of business at 566 Bridgeport Ave., Milford, Connecticut, 06460.
3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For the purposes of this order, the following definitions shall apply:

- A. "Advertisement" shall mean a commercial message in any medium that directly or indirectly promotes a consumer transaction.

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- B. “Clearly and conspicuously” shall mean as follows:
1. In a print advertisement, the disclosure shall be in a type size, location, and in print that contrasts with the background against which it appears, sufficient for an ordinary consumer to notice, read, and comprehend it.
  2. In an electronic medium, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade and appear on the screen for a duration and in a location sufficient for an ordinary consumer to read and comprehend it.
  3. In a television or video advertisement, an audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. A video disclosure shall be of a size and shade, and appear on the screen for a duration, and in a location, sufficient for an ordinary consumer to read and comprehend it.
  4. In a radio advertisement, the disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it.
  5. In all advertisements, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any advertisement or promotion.
- C. “Consumer credit” shall mean credit offered or extended to a consumer primarily for personal, family, or household purposes.
- D. “Consumer lease” shall have the same meaning as that term is defined in Section 213.2 of Regulation M, 12 C.F.R. § 213.2, as amended.

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- E. “Material” shall mean likely to affect a person’s choice of, or conduct regarding, goods or services.
- F. “Motor vehicle” shall mean
1. any self-propelled vehicle designed for transporting persons or property on a street, highway, or other road;
  2. recreational boats and marine equipment;
  3. motorcycles;
  4. motor homes, recreational vehicle trailers, and slide-in campers; and
  5. other vehicles that are titled and sold through dealers.

**I.**

**IT IS HEREBY ORDERED** that Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with any advertisement to promote, directly or indirectly, the provision of consumer credit, in or affecting commerce, shall not, in any manner, expressly or by implication:

- A. Misrepresent that when a consumer trades in a used motor vehicle (“trade-in vehicle”) in order to purchase another motor vehicle (“newly purchased vehicle”), Respondents will pay any remaining loan balance on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan; or
- B. Misrepresent any material fact regarding the cost and terms of financing or leasing any newly purchased vehicle.

**II.**

**IT IS FURTHER ORDERED** that Respondents, directly or through any corporation, subsidiary, division, or other device, in

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connection with an advertisement to promote, directly or indirectly, any extension of consumer credit in or affecting commerce, shall not in any manner, expressly or by implication:

- A. State the amount or percentage of any down payment, the number of payments or period of repayment, the amount of any payment, or the amount of any finance charge, without disclosing clearly and conspicuously all of the following terms:
  - 1. The amount or percentage of the down payment;
  - 2. The terms of repayment; and
  - 3. The annual percentage rate, using the term “annual percentage rate” or the abbreviation “APR.” If the annual percentage rate may be increased after consummation of the credit transaction, that fact must also be disclosed; or
- B. State a rate of finance charge without stating the rate as an “annual percentage rate” or the abbreviation “APR,” using that term.
- C. Fail to comply in any respect with Regulation Z, 12 C.F.R. § 226, as amended, and the Truth in Lending Act, as amended, 15 U.S.C. §§ 1601-1667.

**III.**

**IT IS FURTHER ORDERED** that Respondents, directly or through any corporation, subsidiary, division, or other device, in connection with an advertisement to promote, directly or indirectly, any consumer lease, in or affecting commerce, shall not, in any manner, expressly or by implication:

- A. State the amount of any payment or that any or no initial payment is required at lease signing or delivery, if delivery occurs after consummation, without disclosing clearly and conspicuously the following terms:
  - 1. The total amount due at lease signing or delivery;

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2. Whether or not a security deposit is required;
  3. The number, amounts, and timing of scheduled payments; and
  4. That an extra charge may be imposed at the end of the lease term in a lease in which the liability of the consumer at the end of the lease term is based on the anticipated residual value of the vehicle; or
- B. Fail to comply in any respect with Regulation M, 12 C.F.R. § 213, as amended, and the Consumer Leasing Act, 15 U.S.C. §§ 1667-1667f, as amended.

**IV.**

**IT IS FURTHER ORDERED** that Respondents and their successors and assigns shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**V.**

**IT IS FURTHER ORDERED** that Respondents and their successors and assigns shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject

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matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

**VI.**

**IT IS FURTHER ORDERED** that Respondents and their successors and assigns shall notify the Commission at least thirty (30) days prior to any change in the corporation(s) that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which Respondents learn less than thirty (30) days prior to the date such action is to take place, Respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington, DC, 20580. The subject line must begin: FTC v. Key Hyundai.

**VII.**

**IT IS FURTHER ORDERED** that Respondents and their successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

## Analysis to Aid Public Comment

**VIII.**

This order will terminate on May 4, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint;
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that Respondents did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Ohlhausen not participating.

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission ("FTC") has accepted, subject to final approval, an agreement containing a consent order from Key Hyundai of Manchester, LLC, and Hyundai of Milford, LLC. The proposed consent order has been placed on the public record

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for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the FTC will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

The respondents are motor vehicle dealers. The matter involves their advertising of the purchase, financing, and leasing of their motor vehicles. According to the FTC complaint, respondents have represented that when a consumer trades in a used vehicle in order to purchase another vehicle, respondents will pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. The complaint alleges that in fact, when a consumer trades in a used vehicle with negative equity (*i.e.* the loan balance on the vehicle exceeds the vehicle's value) in order to purchase another vehicle, respondents do not pay off the balance of the loan on the trade-in vehicle such that the consumer will have no remaining obligation for any amount of that loan. Instead, the respondents include the amount of the negative equity in the loan for the newly purchased vehicle. The complaint alleges therefore that the representation is false or misleading in violation of Section 5 of the FTC Act. In addition, the complaint alleges violations of the Truth in Lending Act ("TILA") and Regulation Z for failing to disclose certain costs and terms when advertising credit. The complaint also alleges a violation of the Consumer Leasing Act ("CLA") and Regulation M for failing to disclose the costs and terms of certain leases offered.

The proposed order is designed to prevent the respondent from engaging in similar deceptive practices in the future. Part I of the proposed order prohibits the respondents from misrepresenting that they will pay the remaining loan balance on a consumer's trade-in vehicle such that the consumer will have no obligation for any amount of that loan. It also prohibits misrepresenting any other material fact relating to the financing or leasing of a motor vehicle.

Part II of the proposed order addresses the TILA allegations. It requires clear and conspicuous TILA/Regulation Z disclosures when advertising any of the relevant triggering terms with regard

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to issuing consumer credit. It also requires that if any finance charge is advertised, the rate be stated as an “annual percentage rate” using that term or the abbreviation “APR.” In addition, Part II prohibits any other violation of TILA or Regulation Z.

Part III of the proposed order addresses the CLA allegation. It requires that the respondents clearly and conspicuously make all of the disclosures required by CLA and Regulation M if it states relevant triggering terms, including the monthly lease payment. In addition, Part III prohibits any other violation of CLA and Regulation M.

Part IV of the proposed order requires respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements. Part V requires that respondent provide copies of the order to certain of its personnel. Part VI requires notification of the Commission regarding changes in corporate structure that might affect compliance obligations under the order. Part VII requires the respondent to file compliance reports with the Commission. Finally, Part VIII is a provision “sunsetting” the order after twenty (20) years, with certain exceptions.

The purpose of this analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order’s terms.

## Complaint

## IN THE MATTER OF

**MCWANE, INC.  
AND  
STAR PIPE PRODUCTS, LTD.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. 9351; File No. 101 0080  
Complaint, January 4, 2012 – Decision, May 8, 2012*

This consent order addresses Star Pipe Products, Ltd.'s business methods, which made it easier to coordinate price levels through an entity known as the Ductile Iron Fittings Research Association. The complaint alleges that Star Pipe Products violated Section 5 of the Federal Trade Commission Act by colluding with McWane to increase DIPF prices. The consent order prohibits the respondent from entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors to raise, fix, maintain, or stabilize prices or price levels, or engage in any other pricing action; or to allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

*Participants*

For the *Commission: J. Alex Ansaldo, Jeanine K. Balbach, Michael J. Bloom, Thomas H. Brock, Monica Castillo, Edward D Hassi, Linda M. Holleran, and Andrew K. Mann.*

For the *Respondents: Gregory S.C. Huffman, William Katz, Brian Stoltz and Nicole Williams, Thompson & Knight LLP; William Lavery, Joseph Ostoyich, and Andreas Stagard, Baker Botts LLP; and Thomas W. Thagard III and J. Alan Truitt, Maynard Cooper and Gale P.C.*

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission ("Commission"), having reason to believe that Respondents McWane, Inc. ("McWane") and Star Pipe Products, Ltd. ("Star") have violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, and it appearing to the

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Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues this Complaint stating its charges as follows:

**NATURE OF THE CASE**

1. This action concerns the collusive conduct of Respondents, and the exclusionary conduct of McWane, relating to the marketing and sale of ductile iron pipe fittings (“DIPF”).

2. Beginning in January 2008, McWane and Star, along with their competitor Sigma Corporation (“Sigma”), conspired to raise and stabilize the prices at which DIPF are sold in the United States. McWane, Sigma and Star (collectively, the “Sellers”) exchanged sales data in order to facilitate this price coordination.

3. The passage of the American Recovery and Reinvestment Act of 2009 (“ARRA”) in February 2009 significantly altered the competitive dynamics of the DIPF industry, and upset the terms of coordination among the Sellers. In the ARRA, the United States Congress allocated more than 6 billion dollars to water infrastructure projects, conditioned on the use of domestically produced materials, including DIPF, in those projects (the “Buy American” requirement).

4. At the time the ARRA was passed, McWane was the sole supplier of a full line of domestically produced DIPF in the most commonly used size ranges. Federal stimulus of the domestic DIPF market potentially left McWane in a position to reap a monopoly profit.

5. In response to the passage of the ARRA and its Buy American provision, Sigma, Star and others attempted to enter the domestic DIPF market in competition with McWane.

6. McWane maintained its monopoly in the domestic DIPF market through exclusionary conduct, including (i) entering into a distribution agreement with Sigma that eliminated Sigma as an actual potential entrant into the domestic DIPF market, and (ii) excluding actual and potential competitors, including Star, through the adoption and enforcement of exclusive dealing policies.

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7. Respondents' conduct has restrained competition and led to higher prices for both imported and domestically produced DIPF.

### **THE RESPONDENTS**

8. Respondent McWane is a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal place of business located at 2900 Highway 280, Suite 300, Birmingham, Alabama 35223. McWane manufactures, imports, markets and sells products for the waterworks industry, including DIPF.

9. At all times relevant herein, McWane has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

10. McWane's acts and practices, including the acts and practices alleged herein, are in or affect commerce in the United States, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

11. Respondent Star is a limited partnership organized, existing and doing business under and by virtue of the laws of the State of Texas, with its principal place of business located at 4018 Westhollow Parkway, Houston, Texas 77082. Star imports, markets and sells products for the waterworks industry, including DIPF.

12. At all times relevant herein, Star has been, and is now, a corporation as "corporation" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

13. Star's acts and practices, including the acts and practices alleged herein, are in or affect commerce in the United States, as "commerce" is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

### **THE DIPF INDUSTRY**

14. DIPF are a component of pipeline systems transporting drinking and waste water under pressurized conditions in

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municipal distribution systems and treatment plants. DIPF are used to join pipes, valves and hydrants in straight lines, and to change, divide or direct the flow of water. The end users of DIPF are typically municipal and regional water authorities.

15. DIPF are produced in a broad product line of more than 2000 unique configurations of size, shape and coating. The industry differentiates between “A Items,” or commonly used fittings used routinely and on almost every job, and “oddball” fittings that are either of unusual configuration or size, or both. Although approximately 80 percent of market demand may be serviced with a product line of 100 fittings, DIPF suppliers must be able to supply more than 1900 additional fittings to serve the remaining 20 percent of demand.

16. Independent wholesale distributors, known as “waterworks distributors,” are the primary channel of distribution of DIPF to end users. Waterworks distributors specialize in distributing products for water infrastructure projects, and generally handle the full spectrum of waterworks products, including pipes, DIPF, valves and hydrants. Waterworks distributors employ sales personnel dedicated to servicing the needs of end users, and are generally able to satisfy the needs of end users for rapid service by stocking inventory in relatively close proximity to project sites.

17. Direct sales of DIPF to end users, or to the utility contractors that often serve as the agent of the end user in purchasing and installing DIPF, are uncommon. End users and DIPF suppliers alike prefer to work through waterworks distributors with locations near project sites. As a result, DIPF suppliers need to distribute DIPF through local waterworks distributors in each region of the country in order to compete effectively in that region.

18. Both imported and domestically produced DIPF are commercially available. All of the Sellers sell imported DIPF. Before Star’s entry into domestic production in 2009, McWane was the sole domestic producer of a full line of small and medium-sized DIPF.

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19. The end user of DIPF specifies whether, on a particular project, it will accept both imported and domestically produced DIPF, or only domestically produced DIPF. This specification is often mandated by municipal code, or by state or federal law.

20. Domestically produced DIPF sold for use in projects specified as domestic only are sold at higher prices than imported or domestically produced DIPF sold for use in projects not specified as domestic only.

**THE RELEVANT MARKETS**

21. The relevant product market in which to evaluate Respondents' conduct is the marketing and sale of DIPF, and narrower relevant markets as contained therein (collectively, the "relevant DIPF markets"), including:

- a. DIPF for projects not specified as domestic only;
- b. DIPF for projects specified as domestic only; and
- c. DIPF of certain size ranges (*e.g.*, 24" in diameter and smaller).

22. In particular, the marketing and sale of domestically produced small and medium-sized (3-24" in diameter) DIPF for use in projects specified as domestic only constitutes a separate relevant product market (the "relevant domestic DIPF market").

23. There are no widely used substitutes for DIPF, and no other product significantly constrains the prices of DIPF.

24. Before and after the passage of the ARRA, some end users purchasing DIPF for use in projects specified as domestic only were unable to substitute imported DIPF, or any other product, for domestically produced DIPF. The passage of the ARRA and its Buy American requirement temporarily expanded the relevant domestic DIPF market.

25. The relevant geographic market is no broader than the United States. To compete effectively within the United States, DIPF suppliers need distribution assets and relationships within the United States. DIPF suppliers located outside the United

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States that lack such assets and relationships are unable to constrain the prices of DIPF suppliers that have such assets and relationships.

26. Each and every state within the United States is also a relevant geographic market, and smaller markets within the boundaries of many states exist as well. DIPF suppliers can and do engage in price discrimination based on customers' location. DIPF end users require local and expeditious service and support, and typically do not purchase DIPF from waterworks distributors located more than 200 miles away. Waterworks distributors typically do not resell DIPF to other waterworks distributors or end users outside their service areas in any substantial quantity. As a result, DIPF suppliers charge different prices in different states, and within certain regions within many states.

**THE RELEVANT DIPF MARKETS ARE CONDUCTIVE TO COLLUSION**

27. The relevant DIPF markets have several features that facilitate collusion among the Sellers, including product homogeneity, market concentration of DIPF suppliers, barriers to timely entry of new DIPF suppliers, inelastic demand at competitive prices, and uniform published prices.

- a. DIPF are commodity products produced to industry-wide standards. Product homogeneity enhances the Sellers' ability to collude on prices and to detect deviations from those collusive prices.
- b. The relevant DIPF markets are highly concentrated. In 2008, the Sellers collectively made more than 90 percent of sales in the relevant DIPF markets. A highly concentrated market enhances the Sellers' ability and incentive to collude on prices.
- c. Effective *de novo* entry into the relevant DIPF markets takes several years. Barriers to entry include the need for a new entrant to develop a distribution network and a reputation for quality and service with waterworks distributors and end users. Convincing end users to

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allow the use of a new entrant's DIPF is often a time consuming process.

- d. Demand for DIPF is inelastic to changes in price at competitive levels. DIPF are a relatively small portion of the cost of materials of a typical waterworks project, and there are no widely used substitutes for the product.
- e. The Sellers publish nearly identical price books listing per-unit prices for each unique DIPF item carried by a given supplier, and periodically publish uniform multiplier discounts at which they offer to sell DIPF on a state-by-state basis. By simplifying and standardizing published prices, the DIPF price list/multiplier format enhances the Sellers' ability to collude on prices and to detect deviations from those collusive prices.

**THE SELLERS RESTRAINED PRICE COMPETITION IN  
THE RELEVANT DIPF MARKETS**

28. Senior executives of the Sellers frequently and privately communicate with one another. These communications often relate to DIPF price and output.

29. Beginning in January 2008, the Sellers conspired to raise and stabilize the prices at which DIPF were sold in the United States.

30. Due to rising input costs, all of the Sellers desired price increases in 2008. However, McWane was concerned that Sigma and Star would not adhere to announced price increases, which would result in lost sales for McWane. The Sellers worked together through 2008 to alleviate McWane's concerns, with the common purpose of clearing the way for McWane to support common price increases.

31. On January 11, 2008, McWane publicly announced its first DIPF price increase of 2008. Sigma and Star followed this price increase.

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32. This January 2008 price increase was the result of a combination and conspiracy among the Sellers.

- a. Before announcing the January 2008 price increase, McWane planned to trade its support for higher prices in exchange for specific changes to the business methods of Sigma and Star that would reduce the risk that local sales personnel for these competitors would sell DIPF at prices lower than published levels.
- b. McWane communicated the terms of its plan to Sigma and Star. McWane acted with the intent of conspiring with Sigma and Star to restrain price competition.
- c. Sigma and Star manifested their understanding and acceptance of McWane's offer by publicly taking steps to limit their discounting from published price levels in order to induce McWane to support higher price levels.
- d. On or about March 10, 2008, McWane and Sigma executives discussed by telephone their efforts to implement the January 2008 price increase.

33. On June 17, 2008, McWane publicly announced its second DIPF price increase of 2008. Sigma and Star followed this price increase.

34. The June 2008 price increase was the result of a combination and conspiracy among the Sellers.

- a. Before announcing the June 2008 price increase, McWane planned to trade its support for higher prices in exchange for information from Sigma and Star documenting the volume of their monthly sales of DIPF. This exchange of information was to be achieved under the auspices of an entity styled as the Ductile Iron Fittings Research Association ("DIFRA").
- b. McWane communicated the terms of its plan to Sigma and Star, at least in part through a public letter sent by McWane to waterworks distributors, the common

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customers of the Sellers. A section of that letter was meaningless to distributors, but was intended to inform Sigma and Star of the terms of McWane's offer. McWane acted with the intent of conspiring with Sigma and Star to restrain price competition.

- c. Sigma and Star manifested their understanding and acceptance of McWane's offer by initiating their participation in the DIFRA information exchange in order to induce McWane to support higher price levels.
- d. McWane then led a price increase, and Sigma and Star followed.
- e. On or about August 22, 2008, executives of McWane and Sigma discussed by telephone their efforts to implement the June 2008 price increase.

**DIFRA FACILITATED PRICE COORDINATION AMONG  
THE SELLERS**

35. The DIFRA information exchange operated as follows. The Sellers submitted a report of their previous month's sales to an accounting firm. Shipments were reported in tons shipped, subdivided by diameter size range (*e.g.*, 2-12") and by joint type. Data submissions were aggregated and distributed to the Sellers. Data submitted to the accounting firm was typically no older than 45 days, and the summary reports returned to the Sellers contained data typically no more than 2 months old.

36. During its operation between June 2008 and January 2009, the DIFRA information exchange enabled each of the Sellers to determine and to monitor its own market share and, indirectly, the output levels of its rivals. In this way, the DIFRA information exchange facilitated price coordination among the Sellers on the pricing of DIPF.

37. The acts and practices of Respondents, as alleged herein, have the purpose, capacity, tendency, and effect of (i) fixing, maintaining and raising prices of DIPF in the relevant DIPF

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markets, and (ii) facilitating collusion in the relevant DIPF markets.

38. There are no legitimate procompetitive efficiencies that justify the conduct of Respondents as alleged herein, or that outweigh its anticompetitive effects.

**MCWANE MONOPOLIZED THE RELEVANT DOMESTIC  
DIPF MARKET**

39. At the time of the enactment of the ARRA in February 2009 and thereafter, McWane possessed monopoly power in the relevant domestic DIPF market.

40. At the time of the enactment of the ARRA, McWane was the only manufacturer of a full line of DIPF in the relevant domestic DIPF market and controlled nearly 100 percent of the relevant domestic DIPF market. Despite Star's entry into the relevant domestic DIPF market in late 2009, McWane continues to make more than 90 percent of sales in the relevant domestic DIPF market.

41. McWane's monopoly power in the relevant domestic DIPF market is protected by substantial barriers to effective entry and expansion, including the unfair methods of competition of McWane and Sigma, as alleged in Paragraphs 42 through 63, below.

42. For suppliers of the relevant DIPF that have existing relationships and goodwill with waterworks distributors and established reputations for quality and service in the provision of the relevant DIPF, McWane's unfair and exclusionary methods of competition are the primary barriers to effective entry and expansion in the relevant domestic DIPF market.

43. McWane's monopoly power in the relevant domestic DIPF market is further demonstrated directly by its ability to exclude competitors, to control prices, and to coercively impose unwanted distribution policies on its customers.

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44. Federal stimulus gave Sigma, Star and Serampore Industries Private, Ltd. (“SIP”), another imported DIPF supplier, an incentive to enter the domestic DIPF market.

45. Sigma, Star and SIP all attempted to enter the relevant domestic DIPF market in response to the ARRA.

46. McWane maintained its monopoly in the relevant domestic DIPF market by illegally inducing Sigma to abandon its effort to enter the domestic DIPF market, and by implementing an exclusive dealing policy to prevent other competitors from entering or expanding. Through this conduct, McWane eliminated or delayed competition from the only firms with the ability and incentive to enter the relevant domestic DIPF market in a timely fashion. McWane acted with the specific intent to monopolize the relevant domestic DIPF market.

**McWane Eliminated Sigma as an Actual Potential Entrant**

47. After the enactment of the ARRA, Sigma took steps to evaluate entry into domestic production of DIPF, including but not limited to (i) formulating a complete or nearly complete operational plan, (ii) arranging for an infusion of equity capital to fund domestic production, (iii) obtaining the approval of its Board of Directors for its entry plans, and (iv) casting prototype product.

48. McWane perceived that Sigma was preparing to enter the relevant domestic DIPF market. McWane sought to eliminate the risk of competition from Sigma by inducing Sigma to become a distributor of McWane’s domestic DIPF rather than a competitor in the relevant domestic DIPF market.

49. McWane and Sigma executed a Master Distribution Agreement dated September 17, 2009 (“MDA”). The principal terms of the MDA were as follows:

- a. McWane would sell domestic DIPF to Sigma at a 20 percent discount off of McWane’s published prices;
- b. McWane would be Sigma’s exclusive source for the relevant domestic DIPF;

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- c. Sigma would resell McWane's domestic DIPF at or very near McWane's published prices for domestic DIPF; and
- d. Sigma would resell McWane's domestic DIPF to waterworks distributors only on the condition that the distributor agreed to purchase domestic DIPF exclusively from McWane or Sigma.

50. An unwritten term of the MDA was that McWane would also sell its domestic DIPF at or very near its published prices.

51. In the absence of a sufficiently profitable arrangement with McWane, Sigma would likely have entered the relevant domestic DIPF market in competition with McWane.

52. Under the MDA, McWane controlled the price at which Sigma could sell domestic DIPF and the customers to whom Sigma could sell domestic DIPF. Sigma's participation in the relevant domestic DIPF market under the MDA was not equivalent to, and for consumers not a substitute for, Sigma's competitive entry into the relevant domestic DIPF market.

53. Sigma's independent, competitive entry into the relevant domestic DIPF market would likely have benefitted consumers by constraining McWane's prices for the relevant domestic DIPF and otherwise.

54. Through the MDA, McWane transferred a share of its sales and monopoly profits in the domestic DIPF market to Sigma in exchange for Sigma's commitment to abandon its plans to enter the relevant domestic DIPF market as an independent competitor.

55. Both McWane and Sigma entered into the MDA with the specific intent to maintain and share in McWane's monopoly profits in the relevant domestic DIPF market by eliminating competition among themselves and excluding their rivals.

### **McWane Excluded Star Through Exclusive Dealing**

56. Star announced its entry into the relevant domestic DIPF market in June 2009. McWane knew that, initially, Star would

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have a shorter product line and a smaller inventory than McWane. Star would therefore have difficulty convincing a waterworks distributor to purchase all of its domestic DIPF from Star. McWane nevertheless projected that Star's entry into the domestic DIPF market, if unobstructed by McWane, would place downward pressure on McWane's prices for its domestic DIPF.

57. McWane responded to Star's entry into the relevant domestic DIPF market by adopting restrictive and exclusive distribution policies (collectively, "McWane's exclusive dealing policies"). McWane intended and expected that these policies would impede and delay the ability of Star to enter the domestic DIPF market.

- a. McWane threatened waterworks distributors with delayed or diminished access to McWane's domestic DIPF, and the loss of accrued rebates on the purchase of McWane's domestic DIPF, if those distributors purchased domestic DIPF from Star.
- b. As part of its MDA with McWane, Sigma agreed to implement a similar distribution policy, as alleged in Paragraph 49, above.
- c. McWane threatened some waterworks distributors with the loss of rebates in other product categories, such as ductile iron pipe, waterworks valves, and hydrants, if those distributors purchased domestic DIPF from Star.
- d. Beginning in 2011, McWane changed its rebate structure for domestic DIPF to require waterworks distributors to make certain minimum, and high, shares of their total domestic DIPF purchases from McWane in order to qualify for these rebates.

58. The purpose and effect of McWane's exclusive dealing policies has been and is to compel the majority of waterworks distributors to deal with McWane and Sigma on an exclusive or nearly exclusive basis for their domestic DIPF business.

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- a. Due to Star's perceived or actual status as an untested supplier of domestic DIPF with a shorter product line and smaller inventory than McWane, many distributors interested in purchasing domestic DIPF from Star were unwilling to switch all of their domestic DIPF business to Star.
- b. Instead, many distributors wished to purchase domestic DIPF from both McWane/Sigma and Star, and thereby to garner the benefits of price and service competition.
- c. McWane's exclusive dealing policies increased the risk of purchasing domestic DIPF from Star.
- d. Distributors otherwise interested in purchasing domestic DIPF from Star were and are unwilling to do so under the terms of McWane's exclusive dealing policies, and have remained exclusive or nearly exclusive with McWane and Sigma, contrary to their preference.

59. McWane's exclusive dealing policies have foreclosed Star from a substantial volume of sales opportunities with waterworks distributors.

60. By foreclosing Star from a substantial volume of sales opportunities with waterworks distributors, McWane's exclusive dealing policies tend to minimize and delay Star's ability to compete in the domestic DIPF market and thereby to benefit consumers by constraining the prices of domestically produced DIPF charged by McWane and Sigma, and otherwise.

61. McWane's exclusive dealing policies have also raised barriers to entry into the relevant domestic DIPF market by other potential entrants, including SIP. This conduct has contributed to McWane's monopolization of the relevant domestic DIPF market.

62. The acts and practices of McWane, as alleged herein, have the purpose, capacity, tendency, and effect of (i) maintaining and stabilizing prices of DIPF in the relevant DIPF markets, (ii) eliminating potential competition from Sigma in the relevant domestic DIPF market, (iii) impairing the competitive effectiveness of Star in the relevant domestic DIPF market, and (iv) raising barriers to entry for potential rivals in the relevant

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domestic DIPF market. The conduct of McWane is reasonably capable of making a significant contribution to the enhancement or maintenance of McWane's monopoly power in the relevant domestic DIPF market.

63. There are no legitimate procompetitive efficiencies that justify the conduct of McWane as alleged herein, or that outweigh its anticompetitive effects.

**FIRST VIOLATION ALLEGED****RESTRAINT OF TRADE**

64. As alleged herein, McWane and Star conspired, along with their competitor Sigma, to restrain price competition. These concerted actions unreasonably restrain trade and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**SECOND VIOLATION ALLEGED****RESTRAINT OF TRADE**

65. As alleged herein, McWane and Star conspired, along with their competitor Sigma, to exchange competitively sensitive sales information. These concerted actions unreasonably restrain trade in and constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**THIRD VIOLATION ALLEGED****UNFAIR METHODS OF COMPETITION**

66. As alleged herein, McWane invited its competitors to collude with McWane to restrain price competition. These actions constitute unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and

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practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**FOURTH VIOLATION ALLEGED****RESTRAINT OF TRADE**

67. As alleged herein, McWane and Sigma entered into the MDA. The agreement unreasonably restrains trade and constitutes an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**FIFTH VIOLATION ALLEGED****CONSPIRACY TO MONOPOLIZE**

68. As alleged herein, McWane and Sigma entered into the MDA with the specific intent to monopolize the relevant domestic DIPF market, and took overt acts to exclude their rivals in furtherance of their conspiracy, constituting an unfair method of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**SIXTH VIOLATION ALLEGED****MONOPOLIZATION**

69. As alleged herein, McWane has willfully engaged in anticompetitive and exclusionary acts and practices to acquire, enhance or maintain its monopoly power in the relevant domestic DIPF market, constituting unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

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**SEVENTH VIOLATION ALLEGED****ATTEMPTED MONOPOLIZATION**

70. As alleged herein, McWane has willfully engaged in anticompetitive and exclusionary acts and practices, with the specific intent to monopolize the relevant domestic DIPF market, resulting, at a minimum, in a dangerous probability of monopolizing the relevant domestic DIPF market, constituting unfair methods of competition in or affecting commerce in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45. Such acts and practices, or the effects thereof, will continue or recur in the absence of appropriate relief.

**NOTICE**

Notice is hereby given to Respondents that the fourth day of September, 2012, at 10:00 a.m., is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, NW, Washington D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in the complaint.

You are notified that the opportunity is afforded you to file with the Commission an answer to this complaint on or before the fourteenth (14<sup>th</sup>) day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material allegations to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record

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basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under \_ 3.46 of said Rules.

Failure to file an answer within the time above provided shall be deemed to constitute a waiver of your right to appear and to contest the allegations of the complaint, and shall authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge shall hold a prehearing scheduling conference not later than ten (10) days after an answer is filed by the last answering Respondent. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington DC 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, and Rule 3.31(b) obligates counsel for each party, within five days of receiving the answer of the last answering Respondent, to make certain initial disclosures without awaiting a formal discovery request.

**NOTICE OF CONTEMPLATED RELIEF**

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that Respondents have violated or are violating Section 5 of the FTC Act, as amended, as alleged in the Complaint, the Commission may order such relief against Respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Ordering Respondents to cease and desist from the conduct alleged in the Complaint to violate Section 5 of the FTC Act, and to take all such measures as are appropriate to correct or remedy, or to prevent the recurrence of, the anticompetitive practices engaged in by Respondents.

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2. Prohibiting Respondents from agreeing with any competitor to fix prices or to allocate markets, or from soliciting any competitor to enter into such an agreement.
3. Prohibiting Respondents from agreeing with any competitor to exchange competitively sensitive information unless that information exchange meets sufficient criteria to assure that the information exchange will not facilitate collusion among Respondents and their competitors, such conditions to be determined by the Commission, or soliciting any competitor to enter into such an agreement.
4. Prohibiting Respondents from communicating competitively sensitive information to any competitor, except where such communications are the unavoidable result of announcing the terms on which Respondents propose to sell their products to their customers, or where the information communicated by Respondents relates solely to the terms on which Respondents propose to sell any product to, or purchase any product from, the person to whom the information is communicated by Respondents.
5. Requiring, for a period of time, that Respondents document all communications with any competitor, including by identifying the persons involved, the nature of the communication, and its duration, and that Respondents submit such documentation to the Commission.
6. Requiring that Respondents, upon request, provide the Commission with notification of any public price change relating to DIPF, including copies of pricing letters.
7. Prohibiting McWane from conditioning the sale, or any term of sale (including invoice price, delivery terms, credit allowances, rebates, or discounts), of any product on a customer's dealing, refusal to deal, or terms of dealing with any other supplier of domestically produced DIPF.

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8. Prohibiting McWane, for a period of time, from providing any discounts or other incentives that retroactively reduce the price of previously purchased units of McWane's domestically produced DIPF because of the purchase or sale of an additional unit of that product. Provided, however, that McWane shall be permitted to offer discounts or lower prices based solely on volume, provided that these discounts or lower prices are otherwise in accordance with the law.
9. Prohibiting McWane, for a period of time, from offering bundled rebates involving domestically produced DIPF.
10. Requiring that Respondents' compliance with the order shall be monitored at its expense by an independent monitor, for a term to be determined by the Commission.
11. Requiring that Respondents file periodic compliance reports with the Commission.
12. Any other relief appropriate to correct or remedy the anticompetitive effects in their incipency of any or all of the conduct alleged in the complaint.

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this fourth day of January, 2012, issues its complaint against Respondents.

By the Commission.

**DECISION AND ORDER**

The Federal Trade Commission ("Commission") having heretofore issued its complaint charging, *inter alia*, the Respondent Star Pipe Products, Ltd. with violations of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45 ("First and Second Violations"), and the Respondent having

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been served with a copy of that complaint, together with a notice of contemplated relief and having filed its answer denying such charges; and

The Respondent, its attorneys, and counsel for the Commission having thereafter executed an agreement containing a consent Order, an admission by Respondent of all the jurisdictional facts, solely as those facts relate to the First and Second Violations set forth in the complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than jurisdictional facts related to the First and Second Violations of the complaint, are true and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having considered the matter and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure prescribed in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following Order:

1. Respondent Star is a limited partnership organized and existing under the laws of the State of Texas, with its principal address at 4018 Westhollow Parkway, Houston, Texas 77082.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent, and the proceeding is in the public interest.

## Decision and Order

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “Commission” means the Federal Trade Commission.
- B. “Respondent” means Star Pipe Products, Ltd., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the U.S.-based subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- C. “Communicate” means to transfer or disseminate any information, regardless of the means by which it is accomplished, including without limitation orally, by letter, e-mail, notice, or memorandum. This definition applies to all tenses and forms of the word “communicate,” including, but not limited to, “communicating,” “communicated” and “communication.”
- D. “Competitively Sensitive Information” means any information regarding the cost, price, output, or customers of or for DIPF marketed by Respondent or any other Competitor, regardless of whether the information is prospective, current or historical, or aggregated or disaggregated.

*Provided, however,* that “Competitively Sensitive Information” shall not include:

1. information that is a list of prices or other pricing terms that has been widely Communicated by a Competitor to its customers through a letter, electronic mailing, sales catalog, Web site, or other widely accessible method of posting;

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2. information that relates to the terms on which a Competitor will buy DIPF from, or sell DIPF to, the Person to whom the Competitively Sensitive Information is Communicated;
  3. information that relates to transactions that occurred at least three (3) years prior to the date of the Communication of such information;
  4. information that must be disclosed pursuant to the Federal Securities Laws; or
  5. information obtained from or provided, in the ordinary course of Respondent's business, to: (a) a recognized credit rating Person that relates to the credit history or creditworthiness of a customer(s); or (b) another Competitor in relation to the verification of the salary currently being paid by that Competitor to an individual who is seeking or considering employment with Respondent.
- E. "Competitor" means Respondent and any Person that, for the purpose of sale or resale within the United States: (1) manufactures DIPF; (2) causes DIPF to be manufactured; or (3) imports DIPF.
- F. "Designated Manager" means a Regional Manager or the OEM Manager for sales of DIPF in and into the United States, and any employee performing any job function of a Regional Manager or the OEM Manager with responsibility for sales of DIPF in or into the United States.
- G. "Ductile Iron Pipe Fittings" or "DIPF" means any iron casting produced in conformity with the C153/A21 or C110/A21 standards promulgated by the American Water Works Association, including all revisions and amendments to those standards and any successor standards incorporating the C153/A21 or C110/A21 standards by reference.

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- H. “Federal Securities Laws” means the securities laws as that term is defined in § 3(a)(47) of the Securities Exchange Act of 1934, 15 U.S.C. § 78c(a)(47), and any regulation or order of the Securities and Exchange Commission issued under such laws.
- I. “Industry Statistics” means statistics derived from Input Data and Communicated by the Third Party Manager.
- J. “Input Data” means the Competitively Sensitive Information Communicated by Competitors to the Third Party Manager.
- K. “Information Exchange” means the entity Managed by A Third Party Manager that: (1) Communicates Industry Statistics and (2) includes Respondent and at least one other Competitor.
- L. “Insider” means a consultant, officer, director, employee, agent, or attorney of Respondent. *Provided, however*, that no other Competitor shall be considered to be an “Insider.”
- M. “Managed by A Third Party Manager” means that a Third Party Manager is solely and exclusively responsible for all activities relating to Communicating, organizing, compiling, aggregating, processing, and analyzing any Competitively Sensitive Information.
- N. “McWane, Inc.” means McWane, Inc., its officers, directors, employees, agents, attorneys, representatives, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, successors, and assigns of each.
- O. “Participate” in an entity or an arrangement means (1) to be a partner, joint venturer, shareholder, owner, member, or employee of such entity or arrangement, or

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(2) to provide services, agree to provide services, or offer to provide services through such entity or arrangement. This definition applies to all tenses and forms of the word “participate,” including, but not limited to, “participating,” “participated,” and “participation.”

- P. “Person” means any natural person or artificial person, including, but not limited to, any corporation, unincorporated entity, or government. For the purpose of this Order, any corporation includes the subsidiaries, divisions, groups, and affiliates controlled by it.
- Q. “Third Party Manager” means a Person that (1) is not a Competitor, and (2) is responsible for all activities relating to Communicating, organizing, compiling, aggregating, processing, and analyzing any Competitively Sensitive Information Communicated or to be Communicated between or among Respondent and any other Competitor.

**II.**

**IT IS FURTHER ORDERED** that in connection with the business of manufacturing, marketing or selling DIPF in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device:

- A. Entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors:
1. To raise, fix, maintain, or stabilize prices or price levels, or engage in any other pricing action; or

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2. To allocate or divide markets, customers, contracts, transactions, business opportunities, lines of commerce, or territories.

*Provided, however,* that nothing in Paragraph II.A of this Order prohibits Respondent from entering into an agreement with another Competitor regarding the price of DIPF, if and only if that agreement relates exclusively to the terms under which Respondent will buy DIPF from, or sell DIPF to, that other Competitor.

- B. Communicating to any Person who is not an Insider, that Respondent is ready or willing:
  1. To raise, fix, maintain, or stabilize price or price levels conditional upon any other Competitor also raising, fixing, maintaining, or stabilizing price or price levels; or
  2. To forbear from competing for any customer, contract, transaction, or business opportunity conditional upon any other Competitor also forbearing from competing for any customer, contract, transaction, or business opportunity.
- C. Entering into, adhering to, Participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any Competitors to Communicate or exchange Competitively Sensitive Information.
- D. Communicating Competitively Sensitive Information to any other Competitor.
- E. Attempting to engage in any of the activities prohibited by Paragraphs II.A, II.B, II.C, or II.D.

*Provided, however,* that it shall not of itself constitute a violation of Paragraph II.B, II.C, OR II.D of this Order for Respondent to Communicate:

## Decision and Order

1. Competitively Sensitive Information to a Competitor where such Communication is reasonably related to a lawful joint venture, license, or potential acquisition, and is reasonably necessary to achieve the procompetitive benefits of such a relationship;
2. To any Person reasonably believed to be an actual or prospective purchaser of DIPF, the price and terms of a sale of DIPF; or
3. To any Person reasonably believed to be an actual or prospective purchaser of DIPF that Respondent is ready and willing to adjust the terms of a sale of DIPF in response to a Competitor's offer.

*Provided further*, that it shall not of itself constitute a violation of Paragraphs II.B, II.C, II.D or II.E of this Order for Respondent to Communicate with or Participate in an Information Exchange that is limited exclusively to the Communication of Input Data or Industry Statistics when:

1. Any Input Data relates solely to transactions that are at least six (6) months old;
2. Any Industry Statistic relates solely to transactions that are at least six (6) months old;
3. Industry Statistics are Communicated no more than one time during any six (6) month period;
4. Any Industry Statistic represents an aggregation or average of Input Data for transactions covering a period of at least six (6) months;
5. Any Industry Statistic represents an aggregation or average of Input Data received from no fewer than five (5) Competitors;
6. Relating to price, output, or total unit cost, no individual Competitor's Input Data to any Industry

## Decision and Order

Statistic represents more than twenty-five (25) percent of the total reported sales (whether measured on a dollar or unit basis) of the DIPF product from which the Industry Statistic is derived;

7. Relating to price, output, or total unit cost, the sum of no three Competitors' Input Data to any Industry Statistic represents more than sixty (60) percent of the total reported sales (whether measured on a dollar or unit basis) of the DIPF product from which the Industry Statistic is derived;
8. Any Industry Statistic is sufficiently aggregated or anonymous such that no Competitor that receives that Industry Statistic can, directly or indirectly, identify the Input Data submitted by any other particular Competitor;
9. Respondent does not Communicate with any other Competitor relating to the Information Exchange, other than those Communications (i) occurring at official meetings of the Information Exchange; (ii) relating to topics identified on a written agenda prepared in advance of such meetings; and (iii) occurring in the presence of antitrust counsel;
10. Respondent retains, for submission to a duly authorized representative of the Commission upon reasonable notice, a copy of all Input Data Communicated to the Third Party Manager and all Industry Statistics Communicated by the Third Party Manager to Respondent; and
11. All Industry Statistics are, at the same time they are Communicated to any Competitor, made publicly available.

## Decision and Order

**III.**

**IT IS FURTHER ORDERED** that until a final determination of the litigation with McWane, Inc., in this Docket 9351, including any appeals, and in any Commission action related to Docket 9351 that the Commission may take against McWane, Inc. Respondent shall cooperate with Commission staff, to the same extent to which it would have been required had it continued to be a respondent in the Commission action under Part 3 of the Commission's Rules of Practice, to (1) produce, at its own expense, information and documents in its possession, custody, or control; and (2) make its representatives available to provide deposition or hearing testimony, as such may be requested by any duly authorized representative of the Commission. Respondent shall also make its representatives available, upon reasonable notice, for interviews in person or by telephone with Commission staff. Nothing in this paragraph shall require the production of materials as to which Respondent may assert a valid claim of privilege on its own behalf or pursuant to the terms of any written joint defense agreement with any respondent in any Commission proceeding against McWane, Inc.

**IV.**

**IT IS FURTHER ORDERED** that Respondent shall:

- A. Within sixty (60) days from the date this Order becomes final distribute by first-class mail, return receipt requested, or by electronic mail with return confirmation, a copy of this Order with the Complaint, to each of its officers, directors, and Designated Managers; and
- B. For five (5) years from the date this Order becomes final, distribute by first-class mail, return receipt requested, or by electronic mail with return confirmation, a copy of this Order with the Complaint, within sixty (60) days, to each Person who becomes its officer, director, or Designated Manager and who did not previously receive a copy of this Order and Complaint.

## Decision and Order

- C. Require each Person to whom a copy of this Order is furnished pursuant to Paragraphs III.A and III.B of this Order to sign and submit to Respondent within sixty (60) days of the receipt thereof a statement that: (1) represents that the undersigned has read and understands the Order; and (2) acknowledges that the undersigned has been advised and understands that non-compliance with the Order may subject Respondent to penalties for violation of the Order.

**V.**

**IT IS FURTHER ORDERED** that Respondent shall file verified written reports within ninety (90) days from the date this Order becomes final, annually thereafter for five (5) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require. Each report shall include, among other information that may be necessary:

- A. A description of any Information Exchange, including a description of (i) the identity of any Competitors participating in such exchange; (ii) the Competitively Sensitive Information being exchanged; (iii) the identity of the Third Party Manager and a description of how the Competitively Sensitive Information has been and is expected to be Managed by the Third Party Manager; and (iv) the identity of each employee of the Respondent who received information, directly or indirectly, from the Third Party Manager;
- B. Copies of the signed return receipts or electronic mail with return confirmations required by Paragraphs III.A, III.B, and III.C of this Order;
- C. One copy of each Communication during the relevant reporting period that relates to changes in Respondent's published list price or multiplier discounts for sales of DIPF made in or into the United States when that Communication is to two (2) or more customers and those changes are simultaneously applicable to two (2) or more customers; and

## Decision and Order

- D. A detailed description of the manner and form in which Respondent has complied and is complying with this Order.

**VI.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission:

- A. Of any change in its principal address within twenty (20) days of such change in address; and
- B. At least thirty (30) days prior to any proposed: (1) dissolution of Respondent; (2) acquisition, merger, or consolidation of Respondent; or (3) any other change in Respondent including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**VII.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Respondent, and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession, or under the control, of Respondent relating to compliance with this Order, which copying services shall be provided by Respondent at its expense; and
- B. Upon fifteen (15) days notice, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

Concurring and Dissenting Statement

**VIII.**

**IT IS FURTHER ORDERED** that this Order shall terminate on May 8, 2032.

By the Commission, Commissioner Ohlhausen not participating.

**Statement of Commissioner J. Thomas Rosch,  
Concurring in Part and Dissenting in Part In the Matter of  
McWane, Inc. and Star Pipe Products, Ltd., and In the  
Matter of Sigma Corporation**

The Commission has voted separately (1) to issue a Part 3 Administrative Complaint against Respondents McWane, Inc. (“McWane”) and Star Pipe Products, Ltd. (“Star”), and (2) to accept for public comment a Consent Agreement settling similar allegations in a draft Part 2 Complaint against Respondent Sigma Corporation (“Sigma”). While I have voted in favor of both actions, I respectfully object to the inclusion—in both the Part 3 Administrative Complaint and in the draft Part 2 Complaint—of claims against McWane and Sigma, to the extent that such claims are based on allegations of exclusive dealing, as explained in Part I below. I also respectfully object to naming Star, a competitor of McWane and Sigma, as a Respondent in the Part 3 Administrative Complaint, which alleges, *inter alia*, that Star engaged in a horizontal conspiracy to fix the prices of ductile iron pipe fittings (DIPFs) sold in the United States, and in a related, information exchange, as described in Part II below.

**I.**

For reasons similar to those that I articulated in a recent dissent in another matter, *Pool Corp.*, FTC File No. 101-0115, <http://www.ftc.gov/os/caselist/1010115/111121poolcorpstatementrosch.pdf>, I do not think that the Part 3 Administrative Complaint against McWane and the draft Part 2 Complaint against Sigma

## Concurring and Dissenting Statement

adequately allege exclusive dealing as a matter of law. In particular, there is case law in both the Eighth and Ninth Circuits blessing the conduct that the complaints charge as exclusive dealing.

**II.**

I also object to the allegations in the Part 3 Administrative Complaint and in the draft Part 2 Complaint that name Star as a co-conspirator in the alleged horizontal price-fixing of DIPF sold in the United States and the related, alleged DIFRA information exchange.<sup>1</sup> I do not consider naming Star, along with McWane and Sigma, as a co-conspirator to be in the public interest. There are at least three reasons why this is so. First, although there may be reason to believe Star conspired with McWane and Sigma in this oligopolistic industry, Star seems much less culpable than the others. More specifically, I believe that we must be mindful of the consequences of public law enforcement in assessing whether the public interest favors joining Star as a co-conspirator.<sup>2</sup> Second, I am concerned that a trier of fact may find it hard to believe that Star could be both a victim of McWane's alleged "threats" to deal exclusively with distributors, and at more or less the same time (the "exclusive dealing" program began in September 2009), a co-conspirator with McWane in a price-fixing conspiracy (June 2008 to February 2009). (This concern further explains why I do not have reason to believe that the exclusive dealing theory is a viable one.) Third, I am concerned that Star's alleged participation in the price-fixing conspiracy and information exchange relies, in part, on treating communications to distributors as actionable signaling on prices or price levels.<sup>3</sup> *See,*

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1 *See* McWane/Star Part 3 Administrative Compl. ¶¶ 29–38, 64–65; Sigma draft Part 2 Compl. ¶¶ 23–33.

2 *See* Credit Suisse Secs. (USA) LLC v. Billing, 551 U.S. 264, 281–84 (2007) (questioning the social benefits of private antitrust lawsuits filed in numerous courts when the enforcement-related need is relatively small); Bell Atl. Corp. v. Twombly, 550 U.S. 544, 557–60 (2007) (expressing concern with the burdens and costs of antitrust discovery, and the attendant *in terrorem* effect, associated with private antitrust lawsuits).

3 McWane/Star Part 3 Administrative Compl. ¶ 34b; Sigma draft Part 2 Compl. ¶ 29.

## Analysis to Aid Public Comment

*e.g., Williamson Oil Co., Inc. v. Philip Morris USA*, 346 F.3d 1287, 1305–07 (11th Cir. 2003).

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission (“Commission” or “FTC”) has accepted, subject to final approval, an agreement containing a proposed consent order (“Agreement”) from Star Pipe Products, Ltd. (“Star”). The Agreement seeks to resolve in part an administrative complaint issued by the Commission on January 4, 2012. The complaint charges that Star and certain of its competitors violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. 45, by engaging in collusive acts and practices in the market for ductile iron pipe fittings (“DIPF”).

The Commission anticipates that, with regard to Star, the competitive issues described in the complaint will be resolved by accepting the proposed order, subject to final approval, contained in the Agreement. The Agreement has been placed on the public record for 30 days for receipt of comments from interested members of the public. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Agreement and any comments received, and will decide whether it should withdraw from the Agreement or make final the proposed order contained in the Agreement.

The purpose of this Analysis to Aid Public Comment is to invite and facilitate public comment concerning the proposed order. It is not intended to constitute an official interpretation of the Agreement and proposed order or in any way to modify its terms.

The proposed order is for settlement purposes only and does not constitute an admission by Star that it violated the law, or that the facts alleged in the complaint, other than jurisdictional facts, are true.

## Analysis to Aid Public Comment

**I. The Complaint**

The following allegations are taken from the complaint and publicly available information.

**A. Background**

The largest sellers of DIPF in the United States are Star, McWane, Inc. (“McWane”), and Sigma Corporation (“Sigma”). DIPF are used in municipal water distribution systems to change pipe diameter or pipeline direction. There are no widely available substitutes for DIPF. Both imported and domestically produced DIPF are commercially available.

DIPF suppliers distribute these products through wholesale distributors, known as waterworks distributors, which specialize in distributing products for water infrastructure projects. The end users of DIPF are typically municipal and regional water authorities.

DIPF prices are based off of published list prices and discounts, with customers negotiating additional discounts off of those list prices and discounts on a transaction-by- transaction basis. DIPF suppliers also offer volume rebates.

**B. Challenged Conduct**

Between January 2008 and January 2009, Star allegedly conspired with McWane and Sigma to increase the prices at which DIPF were sold in the United States. In furtherance of the conspiracy, and at the request of McWane, Star changed its business methods to make it easier to coordinate price levels, first by limiting the discretion of regional sales personnel to offer price discounts, and later by exchanging information documenting the volume of its monthly sales, along with sales by McWane and Sigma, through an entity known as the Ductile Iron Fittings Research Association (“DIFRA”).

## Analysis to Aid Public Comment

**II. Legal Analysis**

The January and June 2008 price restraints among Star, McWane, and Sigma alleged in the complaint are naked restraints on competition that are *per se* unlawful.<sup>1</sup>

The June 2008 agreement, which was allegedly reached after a public invitation to collude by McWane, illustrates how price fixing agreements may be reached in public. Here, McWane's invitation to collude was conveyed in a letter sent to waterworks distributors, the common customers of Star, McWane, and Sigma. McWane's letter contained a section that was meaningless to waterworks distributors, but was intended to inform Star and Sigma of the terms on which McWane desired to fix prices.<sup>2</sup>

The DIFRA information exchange was a component of the illegal price fixing agreement. Specifically, the complaint alleges that the DIFRA information exchange played a critical role in the 2008 price fixing conspiracy, first as the *quid pro quo* for a price increase by McWane in June 2008, and then by enabling Star, McWane, and Sigma to monitor each others' adherence to the collusive arrangement through the second half of 2008.

Evaluated apart from the price fixing conspiracy, Star's participation in the information exchange is an independent

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1 FEDERAL TRADE COMMISSION & UNITED STATES DEPARTMENT OF JUSTICE, ANTITRUST GUIDELINES FOR COLLABORATION AMONG COMPETITORS ("Competitor Collaboration Guidelines")§ 1.2 (2000); *In re North Texas Specialty Physicians*, 140 F.T.C. 715, 729 (2005) ("We do not believe that the *per se* condemnation of naked restraints has been affected by anything said either in *California Dental* or *Polygram*").

2 Because McWane's communication informed its rivals of the terms of price coordination desired by McWane without containing any information for customers, this communication had no legitimate business justification. *See In re Petroleum Products Antitrust Litig.*, 906 F.2d 432,448 (9th Cir. 1990) (public communications may form the basis of an agreement on price levels when "the public dissemination of such information served little purpose other than to facilitate interdependent or collusive price coordination").

## Analysis to Aid Public Comment

violation of the antitrust laws because this concerted action facilitated price coordination among the three competitors.<sup>3</sup>

### III. The Proposed Order

The proposed order is designed to remedy the unlawful conduct charged against Star in the complaint and to prevent the recurrence of such conduct.

Paragraph II.A of the proposed order prohibits Star from participating in or maintaining any combination or conspiracy between any competitors to fix, raise or stabilize the prices at which DIPF are sold in the United States, or to allocate or divide markets, customers, or business opportunities.

Paragraph II.B of the proposed order prohibits Star from soliciting or inviting any competitor to participate in any of the actions prohibited in Paragraphs II.A.

Paragraph II.C of the proposed order prohibits Star from participating in or facilitating any agreement between competitors to exchange “Competitively Sensitive Information” (“CSI”), defined as certain types of information related to the cost, price, output or customers of or for DIPF. Paragraph II.D of the proposed order prohibits Star from unilaterally disclosing CSI to a competitor, except as part of the negotiation of a joint venture, license or acquisition, or in certain other specified circumstances. Paragraph II.E of the proposed order prohibits Star from

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<sup>3</sup> The Commission articulated a safe harbor for exchanges of price and cost information in Statement 6 of the 1996 Health Care Guidelines. *See* DEPT OF JUSTICE & FEDERAL TRADE COMM'N, STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTH CARE, STATEMENT 6: ENFORCEMENT POLICY ON PROVIDER PARTICIPATION IN EXCHANGES OF PRICE AND COST INFORMATION (1996). The DIFRA information exchange failed to qualify for the safety zone of the Health Care Guidelines for several reasons. Although the DIFRA information exchange was managed by a third party, the information exchanged was insufficiently historical, the participants in the exchange too few, and their individual market shares too large to qualify for the permissive treatment contemplated by the Health Care Guidelines. While failing to qualify for the safety zone of the Health Care Guidelines is not in itself a violation of Section 5, firms that wish to minimize the risk of antitrust scrutiny should consider structuring their collaborations in accordance with the criteria of the safety zone.

## Analysis to Aid Public Comment

attempting to engage in any of the activities prohibited by Paragraphs II.A, II.B, II.C, or II.D.

The prohibitions on Star's communication of CSI with competitors contained in Paragraphs II.C and II.D of the proposed order are subject to a proviso that permits Star to communicate CSI to its competitors under certain circumstances. Under the proposed order, Star may participate in an information exchange with its competitors in the DIPF market provided that the information exchange is structured in such a way as to minimize the risk that it will facilitate collusion among Star and its competitors. Specifically, the proposed order requires any exchange of CSI to occur no more than twice yearly, and to involve the exchange of aggregated information more than six months old. In addition, the aggregated information that is exchanged must be made publicly available, which increases the likelihood that an information exchange involving Star will simultaneously benefit consumers. The proposed order also prohibits Star's participation in an exchange of CSI involving price, cost or total unit cost of or for DIPF when the individual or collective market shares of the competitors seeking to participate in an information exchange exceed specified thresholds. The rationale for this provision is that in a highly concentrated market the risk that the information exchange may facilitate collusion is high. Due to the highly concentrated state of the DIPF market as currently structured, an information exchange involving Star and relating to price, output or total unit cost of or for DIPF is unlikely to reoccur in the foreseeable future.

Paragraph III of the proposed order requires Star to cooperate with Commission staff in the still-pending administrative litigation against McWane.

The proposed order has a term of 20 years.

## Complaint

## IN THE MATTER OF

**WINCHESTER INDUSTRIES**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4362; File No. 102 3171*  
*Complaint, May 16, 2012 – Decision, May 16, 2012*

This consent order addresses Winchester Industries' marketing and sale of replacement windows for use in residences. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating representations that consumers who replace their windows with Bristol and Winter Lock Super Triple-E A-Plus with Alpha-10 windows are likely to achieve residential energy savings of 47% or to save 47% on their heating and cooling costs when it made them. The consent order prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Participants*

For the *Commission: Robert Frisby, Zachary Hunter, Joshua Millard, and Sarah Waldrop.*

For the *Respondent: Eric Horne, Eckert Seamans Cherin & Mellott, LLC.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Winchester Industries ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Winchester Industries is a Pennsylvania partnership with its principal office or place of business at 500 Leech Avenue, Saltsburg, Pennsylvania 15681. The partnership

## Complaint

was formed in 1983 by Steel Bridge, LTD, LLC, a Canadian corporation, and Winchester Industries, Inc., a Pennsylvania corporation.

2. Respondent manufactures, advertises, offers for sale, sells, and/or distributes windows, including its “Bristol” and “WinterLock Super Triple-E A-Plus with Alpha-10” windows. Respondent distributes these windows to independent dealers and installers who in turn sell them to consumers for residential use.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused the dissemination of advertising and promotional materials, such as advertising on its website as well as brochures and other promotional materials it provided to window dealers and installers, including but not necessarily limited to the attached Exhibits A through H. Respondent’s dealers and installers disseminated or caused the dissemination of these advertising and promotional materials to consumers. The advertising and promotional materials contain the following statements or depictions:

a. Bristol Windows Internet Promotional Material

Manufacturer 47% Energy Savings Pledge

Replace your old drafty, Energy Wasting windows and doors NOW and SAVE, SAVE, SAVE

Exhibit A ([www.bristolwindows.com](http://www.bristolwindows.com)).

[T]he triple-paned design of some replacement windows, such as Bristol windows, can also produce energy savings up to 50% per year.

Exhibit B ([www.bristolwindows.com](http://www.bristolwindows.com)).

Since replacing the double-paned windows, according to Simon, the triple-paned windows have cut his family’s heating and cooling bills in half. ‘With the

## Complaint

Bristol windows, we save over \$2,500 a year in heating and cooling costs . . .

Exhibit C ([www.bristolwindows.com](http://www.bristolwindows.com)).

## b. Bristol Windows Energy Saving Pledge

**47% Energy Savings Pledge**

This pledges a savings of at least 47% of energy consumption for heating and cooling the residence at the address shown hereon during the 12 month period beginning with the first full month after completed installation of Bristol units . . . it is hereby agreed and understood that this Pledge only [sic] be effective if the homeowner, located at the address shown hereon, has purchased a complete installation of Bristol Triple-E, A-Plus with ALPHA-10 insulated replacement windows, and is effective for a one year period after installation.

Exhibit D.

## c. WinterLock windows Promotional Materials

“Reduce energy costs by up to 47%”

Exhibit E.

“Energy savings up to 47%”

Exhibit F.

## d. Bristol Windows Promotional Materials

“Stop Wasting Money On Your Energy Bills!”

“47% Energy Savings Pledge!”

Exhibit G.

However, after reviewing my consumption of gas and electric one year after the installation, I have to admit

## Complaint

that investing in three panes of glass worked for us. We consumed 53.2% less energy after getting the windows.

## Exhibit H.

5. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with Winchester replacement windows are not likely to achieve a 47% reduction in residential energy consumption or heating and cooling costs.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- a. Consumers who replace windows with Bristol or WinterLock Super Triple-E A-Plus with Alpha-10 windows are likely to achieve residential energy savings of 47%; or
- b. Consumers who replace windows with Bristol or WinterLock Super Triple-E A-Plus with Alpha-10 windows are likely to save 47% on residential heating and cooling costs.

7. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time the representation(s) were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time the representation(s) were made. Therefore, the representation set forth in Paragraph 7 was false or misleading.

9. Respondent provided to its independent dealers and installers promotional materials referred to in Paragraph 4. By

## Complaint

doing so, respondent provided them with the means and instrumentalities for the commission of deceptive acts or practices. Therefore, respondent's provision of such materials to its dealers and installers, as described in Paragraph 4 above, constitutes a deceptive act or practice.

10. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission this sixteenth day of May, 2012, has issued this complaint against respondent.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

Complaint

Exhibit A

Products    Research Center    Company    In The News    Sweepstakes    Contact Us    Home

| About Us | Links | Dealer Lookup | Customer Service |

Enter your zip code to find a dealer in your area.

**Manufacturer 47% Energy Savings Pledge and Tax Credit Qualified\***

Replace your old drafty, Energy Wasting windows and doors **NOW** and... **up to \$1,500.00** **SAVE, SAVE, SAVE**

**ONLY THE VIEW IS LEFT THROUGH BRISTOL WINDOWS!**

- Environmentally Triple Glass with Superior Heat, Cold & UV Reflective Properties
- Dual frame reinforced construction
- Deadbolt style locking system
- = Year Round Savings
- = Structural Integrity
- = Comfort & Security

Sold and Installed by EXCLUSIVE Dealers throughout the USA!

\*Bristol Super Glass windows and doors exceed the 2010 AIAA requirements! Thermal and structural performance is guaranteed by 25 years of manufacturing Triple glass units... our legacy of perfection and performance can now be yours. We've been saving the earth's energy for 25 years. Now it's your turn.

WINCHESTER INDUSTRIES • 724-639-3551

Complaint

Exhibit B

...able on my body."

Although maintenance-free is a important goal for many homeowners, the triple-paneled design of some replacement windows, such as Bristol Windows, can also produce energy savings up to 50% per year. When compared to double-paneled windows, typically put a costlier inert gas known as argon between the panes, Bristol's triple-paneled replacement windows have two air spaces filled with their own proprietary mix of thick inert gases that act as a dual thermal insulator. Bristol adds high-tech heat reflective layers and a warm-edge spacer system that creates a ultimate thermal shield that does a much better job of slowing the transfer of cold in or heat out — thus halting the flow of heating and cooling dollars out the window.

A complete selection of aesthetic, virtually maintenance-free, triple-paneled, replacement windows by Winchester Industries are sold under the names of Bristol, Deford, and Baricade. For best results, energy savings and comfort, these windows must be professionally installed. The company is looking for new dealers in certain U.S. regions to round out their national presence.

For more info, visit the website [www.winchesterwindows.net](http://www.winchesterwindows.net); call 800-885-5432; email [inquiry@winchesterwindows.net](mailto:inquiry@winchesterwindows.net); or write to Winchester Industries at PO Box 148, 950 Leech Ave, Salisbury, PA 17361.

#\*#

By Del Williams, a technical writer based in Torrance, California.

[Back to News]

**Installed in 60,000+ Homes! Call Now! Exclusive Territories Available**

**NOT JUST A WINDOW - A COMPLETE WINDOW SYSTEM**  
 R-9 Certified • U-Value .17 (Rate of Heat Transfer - The lower the better)

Complaint

Exhibit C



**How Much Can New Windows Really Save You?**

Can you and your best homeowners find a way to save nearly half their home energy bills by turning to green technology.

Homeowners are dreading another season of sky-high winter heating or blistering summer air conditioning bills. Even if further price hikes don't occur, fairly a blizz snowy, homeowners are realizing that typical weather stripping and insulation may not be enough to curb soaring energy costs -- not when the windows themselves are bleeding precious winter heat, summer cooling, and hard-earned dollars.

The government Energy Star website, which promotes energy efficiency among U.S. consumers and businesses, acknowledges the need for better alternatives. "All energy-efficient windows have at least two panes, but not all double-paned windows are energy efficient," states the website. "Twenty years ago, double-paned meant energy efficient; today, advanced technologies have enabled the development of windows that are much more efficient than traditional clear-glass double-paned windows."

While it's no-brainer to upgrade windows if you're replacing them for resistance or aesthetic reasons anyway, more homeowners are switching from traditional single and double-paned windows to state-of-the-art, triple-paned units for comfort, cost and energy savings up to 50% per year.

**We Juggle the Living on the Inside**

Against windows as cold as -13° F, John and Kelly Simon's whole-house, gas heater and fireplace could make little headway. The family learned themselves as swimmers and bankers indoors, bracing themselves against the bone-chilling cold they felt coming through the double-paned windows in their 2,300-sq.-foot Grandpeter Park, Michigan home.

"The cold penetrated even when we had our thermal drapes drawn, with the heater and fireplace going full blast," says John Simon. "We have to always be cold during winter, even though the heating bill was going through the roof." The first straw was when ice crystals formed on the windows -- inside the house. "It was like living on the tundra at home," says Simon. "We realized the cold transferred right through the double-paned windows, and we had to do something about it."

Simon went on a mission to bring comfort and manageable fuel bills to his family. He checked all the window companies in his area. He visited showrooms and other people's homes. He tested the thermal protection of energy-efficient, double-paned windows, but none fully satisfied him.

"Most windows can keep out drafts, but that doesn't mean they're efficient in keeping out winter cold or locking in heat," says Simon, who checked out as many actual install sites as he could, feeling the panes for heat or cold transfer first-hand. "Even the most energy-efficient, double-paned windows let cold penetrate or heat escape."

One window technology called triple-paned windows jumped to his attention. The triple-paneled design with high-tech thermal spacers between each pane of glass helped prevent both cold and heat from radiating either inside or outside.

Where competitors' double-paned window systems put a common inert gas, argon, between the panes, the triple-paneled replacement windows, offered by Saltzman, Pennsylvania-based Winchester Industries, provided two air spaces filled with their own proprietary mix of gases as a dual thermal insulator. Like a thermal shield, the double layer of thick gases does a much better job of slowing the transfer of cold in or heat out -- that's holding the line of heating and cooling dollars out the window.

The Simons had the windows professionally installed in their home, and there's been no need for layered clothing layers since. "Because the triple-paneled windows are so thermally efficient, there's no need to fiddle with the thermostat in winter or summer," says Simon. "Once I set the thermostat at a comfortable temperature, I don't have to touch it all year long. You can't say that about other windows."

Since replacing the double-paned windows, according to Simon, the triple-paneled windows have cut his family's heating and cooling bills in half. "With the Bristol Windows, we save over \$2,500 a year in heating and cooling costs and are protected from spikes in energy cost. Best of all, we're comfortable and can finally enjoy our home year-round."

**Not needing summer heat anymore**

During Sandra King's first summer in her Mesa, Arizona home it got up to 110° F outside. She found no refuge from the heat inside her two-story, 2,000-sq.-foot home on cooling a self course. Inside she had the air conditioning cranked all the way up, so calling fan going full blast, and two quiet floor fans placed on either side of a dining nook in her home office. "The fans were so noisy I couldn't hear the phone," says King. "Standing in front of a mirror, I'd break out in a sweat or burn my feet on the hardwood floor."

A thermal reading of the triple-paneled, aluminum windows in her home read 13.5° F, while the home's interior topped 96° F. At a contractor's recommendation, she installed energy-efficient, double-paned windows in a new addition to her home, but was sorely disappointed at the amount of heat they still let through.

King took action, asking eight window companies to visit her home. She carefully compared their offerings and paid particular attention to the heat loss demonstrations, which were designed to show how their windows would repel heat. While the energy-efficient, double-paned windows retained heat transmission better than single-pane windows, each allowed a significant amount of heat to pass. None, she felt, would cut heat from the summer sun to a comfortable level. When King investigated the triple-paneled windows, however, she immediately noticed a difference. "Under a heat lamp so hot it felt like lava, the Bristol Windows passed absolutely no heat," she says.

Besides the triple-paneled windows' high-tech spacer system and insulating inert gases between each pane, King credits the windows' multiple low-E layers on two panes; these reflect more heat than the single low-E layer on energy-efficient, double-paned windows. The triple-paneled windows' multiple, soft-coat low-E layers not only provide better heat reflective performance than the single hard-coat, low-E layer of typical double-paned windows, but also greatly reduce harmful ultraviolet rays.

King decided to replace her single-paneled windows with triple-paneled ones, and within the moment her hot house became a home for her. "The day they came to install my new windows, I was working in my home office as usual," says King. "When they removed the picture window, the heat was so intense I thought I'd die. But the instant they fitted these windows into place, the heat disappeared. I nearly got myself tangled up ahead around, trying to figure out what happened to the heat."

King estimates saving at least \$3,000 a year in cooling and heating costs since installing the Bristol Windows. She's so happy with the triple-paneled windows that she's planning to replace her year-old, double-paned windows with them. "The first day the triple-paneled windows blocked the heat and made me comfortable, that was it -- I got my life," says King. "I'm more productive and I like being home now."

**Beating extremes and alternatives on foreign soil**

Debra Duggert's family had battled weather extremes in their 2,000-sq.-foot, Lakewood, Colorado home for too long. With winter

Houseful of FREE Windows Sweepstakes



Contact us for additional details

## Complaint

## Exhibit D

## Winchester Industries

*Manufacturer of the Ultimate Bristol Replacement Windows and Doors*

### 47% Energy Savings Pledge

This pledges a savings of at least 47% of energy consumption for heating and cooling the residence at the address shown hereon during the 12 month period beginning with the the first full month after completed installation of Bristol units. In the event energy savings are less than 47% of the previous 12 months' energy consumption, the homeowner should notify Winchester Industries who will provide the homeowner with the necessary forms to file for benefits under this Pledge. If energy savings are less than 47% of the previous 12 months' energy consumption, the homeowner will be reimbursed the difference between actual savings and 47% of energy cost for the previous 12 months.

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this Pledge only be effective if the homeowner, located at the address shown hereon, has purchased a complete installation of Bristol Triple-E, A-Plus with ALPHA-10 insulated replacement windows, and is effective for a one year period after installation.

**THIS PLEDGE IS BASED ON ENERGY(FUEL) CONSUMPTION, NOT COST. IT IS SUBJECT TO THE FOLLOWING PROVISIONS:**

- 1) This factory pledge covers only Bristol SUPER Triple-E, A-Plus with Alpha-10 insulating glass replacement windows.
- 2) A complete, full-house, installation of Bristol's SUPER Triple-E with Alpha-10 is defined as all windows, not less than eight, on this residence excluding basement, attic and porch.
- 3) This pledge covers only single and two family dwellings.
- 4) Maximum payment under this Pledge shall be \$500.00 and is strictly for the time period indicated on the reverse side. Reimbursements, if any, can only be issued to a homeowner that has resided at the specified address for a full 12 month period before and after the completed installation date.
- 5) Homeowners must properly maintain heating and cooling system.
- 6) Appropriate allowances for abnormal weather conditions may be made in adjusting a claim.
- 7) Claims under this Pledge must be submitted in writing with supporting evidence to Winchester Industries within 30 days after expiration of this Pledge. Also forward a copy to the Bristol Distributor where purchased.
- 8) Proper allowance shall be made for cost of operation, taxes and service fees, of any utilities included in the fuel bill in adjusting a claim.
- 9) Claim adjustments, if any, will be issued from Winchester Industries within 90 days after all information has been verified and found to be accurate.
- 10) The homeowner referred to on the reverse side as the purchaser of Bristol units must have resided at the specified residence address for a full one year period preceding the installation.
- 11) Apparent changes such as room additions, i.e., sunrooms, heated garages, etc., to the said residence during the 12 month period of the claim shall make such claims invalid.
- 12) Homes moved from one utility service to another shall make this claim null and void.
- 13) Reimbursement at rates prevailing at time of window purchase. Comparison will be based on units of energy used rather than actual dollars to compensate for inflationary increases from one year to the next.
- 14) Complete utility bills for the 24 months in question or a summary form from the authorized utility must be submitted to claim a refund.



Claims must be submitted in writing along with proof of purchase and utility bills and addressed to:

Energy Savings Dept. • Winchester Industries • P.O. Box 160, Saltsburg, PA 15681

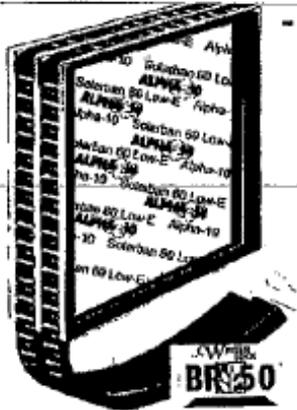
Complaint

Exhibit E



A beautiful, durable, low  
maintenance and environmentally  
responsible choice

- Renew and Improve your home's appearance
- The last window you will ever need
- A Green Choice:



- Reduce energy costs by up to 47%



Complaint

Exhibit F

# Energy Savings up to 47%



Super Triple E A+ High Performance Low-E & Special Gas Mixture Saves You Money and Energy!

Average Monthly Energy Cost	10 Years with no Increase in Energy Costs	Annually			Reflected Savings Using 10% Energy Cost Increase			
		10 Years with 5% Increase per year	10 Years with 10% Increase per year	10 Years with 15% Increase per year	15% Savings	25% Savings	40% Savings	47% Savings
\$100	\$12,000	\$15,090	\$18,125	\$24,364	\$2,869	\$4,761	\$7,850	\$8,388
\$125	\$15,000	\$18,867	\$23,908	\$30,456	\$3,586	\$5,877	\$9,582	\$11,284
\$150	\$18,000	\$22,640	\$29,687	\$36,547	\$4,303	\$7,172	\$11,475	\$13,483
\$175	\$21,000	\$26,414	\$33,469	\$42,638	\$5,020	\$8,367	\$13,387	\$15,730
\$200	\$24,000	\$30,187	\$38,250	\$48,729	\$5,737	\$9,562	\$15,300	\$17,977
\$225	\$27,000	\$33,960	\$43,031	\$54,820	\$6,455	\$10,758	\$17,212	\$20,225
\$250	\$30,000	\$37,734	\$47,812	\$60,911	\$7,172	\$11,953	\$19,125	\$22,472
\$275	\$33,000	\$41,507	\$52,594	\$67,002	\$7,889	\$13,148	\$21,037	\$24,719
\$300	\$36,000	\$45,280	\$57,375	\$73,093	\$8,606	\$14,344	\$22,950	\$26,966
\$325	\$39,000	\$49,054	\$62,156	\$79,185	\$9,323	\$15,539	\$24,862	\$29,213
\$350	\$42,000	\$52,827	\$66,937	\$85,276	\$10,041	\$16,734	\$26,775	\$31,460
\$375	\$45,000	\$56,601	\$71,718	\$91,367	\$10,758	\$17,930	\$28,687	\$33,708
\$400	\$48,000	\$60,374	\$76,500	\$97,458	\$11,475	\$19,125	\$30,600	\$35,955



Complaint

**Exhibit G**

**STOP WASTING MONEY  
ON YOUR  
ENERGY BILLS!**

**47%  
Energy Savings  
Predicted!**

**Bristol**

**THE ULTIMATE REPLACEMENT WINDOWS & DOORS!**  
Eliminates Maintenance - Improves Security - Provides Energy Efficiency

[www.bristolwindows.com](http://www.bristolwindows.com)

888-101 **EPG** Glass Technology SINCE 1988

## Complaint

## Exhibit H

*"I must tell you I am so elated over the change in my home. I used to think my air conditioning wasn't working properly and I would ask the technician if I needed Freon when he did the regular check ups. He always said it was fine. I sit in front of my windows and do a lot of crafts and saw a change immediately the next day. I have the sun come in from the west and afternoons are the hottest part of the day. I realized my air conditioning was blowing hot air around before that was coming in through the windows. Now my air conditioning is blowing cool air and it reaches across the whole room. I sit in my chair now and can't get over the change. I am so comfortable and this week has been a good test. I even raised my temp to 82° and the whole place is comfortable. I do have a fan on in the living room. Sorry to write such a long letter but I must tell you I also get the full hot sun from west. I used to close my bathroom door in the summer it was like an oven and in the winter it was so cold. I hated to go in to shower. Now I have the door open during the day and night and the temperature is the same as rest of the house. I wish I had done the windows sooner. I have lived here ten years. It is well worth the investment. I am enjoying my small place so much more. The heat outside is not coming in and I know I will be more comfortable this winter. I'm sure I will get more benefit from the heating system. A job well done and your men were fine gentlemen and I will be telling my friends what a difference the windows make."*

Evelyn Rokart, AZ

*"This is a testimonial to the changes in my energy bills since I began replacing my old windows with Bristol windows. Prior to the initial installation in 2001, my energy bills (gas and electricity) were running \$108 per month using the budget system. Since that time, I have been replacing windows at the rate of 2-3 per year. As of November 2003, I was spending \$82 per month for energy. As of this December, I was spending \$71 per month on energy after replacing 8 windows. It definitely has made a difference and I expect the savings to continue as I work toward replacing all my windows."*

Mary Ann Melnor, NE

*"I just wanted to send a note of appreciation to your organization. Everyone involved with the manufacturing process should know that they are doing a great job and that the windows your organization manufactures really do work! I was skeptical about the three-pane system and the projected energy savings that the sales person made. However, after reviewing my consumption of gas and electric one year after the installation, I have to admit that investing in three panes of glass worked for us. We consumed 53.2% less energy after getting the windows."*

*I like the lower energy bills...my wife likes the change in comfort level. Prior to investing in the windows, my wife would complain about how cold it was during the winter months and how hot it was upstairs (mainly in the bedrooms) during the summer months. We have not had that conversation since having your windows installed."*

*What a great investment! Throughout the year I'm saving on average \$180.00 per month. The monthly payment for the windows is less than \$150.00 (I think that's awesome)! I read in an article that new home construction will have to install a three-pane system if the builder wants to promote the home as a "green home." Excellent! Please give this letter to potential clients; the average consumer, unfortunately, doesn't know what I know. Energy bills go down...comfort levels change...it's such a great investment. Everyone should have your windows! More than Satisfied."*

K. Niss, Hosan, VA



*"We had Bristol Windows replace 12 of our existing windows in our home 2 years ago. It was a big decision for us because they are not the cheap variety, but we were convinced it was a good investment. We would get what we paid for, and we should do it. We only had 12 done instead of the 17 windows we have, and they said we could do the rest later if we were satisfied, and have time to pay it off. The time is now! We absolutely LOVE these windows. When everyone else was screaming about the heating cost when prices went up, ours stayed the same. This year our heating bill has actually gone down instead of up. They are SOOOO easy to clean, all from the inside, no ladders, we never have to struggle to get old windows open, some didn't open at all before. No more frosted over windows in winter either. Fresh air in the fall and spring is so easy to have. And they worked with us to make it affordable for us. It is definitely one of our best investments, and now we are getting the other 6 windows replaced."*

Jim & Annette Hattan - Fremont, NE

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Winchester Industries is a Pennsylvania partnership with its principal office or place of business at 500 Leech Avenue, Saltsburg, Pennsylvania 15681. The partnership was formed in 1983 by Steel Bridge, LTD, LLC, a Canadian

## Decision and Order

corporation, and Winchester Industries, Inc., a Pennsylvania corporation.

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

**ORDER**

**DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Clearly and prominently” means
  1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
  2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade,

## Decision and Order

contrast to the background against which it appears, the length of time it appears on the screen, and its location, for an ordinary consumer to notice, read and comprehend it; and

3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- B. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
  - C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
  - D. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.
  - E. “Covered product or service” means any fenestration product, any component thereof, and any product or any service for which respondent makes any claim about energy savings, energy costs, energy consumption, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy.
  - F. “Fenestration product” means any window, sliding glass door, or skylight.

## Decision and Order

- G. “K-value” is a measure of a material’s thermal conductivity.
- H. Unless otherwise specified, “respondent” shall mean Winchester Industries, a partnership, its successors and assigns, and its officers, agents, representatives, and employees.
- I. “R-value” is a measure of a material’s resistance to heat flow.
- J. “SHGC” means solar heat gain coefficient, which is the fraction of incident solar radiation admitted through a window, both directly transmitted and absorbed and subsequently released inward.
- K. “U-factor” is a measure of the rate of heat loss.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names that:

- A. Consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or
- B. Respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all

## Decision and Order

or almost all consumers are likely to receive the maximum represented savings or reduction.

*Provided, however,* that if respondent represents that consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, or if respondent guarantees or pledges up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, it must disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge and it must substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region).

**II.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names:

- A. That any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or
- B. About energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy of any covered product or service;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon

## Decision and Order

competent and reliable scientific evidence to substantiate that such representation is true.

**III.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation of material fact. For the purposes of this Part, “means and instrumentalities” shall mean any information, including, but not necessarily limited to, any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any covered product or service, in or affecting commerce.

**IV.**

**IT IS FURTHER ORDERED** that respondent Winchester Industries, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that respondent Winchester Industries, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

**VI.**

**IT IS FURTHER ORDERED** that respondent Winchester Industries, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the partnership that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the partnership name or address. *Provided, however,* that, with respect to any proposed change in the partnership about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "Winchester Industries, File No. 102 3171, Docket No. C-4362."

## Decision and Order

**VII.**

**IT IS FURTHER ORDERED** that respondent Winchester Industries, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

**VIII.**

This order will terminate twenty on May 16, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

Analysis to Aid Public Comment

### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Winchester Industries, a partnership (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves respondent’s marketing and sale of replacement windows for use in residences. According to the FTC complaint, respondent represented that consumers who replace their windows with Bristol and Winter Lock Super Triple-E A-Plus with Alpha-10 windows are likely to achieve residential energy savings of 47% or to save 47% on their heating and cooling costs. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating these representations when it made them. Many factors determine the savings homeowners can realize by replacing their windows, including the home’s geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with Winchester replacement windows are not likely to achieve a 47% reduction in residential energy consumption or heating and cooling costs. The complaint also alleges that, by providing its independent dealers and installers with advertising and other promotional materials making the above unsubstantiated representations, respondent provided the means and instrumentalities to engage in deceptive practices. Thus, the complaint alleges that respondent engaged in unfair or deceptive practices in violation of Section 5(a) of the FTC Act.

Some promotional materials challenged in the FTC’s complaint include the words “up to” in an apparent attempt to

## Analysis to Aid Public Comment

qualify representations that consumers who replace windows with respondent's windows are likely to achieve specified amounts of residential energy savings or reduction in residential heating and cooling costs. In the context of specific ads in this case, the words "up to" do not effectively qualify such representations for replacement windows. The FTC's complaint and the proposed consent order should not be interpreted as a general statement of how the Commission may interpret or take other action concerning representations including the words "up to" for other products or services in the future.

The proposed consent order contains three provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I addresses the marketing of windows. It prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction. Further, if respondent represents, guarantees, or pledges that consumers achieve such energy savings or heating and cooling cost reductions under specified circumstances, it must: disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge; and substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region). The performance standard imposed under this Part constitutes fencing-in relief reasonably necessary to ensure that any future energy savings or reduction claims are not deceptive.

## Analysis to Aid Public Comment

Parts II and III address any product or service for which respondent makes any energy-related efficacy representation. Part II prohibits respondent from making any representation: (A) that any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or (B) about energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, solar heat gain coefficient, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy; unless the representation is non-misleading and substantiated by competent and reliable scientific evidence. Part III prohibits respondent from providing to others the means and instrumentalities with which to make any false, unsubstantiated, or otherwise misleading representation of material fact. It defines "means and instrumentalities" to mean any information, including any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any such product or service.

Parts IV through VII require respondent to: keep copies of advertisements and materials relied upon in disseminating any representation covered by the order; provide copies of the order to certain personnel, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in its structure that might affect compliance obligations under the order; and file a compliance report with the Commission and respond to other requests from FTC staff. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify the proposed order's terms in any way.

## Complaint

## IN THE MATTER OF

**SERIOUS ENERGY, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4359; File No. 112 3001*  
*Complaint, May 16, 2012 – Decision, May 16, 2012*

This consent order addresses Serious Energy, Inc.'s marketing and sale of replacement windows for use in residences. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating representations that consumers who replace their windows with SeriousWindows 501 Series windows are likely to achieve residential energy savings of 40% or save 40% on residential heating and cooling costs or that consumers who replace their windows with SeriousWindows 600 Quantum 2 Series windows are likely to achieve residential energy savings of 49% or save 49% on residential heating and cooling costs when it made them. The consent order prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Participants*

For the *Commission: Robert Frisby, Zachary Hunter, Joshua Millard, and Sarah Waldrop.*

For the *Respondent: Lydia Parnes, Wilson Sonsini Goodrich & Rosati, PC.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Serious Energy, Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

## Complaint

1. Respondent Serious is a Delaware corporation with its principal office or place of business at 1250 Elko Drive, Sunnyvale, CA 94089. Respondent does business under its own name and formerly did business under the name “Serious Materials, Inc.”

2. Respondent manufactures, advertises, offers for sale, sells, and/or distributes windows, including “SeriousWindows” replacement window lines. Respondent distributes these windows to independent dealers and installers who in turn sell them to consumers for residential use.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused the dissemination of advertising and promotional materials, including printed advertisements, website advertising, and other promotional materials provided to window dealers and installers, including but not necessarily limited to the attached Exhibits A through D. Respondent’s dealers and installers disseminated or caused the dissemination of these advertisements and promotional materials to consumers. The advertisements and promotional materials contain the following statements or depictions:

a. SeriousWindows Printed Promotional Material:

**Guaranteed to reduce your heating and cooling use by up to 49%\***. When you replace all of your old windows with SeriousWindows 600 Series, you’ll not only improve your living comfort and your home’s value, but you can significantly lower your heating and cooling consumption. If you spend \$300 a month in heating and cooling, with Quantum2 windows you can potentially save up to 49%, that’s a savings of over \$14,400 in a decade. That’s why we say SeriousWindows 600 products are an annuity, because they will pay for themselves over time.

\* Energy savings may vary and depends on numerous factors and variables pertaining to your windows and

Complaint

dwelling. Cost savings in this example does not include any energy cost increases.

Exhibit A (SeriousWindows 600 Quantum 2 Series Brochure).

b. SeriousWindows Printed Promotional Material:

SeriousWindows

SAVES MORE ENERGY THAN ANY OTHER WINDOW. PERIOD.

....

· Reduces heating & cooling

costs by up to 50%.\*

....

\*According to internal modeling with ResFen software & modeling parameters established by the Efficient Windows Collaborative.

Exhibit B (Print Brochure).

c. SeriousWindows Energy Savings Pledge:

**49%**

***FUEL SAVINGS PLEDGE***

....

***ENERGY SAVINGS PLEDGE***

**This Pledges a savings of at least 49% of "Energy Consumption" for heating and cooling this residence at the address shown below during the 12 month period beginning with the date of this Pledge. If energy savings are less than 49% of the previous 12 months' energy consumption, the**

## Complaint

**homeowner will be reimbursed the difference between actual savings and 49% of energy cost for the previous 12 months. In the event energy savings are less than 49% of the previous 12 months' energy consumption, the homeowner should notify the SeriousWindows™ Quantum2 Dealer who will provide the homeowner with the necessary forms to file for benefits under this Pledge.**

....

Exhibit C.

d. SeriousWindows Printed Promotional Material:

**Cut Your Energy Bills By Up to 40%**  
SeriousWindows 501 Series offers some of the most energy efficient residential windows on the market today. You'll save money on heating and cooling costs, as well as energy. If you spend \$200 a month on heating and cooling that's \$2,400 a year. SeriousWindows 501 products cut 40% off that figure and would save you \$960 in just the first year and over \$9,600 over the next decade.

Exhibit D (SeriousWindows 501 Series Brochure).

5. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with SeriousWindows replacement windows are not likely to achieve a 40% or 49% reduction in residential energy consumption or heating and cooling costs.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- a. Consumers who replace windows with SeriousWindows 600 Quantum 2 Series windows are likely to achieve residential energy savings of 49%;

## Complaint

- b. Consumers who replace windows with SeriousWindows 600 Quantum 2 Series windows are likely to save 49% on residential heating and cooling costs;
- c. Consumers who replace windows with SeriousWindows 501 Series windows are likely to achieve residential energy savings of 40%; or
- d. Consumers who replace windows with SeriousWindows 501 Series windows are likely to save 40% on residential heating and cooling costs.

7. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time that the representation(s) were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time that the representation(s) were made. Therefore, the representation set forth in Paragraph 7 was false or misleading.

9. Respondent provided to its independent dealers and installers promotional materials referred to in Paragraph 4. By doing so, respondent provided them with the means and instrumentalities for the commission of deceptive acts or practices. Therefore, respondent's provision of such materials to its dealers and installers, as described in Paragraph 4 above, constitutes a deceptive act or practice.

10. Respondent's practices, as alleged in this complaint, constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission, this sixteenth day of May, 2012, has issued this complaint against respondent.

## Complaint

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

**Exhibit A**

**Guaranteed to reduce your heating and cooling use by up to 49%\*.** When you replace all of your old windows with SeriousWindows 600 Series, you'll not only improve your living comfort and your home's value, but you can significantly lower your heating and cooling consumption. If you spend \$300 a month in heating and cooling, with Quantum2 windows you can potentially save up to 49%, that's a savings of over \$14,400 in a decade. That's why we say SeriousWindows 600 products are an annuity, because they will pay for themselves over time.

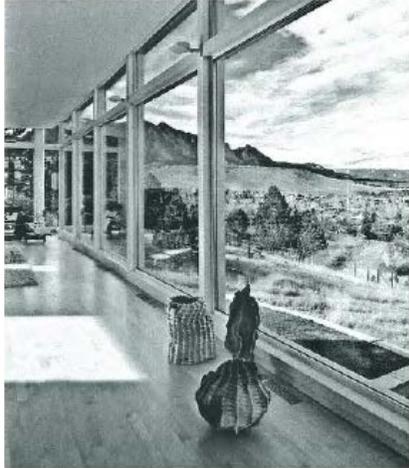
Energy savings may vary and depends on numerous factors and variables pertaining to your windows and dwelling. Cost savings in this example does not include any energy cost increases.

Complaint

Exhibit B

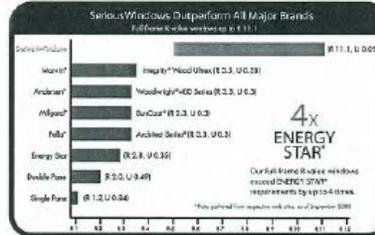
# SeriousWindows

SAVES MORE ENERGY THAN ANY OTHER WINDOW PERIOD.



Our windows save more energy than any other window while improving comfort and providing the design & style you expect from premium windows.

- Reduces heating & cooling costs by up to 50%.\*
- 18% warmer glass than standard dual-pane low-E windows.
- Highest insulating full-frame R-value windows.
- Blocks 99.5% UV rays vs. 84% standard dual-pane low-E windows.



**SERIOUS MATERIALS** (800)797-8159  
[www.seriouswindows.com](http://www.seriouswindows.com)  
[www.seriousmaterials.com](http://www.seriousmaterials.com)

\* According to internal modeling with Radiance software & modeling parameters established by the Efficient Windows Collaborative.

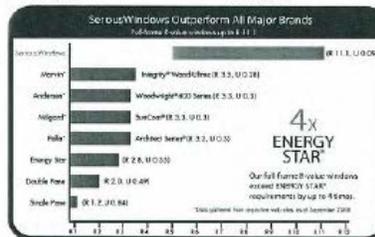
# SeriousWindows

SAVES MORE ENERGY THAN ANY OTHER WINDOW PERIOD.



Our windows save more energy than any other window while improving comfort and providing the design & style you expect from premium windows.

- Reduces heating & cooling costs by up to 50%.\*
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[www.seriousmaterials.com](http://www.seriousmaterials.com)

\* According to internal modeling with Radiance software & modeling parameters established by the Efficient Windows Collaborative.

SM 001747

COMPLAINT EXHIBIT B

Complaint

Exhibit C

**ENERGY SAVINGS PLEDGE**

This Pledge a savings of at least 49% of "Energy Consumption" for heating and cooling this residence at the address shown below during the 12 month period beginning with the date of this Pledge. If energy savings are less than 49% of the previous 12 months' energy consumption, the homeowner will be reimbursed the difference between actual savings and 49% of energy cost for the previous 12 months. In the event energy savings are less than 49% of the previous 12 months' energy consumption, the homeowner should notify the *SeriousWindows™ Quantum2 Dealer* who will provide the homeowner with the necessary forms to file for benefits under this Pledge.

**THIS PLEDGE IS BASED ON ENERGY CONSUMPTION, NOT COST.  
IT IS SUBJECT TO THE FOLLOWING PROVISIONS:**

1. This Pledge covers only the *SeriousWindows Quantum2* window with high performance glass.\*
2. This Pledge covers only single and two family dwellings.
3. Complete installation of these windows is defined as all the windows and glass patio doors on this residence except in the unheated or cooled areas such as attics, basements and outside porches.
4. Maximum payment under this Pledge is \$500.00.
5. Claims under this Pledge must be filed in writing with support evidence within 30 days after expiration of this Pledge to the *SeriousWindows Quantum2 Dealer*.
6. Homeowners must properly maintain heating and cooling systems.
7. All other doors must be energy efficient and weather tight.
8. Proper allowance for abnormal weather conditions shall be made in adjusting a claim.
9. Reimbursement at rates prevailing at the time of window purchase.
10. All claims are subject to an inspection by a *SeriousWindows Quantum2 Dealer* system engineer.

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Date of Issue \_\_\_\_\_

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this Pledge only be effective if the homeowner located at the address shown above has purchased a "Complete" installation of residential replacement windows with "high performance glass" and is effective on the date shown.  
\* High performance glass is the *SeriousGlass™ 10-PowerQ* system.

PN #114-002B-021629

SM 001778

COMPLAINT EXHIBIT C

Complaint

SM 001779



**FUEL SAVINGS PLEDGE**

Installation Date\* \_\_\_\_\_  
Issued to (Name) \_\_\_\_\_  
Address \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_  
Authorized \_\_\_\_\_ Officer \_\_\_\_\_



\*Expires 12 months from installation date.

## Complaint

**Exhibit D**

**Cut Your Energy Bills By Up to 40%** SeriousWindows 501 Series offers some of the most energy efficient residential windows on the market today. You'll save money on heating and cooling costs, as well as energy. If you spend \$200 a month on heating and cooling that's \$2,400 a year. SeriousWindows 501 products cut 40% off that figure and would save you \$960 in just the first year and over \$9,600 over the next decade.



## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Serious Energy, Inc. ("Serious") is a Delaware corporation with its principal office or place of business at 1250 Elko Drive, Sunnyvale, CA 94089.

## Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Clearly and prominently” means
  1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
  2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen,

## Decision and Order

and its location, for an ordinary consumer to notice, read and comprehend it; and

3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- B. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
  - C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
  - D. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.
  - E. “Covered product or service” means any fenestration product, any component thereof, and any product or any service for which respondent makes any claim about energy savings, energy costs, energy consumption, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy.
  - F. “Fenestration product” means any window, sliding glass door, or skylight.
  - G. “K-value” is a measure of a material’s thermal conductivity.

## Decision and Order

- H. Unless otherwise specified, “respondent” shall mean Serious Energy, Inc., its successors and assigns, and its officers, agents, representatives, and employees.
- I. “R-value” is a measure of a material’s resistance to heat flow.
- J. “SHGC” means solar heat gain coefficient, which is the fraction of incident solar radiation admitted through a window, both directly transmitted and absorbed and subsequently released inward.
- K. “U-factor” is a measure of the rate of heat loss.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names that:

- A. Consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or
- B. Respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

## Decision and Order

*Provided, however*, that if respondent represents that consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, or if respondent guarantees or pledges up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, it must disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge and it must substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region).

**II.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names:

- A. That any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or
- B. About energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy of any covered product or service;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that such representation is true.

## Decision and Order

**III.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation of material fact. For the purposes of this Part, “means and instrumentalities” shall mean any information, including, but not necessarily limited to, any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any covered product or service, in or affecting commerce.

**IV.**

**IT IS FURTHER ORDERED** that respondent Serious, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials in its possession or control containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that respondent Serious, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

**VI.**

**IT IS FURTHER ORDERED** that respondent Serious, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "Serious Energy, Inc., File No. 112 3001, Docket No. C-4359."

## Decision and Order

**VII.**

**IT IS FURTHER ORDERED** that respondent Serious, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

**VIII.**

This order will terminate on May 16, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

## Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Serious Energy, Inc., a corporation (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves respondent’s marketing and sale of replacement windows for use in residences. According to the FTC complaint, respondent represented that consumers who replace their windows with SeriousWindows 600 Quantum 2 Series windows are likely to achieve residential energy savings of 49% or save 49% on residential heating and cooling costs. Additionally, according to the FTC complaint, respondent represented that consumers who replace their windows with SeriousWindows 501 Series windows are likely to achieve residential energy savings of 40% or save 40% on residential heating and cooling costs.

The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating these representations when it made them. Many factors determine the savings homeowners can realize by replacing their windows, including the home’s geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with SeriousWindows replacement windows are not likely to achieve a 40% or 49% reduction in residential energy consumption or heating and cooling costs. The complaint also alleges that, by providing its independent dealers and installers with advertising and other promotional materials making the above unsubstantiated representations, respondent provided the means and instrumentalities to engage in deceptive

## Analysis to Aid Public Comment

practices. Thus, the complaint alleges that respondent engaged in unfair or deceptive practices in violation of Section 5(a) of the FTC Act.

Some promotional materials challenged in the FTC's complaint include the words "up to" in an apparent attempt to qualify representations that consumers who replace windows with respondent's windows are likely to achieve specified amounts of residential energy savings or reduction in residential heating and cooling costs. In the context of specific ads in this case, the words "up to" do not effectively qualify such representations for replacement windows. The FTC's complaint and the proposed consent order should not be interpreted as a general statement of how the Commission may interpret or take other action concerning representations including the words "up to" for other products or services in the future.

The proposed consent order contains three provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I addresses the marketing of windows. It prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction. Further, if respondent represents, guarantees, or pledges that consumers achieve such energy savings or heating and cooling cost reductions under specified circumstances, it must: disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge; and substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region). The

## Analysis to Aid Public Comment

performance standard imposed under this Part constitutes fencing-in relief reasonably necessary to ensure that any future energy savings or reduction claims are not deceptive.

Parts II and III address any product or service for which respondent makes any energy-related efficacy representation. Part II prohibits respondent from making any representation: (A) that any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or (B) about energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, solar heat gain coefficient, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy; unless the representation is non-misleading and substantiated by competent and reliable scientific evidence. Part III prohibits respondent from providing to others the means and instrumentalities with which to make any false, unsubstantiated, or otherwise misleading representation of material fact. It defines "means and instrumentalities" to mean any information, including any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any such product or service.

Parts IV through VII require respondent to: keep copies of advertisements and materials relied upon in disseminating any representation covered by the order; provide copies of the order to certain personnel, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in its structure that might affect compliance obligations under the order; and file a compliance report with the Commission and respond to other requests from FTC staff. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify the proposed order's terms in any way.

## Complaint

## IN THE MATTER OF

**GORELL ENTERPRISES, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket No. C-4360; File No. 112 3053**Complaint, May 16, 2012 – Decision, May 16, 2012*

This consent order addresses Gorell Enterprises, Inc.'s marketing and sale of replacement windows for use in residences. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating representations that consumers who replace their windows with respondent's Thermal Master III<sup>®</sup> glass system windows are likely to achieve residential energy savings of 40% or save 40% on residential heating and cooling costs when it made them.. The consent order prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Participants*

For the *Commission: Robert Frisby, Zachary Hunter, Joshua Millard, and Sarah Waldrop.*

For the *Respondent: Steve Stallings, Burns White LLC.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that Gorell Enterprises, Inc. ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Gorell is a Pennsylvania corporation with its principal office or place of business at 1380 Wayne Avenue, Indiana, Pennsylvania 15701. Respondent has done business as

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“Gorell Window & Doors, LLC” and “American Conservatory Systems.”

2. Respondent manufactures, advertises, offers for sale, sells, and/or distributes windows, including “Gorell” replacement window lines. Respondent distributes these windows to independent dealers and installers who in turn sell them to consumers for residential use.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused the dissemination of advertising and promotional materials, including content for presentation books and other promotional materials provided to window dealers and installers, including but not necessarily limited to the attached Exhibit A. Respondent’s dealers and installers disseminated or caused the dissemination of these advertisements and promotional materials to consumers. The advertisements and promotional materials contain the following statements or depictions:

- a. Gorell Energy Savings Pledge:

**40%**

**ENERGY SAVINGS PLEDGE!!!**

....

**40% Energy Savings Pledge**

Gorell Windows & Doors pledges that you will save at least 40% on home fuel consumption for both heating and cooling at your residence . . . during the 12-month period beginning with the date of this pledge (after installation and final payment).

If your energy savings during the first year after the installation of your new windows are less than 40% of your previous 12-month energy consumption – with all

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things being equal except for your new Gorell windows – you will be reimbursed the difference between the actual savings and 40% of your energy costs for the previous 12 months, up to \$500.

If the sum of heating and cooling degree days after installation is within 5% of the same data from the 12 months prior to installation, Gorell will honor the full request, up to \$500. However, if the sum of heating and cooling degree days after the installation of Gorell products is between 5% and 20% more, Gorell will honor 75% of the pledge claim, up to \$375. If the heating and cooling degree days are more than 20% greater after the installation, Gorell will honor 50% of the pledge claim, up to \$250.

....

## Exhibit A.

5. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with Gorell replacement windows are not likely to achieve a 40% reduction in residential energy consumption or heating and cooling costs.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- a. Consumers who replace windows with respondent's Thermal Master III® glass system windows are likely to achieve residential energy savings of 40%; or
- b. Consumers who replace windows with respondent's Thermal Master III® glass system windows are likely to save 40% on residential heating and cooling costs.

7. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and

## Complaint

relied upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time that the representation(s) were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time that the representation(s) were made. Therefore, the representation set forth in Paragraph 7 was false or misleading.

9. Respondent provided to its independent dealers and installers promotional materials referred to in Paragraph 4. By doing so, respondent provided them with the means and instrumentalities for the commission of deceptive acts or practices. Therefore, respondent's provision of such materials to its dealers and installers, as described in Paragraph 4 above, constitutes a deceptive act or practice.

10. Respondent's practices, as alleged in this complaint, constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission, this sixteenth day of May, 2012, has issued this complaint against respondent.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

Complaint

**Exhibit A**

**40%**  
**ENERGY SAVINGS PLEDGE !!!**

Effective From (Date): \_\_\_\_\_ to (Date) \_\_\_\_\_

Issued to (Name): \_\_\_\_\_

Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

**Gorell**  
**WINDOWS & DOORS**

©1993 CH 1004-020 Thomas Moore Inc

EXHIBIT A

Gorell-FTC-11-000010

Complaint

09/05

## 40% Energy Savings Pledge

Gorell Windows & Doors pledges that you will save at least 40% on home fuel consumption for both heating and cooling at your residence (address shown below) during the 12-month period beginning with the date of this pledge (after installation and final payment).

If your energy savings during the first year after the installation of your new windows are less than 40% of your previous 12-month energy consumption — with all things being equal except for your new Gorell windows — you will be reimbursed the difference between the actual savings and 40% of your energy costs for the previous 12 months, up to \$500.

If the sum of heating and cooling degree days after installation is within 5% of the same data from the 12 months prior to installation, Gorell will honor the full request, up to \$500. However, if the sum of heating and cooling degree days after the installation of Gorell products is between 5% and 20% more, Gorell will honor 75% of the pledge claim, up to \$375. If the heating and cooling degree days are more than 20% greater after the installation, Gorell will honor 50% of the pledge claim, up to \$250.

To make a claim under this pledge, please contact your Gorell dealer for the necessary forms to file for your benefits.

**This pledge is based on energy consumption, not cost, and is subject to the following provisions:**

1. This program applies only to "complete installations" in which all windows (minimum 12) and patio doors in a single-family home have been replaced with Gorell replacement window and door products that incorporate the Thermal Master III® glass system. All Gorell products must have been replaced at the same time, prior to the effective date of the pledge.
2. Heating and cooling systems of the residence must be properly maintained, per manufacturers' instructions.
3. Attic and wall insulation must meet current building code requirements, and all doors must be energy efficient and weather-tight.
4. There can be no change in the number of residents or in the use of the residence over 24 months.
5. Only central air conditioning energy usage for cooling is included in the calculations. Energy consumption from window air conditioners cannot be included.
6. All claims are subject to an inspection by and approval of a Gorell system engineer or representative.

**Thank you for selecting Gorell windows and doors. We are confident that you will experience decades of improved comfort in your home.**

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Date of installation \_\_\_\_\_

Gorell Dealer Name \_\_\_\_\_

Gorell Dealer Signature \_\_\_\_\_



**WINDOWS & DOORS**

Gorell-FTC-11-000011

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Gorell Enterprises, Inc. ("Gorell") is a Pennsylvania corporation with its principal office or place of business at 1380 Wayne Avenue, Indiana, Pennsylvania 15701.

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2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Clearly and prominently” means
  1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
  2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen,

## Decision and Order

and its location, for an ordinary consumer to notice, read and comprehend it; and

3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- B. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.
- E. “Covered product or service” means any fenestration product, any component thereof, and any product or any service for which respondent makes any claim about energy savings, energy costs, energy consumption, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy.
- F. “Fenestration product” means any window, sliding glass door, or skylight.
- G. “K-value” is a measure of a material’s thermal conductivity.

## Decision and Order

- H. Unless otherwise specified, “respondent” shall mean Gorell Enterprises, Inc., its successors and assigns, and its officers, agents, representatives, and employees.
- I. “R-value” is a measure of a material’s resistance to heat flow.
- J. “SHGC” means solar heat gain coefficient, which is the fraction of incident solar radiation admitted through a window, both directly transmitted and absorbed and subsequently released inward.
- K. “U-factor” is a measure of the rate of heat loss.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names that:

- A. Consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or
- B. Respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

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*Provided, however*, that if respondent represents that consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, or if respondent guarantees or pledges up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, it must disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge and it must substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region).

**II.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names:

- A. That any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or
- B. About energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy of any covered product or service;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that such representation is true.

## Decision and Order

**III.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation of material fact. For the purposes of this Part, “means and instrumentalities” shall mean any information, including, but not necessarily limited to, any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any covered product or service, in or affecting commerce.

**IV.**

**IT IS FURTHER ORDERED** that respondent Gorell, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that respondent Gorell, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

**VI.**

**IT IS FURTHER ORDERED** that respondent Gorell, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however,* that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: "Gorell Enterprises, Inc., File No. 112 3053, Docket No. C-4360."

## Decision and Order

**VII.**

**IT IS FURTHER ORDERED** that respondent Gorell, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

**VIII.**

This order will terminate on May 16, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

## Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Gorell Enterprises, Inc., a corporation (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter involves respondent’s marketing and sale of replacement windows for use in residences. According to the FTC complaint, respondent represented that consumers who replace their windows with respondent’s Thermal Master III® glass system windows are likely to achieve residential energy savings of 40% or save 40% on residential heating and cooling costs. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating these representations when it made them. Many factors determine the savings homeowners can realize by replacing their windows, including the home’s geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with Gorell replacement windows are not likely to achieve a 40% reduction in residential energy consumption or heating and cooling costs. The complaint also alleges that, by providing its independent dealers and installers with advertising and other promotional materials making the above unsubstantiated representations, respondent provided the means and instrumentalities to engage in deceptive practices. Thus, the complaint alleges that respondent engaged in unfair or deceptive practices in violation of Section 5(a) of the FTC Act.

The proposed consent order contains three provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I addresses the marketing of

## Analysis to Aid Public Comment

windows. It prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction. Further, if respondent represents, guarantees, or pledges that consumers achieve such energy savings or heating and cooling cost reductions under specified circumstances, it must: disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge; and substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region). The performance standard imposed under this Part constitutes fencing-in relief reasonably necessary to ensure that any future energy savings or reduction claims are not deceptive.

Part I of the order requires substantiation for representations including the words "up to" because the respondent may elect to make such representations in the future. The words "up to" do not effectively qualify representations regarding the energy savings or cost reductions likely to be achieved through replacement windows. Therefore, Part I requires the same level of substantiation regardless of whether the covered representation includes the words "up to." The FTC's proposed consent order should not be interpreted as a general statement of how the Commission may interpret or take other action concerning representations including the words "up to" for other products or services in the future.

Parts II and III address any product or service for which respondent makes any energy-related efficacy representation.

## Analysis to Aid Public Comment

Part II prohibits respondent from making any representation: (A) that any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or (B) about energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, solar heat gain coefficient, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy; unless the representation is non-misleading and substantiated by competent and reliable scientific evidence. Part III prohibits respondent from providing to others the means and instrumentalities with which to make any false, unsubstantiated, or otherwise misleading representation of material fact. It defines "means and instrumentalities" to mean any information, including any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any such product or service.

Parts IV through VII require respondent to: keep copies of advertisements and materials relied upon in disseminating any representation covered by the order; provide copies of the order to certain personnel, agents, and representatives having responsibilities with respect to the subject matter of the order; notify the Commission of changes in its structure that might affect compliance obligations under the order; and file a compliance report with the Commission and respond to other requests from FTC staff. Part VIII provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify the proposed order's terms in any way.

## Complaint

## IN THE MATTER OF

**THV HOLDINGS LLC**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket No. C-4361; File No. 112 3057*  
*Complaint, May 16, 2012 – Decision, May 16, 2012*

This consent order addresses THV Holdings LLC's marketing and sale of replacement windows for use in residences. The complaint alleges that respondent did not possess and rely upon a reasonable basis substantiating representations that its windows likely pay for themselves in energy savings alone within eight years, when consumers replace their windows with THV Compozit windows with Alter-Lite® triple pane glass; that consumers who replace their windows with these THV windows are likely to achieve residential energy savings of 40%, save 40% on residential heating and cooling costs, or reduce their energy bills by half; and that homeowners have saved 35%-55% off their energy bills by replacing their windows with THV windows when it made them. The consent order prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent's windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

*Participants*

For the *Commission: Robert Frisby, Zachary Hunter, Joshua Millard, and Sarah Waldrop.*

For the *Respondent: Eric Berman, Baker Botts, LLP; and Cory Skolnick, Frost Brown Todd LLC.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that THV Holdings LLC ("respondent") has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

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1. Respondent THV Holdings LLC is a Delaware limited liability company with its principal office or place of business at 5611 Fern Valley Road, Louisville, Kentucky 40228. It does business as THV Compozit Windows & Doors, Leingang Home Center, Primax Home Center, True Home Value, Rolox Home Center, and Thomas Construction.

2. Respondent manufactures, advertises, offers for sale, sells, installs, and/or distributes windows, including its THV Compozit Window line with Alter-Lite® triple pane glass. Respondent sells these windows directly to consumers for residential use, and distributes the windows to numerous independent distributors who in turn sell them to consumers for residential use.

3. The acts and practices of respondent alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

4. Respondent has disseminated or has caused the dissemination of advertising and promotional materials, such as web page, newspaper and magazine advertising, brochures, telemarketing scripts, and sales training materials, including but not necessarily limited to the attached Exhibits A through I. Respondent and its independent distributors disseminated or caused the dissemination of these advertising and promotional materials and representations to consumers. The advertising and promotional materials contain the following statements or depictions:

a. THV Window Systems Premium Warranty

THV Window Systems will pay for themselves in energy savings within eight years or we pay the difference! . . .

This warranty guarantees a total energy savings equal to or greater than the total purchase price of a full house installation of THV Window Systems at the address shown hereon for a period of eight (8) years. The eight year total energy savings begin the first day of the month subsequent to the completed installation of THV Window Systems. In the event total energy

## Complaint

savings over the eight-year period are less than the complete installation purchase price, the Purchaser shall notify THV using the provided claim forms to file for benefits under this warranty. If energy savings over the eight-year period are less than the completed installation, THV will reimburse the difference between actual savings and the purchase price.

Exhibit A.

- b. Thermal Line Windows - THV Composit Window Systems

**Sales Training Manual**

■ *What would happen to your fuel bills if I were able to build a window that acted more like a thermos bottle than a jelly jar? Do you think they would go up or down?*

Get Answer: They'd go down!

**State answer pointing to the fuel savings warranty saying:**

*They would pay for themselves in energy savings alone within 8 years!*

....

Now ask the question that clears the deck for the Closing Sequence. The goal of this question is to make sure the only thing holding them back is the money.

*Great window isn't it? Other than the cost, is there any reason you wouldn't want to own these windows and cut that energy bill in half?*

Exhibit B.

## Complaint

## c. THV Sales Training Materials

*Why are our windows better than everyone else's?*

It is the only product that is FREE! That's right, FREE! Homeowners will typically experience a 35% to 55% reduction in monthly energy bills. Our windows will pay for themselves in energy savings alone within eight years or we will pay the difference. **And that's the Thomas promise!**

Exhibit C.

## d. THV Telemarketing Sales Script

THOMAS CONSTRUCTION MANUFACTURES OUR OWN COMPOSIT WINDOW. OUR HOME OWNERS HAVE NOTICED THAT OUR WINDOWS HAVE SAVED THEM 35-55% OFF THEIR ENERGY BILLS AND OUR WINDOWS SYSTEM WILL PAY FOR THEMSELVES IN ENERGY SAVINGS ALONE WITHIN 8 YEARS OR WE WILL PAY THE DIFFERENCE!!

WHAT THIS MEANS TO OUR HOME OWNERS!!

**OUR WINDOWS ARE FREE!!! THAT'S THE THOMAS PROMISE!!!**

Exhibit D.

## e. THV Telemarketing Sales Script

CASH BACK DIRECT MAIL PITCH

STEP I Hello is Mr. \_\_\_\_\_ in?

Hi this is \_\_\_\_\_ with Rolox Industries. I'm calling to see if you looked over the material we mailed to you?

STEP II What it tells about is a special neighborhood savings program, offering you up to a thousand dollars off on your next home improvement.

## Complaint

So you can remodel your home with triple glass, energy efficient windows and reduce your heating and cooling bills by at least 40%.

Exhibit E.

## f. THV Newspaper Advertising

LOWER ENERGY BILLS & INCREASE YOUR COMFORT WITH THV REPLACEMENT WINDOWS

....

■ 40% Fuel Savings

...

THV GUARANTEES IN WRITING . . .

Our windows will pay for themselves in utility bills alone or we will pay you the difference.

Exhibit F.

Up to 40% FUEL SAVINGS

Composit frame for superior energy performance and savings. . . . Our fuel pledge is that THV windows will pay for themselves or we will pay you the difference.

GUARANTEED!

Exhibit G.

## g. THV Magazine Advertisement

WINNING THE WAR ON HIGH ENERGY BILLS

40% FUEL SAVINGS *Guaranteed*

Our windows pay for themselves or we pay you the difference! GUARANTEED!

## Complaint

## Exhibit H.

## h. THV 40% Fuel Pledge

Our pledge: Your new THV Compozit windows will give you an energy savings of 40% on your fuel consumption during the first 12 months after installation or we will pay you the difference!

....

This pledges a savings of 40% on your heating and cooling consumption for this residence at the address shown hereon during the 12 month period beginning with the date of this Pledge.

....

## Exhibit I.

5. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with THV replacement windows are not likely to achieve a 40%, 50%, or 35%-55% reduction in residential energy consumption or heating and cooling costs.

6. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that:

- a. Its windows likely pay for themselves in energy savings alone within eight years, when consumers replace their windows with THV composit windows with Alter-Lite® triple pane glass;
- b. Consumers who replace windows with THV composit windows with Alter-Lite® triple pane glass are likely to achieve residential energy savings of 40%;

## Complaint

- c. Consumers who replace windows with THV composited windows with Alter-Lite® triple pane glass are likely to save 40% on residential heating and cooling costs;
- d. Consumers who replace windows with THV composited windows with Alter-Lite® triple pane glass are likely to reduce their energy bills by half; or
- e. Home owners have saved 35-55% off their energy bills by replacing their windows with THV composited windows.

7. Through the means described in Paragraph 4, respondent has represented, expressly or by implication, that it possessed and relied upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time the representation(s) were made.

8. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representation(s) set forth in Paragraph 6 at the time the representation(s) were made. Therefore, the representation set forth in Paragraph 7 was false or misleading.

9. Respondent provided to its independent distributors promotional materials referred to in Paragraph 4. By doing so, respondent provided them with the means and instrumentalities for the commission of deceptive acts or practices. Therefore, respondent's provision of such materials to its distributors, as described in Paragraph 4 above, constitutes a deceptive act or practice.

10. The acts and practices of respondent as alleged in this complaint constitute unfair or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act.

**THEREFORE**, the Federal Trade Commission this sixteenth day of May, 2012, has issued this complaint against respondent.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

Complaint

Exhibit A



The Industry's **FIRST** Energy Savings **GUARANTEE**  
 THV Window Systems will pay for themselves in energy savings  
 within eight years or we pay the difference!

Issued to: \_\_\_\_\_ Phone# (\_\_\_\_) \_\_\_\_\_  
Purchaser (Homeowner)

Residence Street Address \_\_\_\_\_ City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

# of Units Installed \_\_\_\_\_ Warranty/Contract No. \_\_\_\_\_

Effective \_\_\_\_\_ to \_\_\_\_\_  
Date Installed (Eight Years Later)

Validated by: \_\_\_\_\_  
THV Window Systems Certified Home Remodeler

See reverse side for complete instructions

The THV Window Systems are distributed by THV Certified Home Remodelers  
 PO Box 34749, Louisville, Kentucky 40232  
 Copyright © 2004, ThermoView Industries, Inc.



**CUSTOMER ACTIVATION RECEIPT -**  
 Fill out and return to THV within 30 days of your completed installation or  
 Warranty is Null and Void. Mail with previous 12 months of utility bills/summary to:  
 THV, PO Box 34749, Louisville, KY 40232

Issued To _____	Phone # _____	Number of Units Installed _____	Warranty/Contract No. _____
Residence Street Address _____		Contract # _____	Date _____
City _____ State _____ Zip _____		Effective _____ to _____	Date Installed _____ Eight years later _____
Purchaser's Signature _____	Date _____	Certified Home Remodeler (Installer) _____	Date _____



**SUBSIDIARY ACTIVATION RECEIPT -**  
 Fill out and return to THV upon completion of approved contract. Once received  
 and processed at THV, a deduction will be made from your Subsidiary Account.  
 THV, PO Box 34749, Louisville, KY 40232

Issued To _____	Phone # _____	Number of Units Installed _____	Warranty/Contract No. _____
Residence Street Address _____		Contract # _____	Date _____
City _____ State _____ Zip _____		Effective _____ to _____	Date Installed _____ Eight years later _____
Measurer's Signature _____	Date _____	Finance/Ordering Dept. Signature _____	Date _____

THV 0326

## Complaint

## THV LIMITED PREMIUM WARRANTY

This warranty guarantees a total energy savings equal to or greater than the total purchase price of a full house installation of THV Window Systems at the address shown hereon for a period of eight (8) years. The eight year total energy savings begin the first day of the month subsequent to the completed installation of THV Window Systems. In the event total energy savings over the eight-year period are less than the complete installation purchase price, the Purchaser shall notify THV using the provided claim forms to file for benefits under this warranty. If energy savings over the eight-year period are less than the completed installation, THV will reimburse the difference between actual savings and the purchase price.

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this warranty shall only be effective if the Purchaser, located at the address indicated above, has purchased a complete installation of THV Window Systems units, remains the owner at such residence for an eight-year period after installation and is in compliance with the terms and conditions stated below. This warranty is based on energy (fuel) consumption, not cost. It is subject to the following provisions:

## TERMS AND CONDITIONS OF THV LIMITED PREMIUM WARRANTY

1. The Premium Warranty covers only Total Energy Savings resulting from a complete installation of THV Window Systems units.
2. A "complete installation" is defined as all windows at the residence except basement, attic and porch. The Premium Warranty covers only energy savings of installations at single and two family dwellings.
3. To activate Premium Warranty the Customer Activation Receipt must be submitted to THV, PO Box 34749, Louisville, KY 40232 within 30 days of completed installation, and include 12 months of utility bills evidencing energy usage.
4. Premium Warranty claims, if any, can only be issued by a purchasing homeowner that resides at the specified address for a full eight-year period after completed installation date.
5. Heating/cooling system at the residence must be properly maintained.
6. Appropriate allowances for abnormal weather conditions may be made in adjusting a claim.
7. Purchaser must submit claims under this Premium Warranty, in writing within 90 days after the complete installation eight-year anniversary.
8. Total energy savings includes eligible tax credits available to the Purchaser as a result of the purchase of THV Window Systems units.
9. Claim determinations or adjustments, if any, will be made within 90 days after all claim information has been received, authenticated and verified.
10. Modifications that could increase energy consumption, such as room additions, i.e., sun-rooms, heated garages, etc., to the said residence during the eight-year time period of the claim shall make such claims invalid unless submitted to THV for prior approval.
11. A change of energy related utility service (e.g., change from electric to gas) at the residence shall make the Premium Warranty null and void.
12. Reimbursement, if any, is determined using average energy rates during the Premium Warranty period. Reimbursement calculations are based on reduced units of energy (e.g. MCF dollars per thousand cubic feet) not reduction in actual dollars. Reimbursement, if any, is calculated using the change in energy usage, excluding the impact of changes in weather (measured by non-heating and cooling days derived from statistics gathered from the National Oceanic and Atmospheric Administration) multiplied by average energy rate over the warranty period. Cost of operation, taxes and service fees of any utilities are excluded from reimbursement calculation.
13. Purchaser must submit complete utility bills for the 96 month Premium Warranty period, or a summary form, from the authorized utility to claim a refund. The claim must be forwarded to THV, PO Box 34749, Louisville, KY 40232 within 90 days of the eight-year anniversary date.
14. Implied warranties shall be limited to the duration of this limited Warranty. Some States do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.
15. This Warranty excludes incidental and consequential damages. Some states do not allow the exclusion or limitation of incidental or consequential damages so the above limitation or exclusion may not apply to you.
16. This Warranty gives you specific legal rights, and you may have other rights which vary from State to State.

## Warranty Activation:

Following completion of a "complete installation" of THV Window System units, the eligible homeowner must take the following action to initiate the THV Limited Premium Warranty:

1. Complete the Customer Activation Receipt provided by THV at the completion of installation.
2. Obtain 12 months prior energy usage from utility company.
3. Within 30 days after completed installation mail Customer Activation Receipt and a copy of the 12 months prior energy usage to THV  
PO Box 34749  
Louisville, KY 40232
4. Within 90 days Purchaser will receive "Your Personal Warranty Packet" and THV confirmation letter.

## Subsidiary Warranty Activation:

1. Salesperson must validate offer and acceptance of Premium Warranty in writing on contract and include signature and date of Seller and Purchaser.
2. Contract number shall serve as Premium Warranty number.
3. Contract number/Premium Warranty number must be applied to Customer Premium Warranty, Customer Activation Receipt and Subsidiary Activation Receipt and checked for accuracy against original contract.
4. Upon approval of contract, fill out front of Subsidiary Activation Receipt and mail to:  
THV  
PO Box 34749  
Louisville, KY 40232
5. Once received and processed at THV, a deduction will be made from your Subsidiary Account.
6. Installer must return Customer Premium Warranty and Customer Activation Receipt to Purchaser at the time of completed installation.
7. Installer must verbally communicate instructions for Activation Receipt to Purchaser.

THV 0327

## Complaint

**Exhibit B****THE THERMOS®  
COMPARISON****Your response:**

*No, you heat with money...*

Point to the estimated fuel usage on the fuel savings warranty sheet you talked about during the company story.

**Major statement – memorize:**

*Your present windows can keep your home no warmer than this jelly jar can keep your coffee hot! And in the summer you have the same situation keeping the heat out.*

Pull out your thermos and separate the liner from the case:

- *You would use a thermos if you wanted to keep your coffee hot for longer than 10 minutes, wouldn't you?*

Get answer: Yes

- *If I were to put hot coffee in this thermos and put it outside in the winter's night, how long before it would get cold?*

Get answer: 10 hours! — Sixty times more effective!

- *What would happen to your fuel bills if I were able to build a window that acted more like a thermos bottle than a jelly jar? Do you think they would go up or down?*

Get Answer: They'd go down!

**State answer pointing to the fuel savings warranty saying:**

*They would pay for themselves in energy savings alone within 8 years!*

- *That's what we set out to do, build a window that thinks it's a Thermos bottle!*

*Why? To offer homeowners a window that is an investment, not an expense.*

- *We need the two elements of a Thermos bottle:*

1. *Dead air space.*
2. *Reflective surface*

**Hold up your THV Composit Corner Section.**

- *We thought if one air space was good, two had to be better! Makes sense, doesn't it?*

Get Answer: Yes

- *The silver lining was a bit more difficult. We use a "soft coat" Low-E rather than the less expensive hard coat. You may get a flyer in the mail from my competition giving away free Low-E... they use hard coat; it's not nearly as effective as soft coat!*

THV 0550

## Complaint

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### GET AN ANSWER

#### **You may have to help get a conclusion.**

*We are very flexible on monthly payments and terms. Again, the many people I deal with feel differently about the monthly payments. Our goal is to keep it comfortable, so you enjoy the windows without payment pressure.*

*What type of payment would fit you best?*

#### **Write both figures down. Make them important.**

Now ask the question that clears the deck for the Closing Sequence. The goal of this question is to make sure the only thing holding them back is the money.

*Great window isn't it? Other than the cost, is there any reason you wouldn't want to own these windows and cut that energy bill in half?*

THV 0568

## Complaint

**Exhibit C**

## Product Knowledge

Show & sell training  
Bill D.  
NOT APPROVED 6 months

*Division #1: Windows and Siding*

The window and siding division is the largest division and the bread and butter of the company. This means that these should be the first products you promote! Why? Windows and siding projects are likelier to issue, demo and approve than many other products. The more you promote windows and siding, the more money you'll make. **Don't forget, your income is under your control!**

**Windows**

- We manufacture our very own Thomas Construction Window at a manufacturing plant in Mandan, North Dakota! The window is made out of an aerated polymer, which is 214% more efficient than vinyl.
- We are the exclusive carriers of this window.
- Products in this division come with a 50 year warranty and 3 year glass breakage warranty.
- The window in triple paned with a krypton/argon gas mix and tilts in for easy cleaning.
- Many types are available, including bay, bow, garden, casement, slider and double hung windows. There are also many colors available including a wood grain finish.
- This division also includes entry, French and patio doors by precision.

*Why are our windows better than everyone else's?*

It is the only product that is FREE! That's right, FREE! Homeowners will typically experience a 35% to 55% reduction in monthly energy bills. Our windows will pay for themselves in energy savings alone within eight years or we will pay the difference. **And that's the Thomas promise!**

**Siding**

- \_\_\_\_\_ is the manufacturer of our siding and Thomas is the exclusive carrier of the product.
- Our siding is solid vinyl, not recycled.
- The siding is maintenance free, which means the homeowner will NEVER have to paint the house again.
- We can cover the whole home, including soffit and fascia.
- Several colors and styles are available, including vertical siding.
- Siding comes with a lifetime warranty.
- We use styrene wrap on the back of the siding for flat surface and air flow.

*Division #2: Roofing*

- Our roofing manufacturer is \_\_\_\_\_.
- This is the last roof a homeowner will ever need to replace on their home.
- Our 50 year warranty is transferable, which is attractive to homeowners who are thinking about selling and hoping to add more value.
- The roof is hail resistant.
- We can also put in aluminum gutters with roof installation.

Complaint

**Exhibit D**

*Tel2 market script*

**WINDOWS:**

THOMAS CONSTRUCTION MANUFACTURES OUR OWN  
COMPOSIT WINDOW. OUR HOME OWNERS HAVE NOTICED  
THAT OUR WINDOWS HAVE SAVED THEM 35-55% OFF THEIR  
ENERGY BILLS AND OUR WINDOWS SYSTEM WILL PAY FOR  
THEMSELVES IN ENERGY SAVINGS ALONE WITHIN 8 YEARS  
OR WE WILL PAY THE DIFFERENCE!!

WHAT THIS MEANS TO OUR HOME OWNERS!!

**OUR WINDOWS ARE FREE!!! THAT'S THE  
THOMAS PROMISE!!!**

DO YOU WORK DURING THE DAY OR EVENINGS? THE  
REASON I ASK IS BECAUSE WHAT WE WOULD LIKE TO DO IS  
SHOW YOU WHAT WE HAVE TO OFFER AND ANSWER ANY  
QUESTIONS YOU MAY HAVE AND LEAVE YOU WITH A COST  
FREE NO OBLIGATION ESTIMATE.

I HAVE AN APPOINTMENT AVAILABLE TOMORROW  
@\_\_\_\_\_ WHICH WOULD BE BETTER FOR YOU?

**(ABC) ALWAYS BE CLOSING!!  
(GO TO BUTTON UP)**

## Complaint

**Exhibit E**

## CASH BACK DIRECT MAIL PITCH

- STEP I Hello is Mr. \_\_\_\_\_ in?
- Hi this is \_\_\_\_\_ with Rolox Industries. I'm calling to see if you looked over the material we mailed to you?
- STEP II What it tells about is a special neighborhood savings program, offering you up to a thousand dollars off on your next home improvement. So you can remodel your home with triple glass, energy efficient windows and reduce your heating and cooling bills by at least 40%.
- STEP III But first, let me ask:
1. How old is your home? How long have you owned it?
  2. Is that a frame or brick house?
  3. When you folks eventually change to a window that cuts your utility bills, how many will you need?
- (SECONDARY WINDOW QUESTION)
- I guess what I'm asking is, if Rolox could show you a window that you liked, and a way to get up to 100% of your investment back, how many of your windows would you change?
- STEP IV Right now our factory reps are going directly to homeowners to demonstrate the advantages of our windows and for a limited time we have a cash back offer which will enable you to put Rolox windows in your home and in 3 years, you can claim and receive up to 100% of your investment back. While we are doing this, I'll have him stop by!
- STEP V
1. But how did I catch you at home, do you work days?
  2. Does Mrs/Mr work days or nights?
  3. What time are you both home from work?
- STEP VI Ok, I'll put you on our factory reps schedule for (time). Now tomorrow being (day), that isn't club, church, bowling or anything like that is it? In case he's a little late, you folks will be home all evening anyway, won't you?
- STEP VII By the way, what is your wife/husband name? Do me a favor Mr/Mrs \_\_\_\_\_ tell \_\_\_\_\_ that this is our factory rep coming out, not some door-to-door salesman. What he will do is show you a working model of our window. If you see something you like he can measure your opening and let you know exactly what our cost would be. If it's something we can help you with, great! If not, we'll shake hands and part friends.
- Now our factory rep only leaves the office on the appointments I set for him, so I can count on you and Mrs/Mr both being there, can't I? Ok great, what is your correct address? And that's in \_\_\_\_\_. Ok, what's your zip code? Well thanks a lot for the appointment and we'll look forward to seeing you both (day & time).

THV 1241

Complaint

**Exhibit F**

**LOWER ENERGY BILLS & INCREASE YOUR COMFORT WITH THV REPLACEMENT WINDOWS**

- 50 Year Warranty
- 40% Fuel Savings
- Easy to clean tilt-in feature
- Maintenance free inside and out

**THV GUARANTEES IN WRITING...**  
Our windows will pay for themselves in utility bills alone or we will pay you the difference.

**ALTER-LITE®**  
TRIPLE PANE GLASS

**THV**  
composit  
WINDOW SYSTEMS

**7**  
Estimate Colors

**ACT NOW!**

**FREE INSTALL**  
WITH PURCHASE OF 5 OR MORE WINDOWS  
Offer Ends in 30 Days. One offer per household. Not valid with any other offer or sale.

**WE SELL ENERGY STAR**

---

**CREATE IMPACT WITH DOORS**

**THV**  
composit  
DOOR SYSTEMS  
PATIO DOORS

**STEEL DESIGNER ENTRY DOORS**

**\$150 OFF**

**\$250 OFF**

**THV**  
True Home Value, Inc.  
www.thvstores.com

**CALL FOR YOUR FREE ESTIMATE**  
**(800) 460-3129**  
LOCALLY OPERATED

Complaint

# Relax with the safety and convenience of **MAINTENANCE-FREE GUTTERS**

- Diverts leaves and debris
- Prevents mold growth
- Prevents mosquito breeding
- Resistant to fading from the sun and cleaning solvents
- Prevents termite damage
- Protects your home against foundation and landscape damage
- Keeps you safe from climbing to clean gutters



**25%  
OFF  
GUTTER  
PROTECTION**

Offer Ends In 30 Days. One offer per household. Not valid with any other offer or sales.

THV is the exclusive supplier of:

**CLEAR WATER**  
Gutter Protection System

## ADD VALUE AND CURB APPEAL WITH SIDING



**VISIT OUR SHOWROOM**  
5140 Frederica St Ste C  
Between Applebee's & Olive Garden  
9-6 M-F, 9-1 Sat., Sun. by appt.

**CALL FOR YOUR FREE ESTIMATE**  
**(800) 460-3129**



**\$99 OFF  
Per Square**

Offer Ends In 30 Days. One offer per household. Not valid with any other offer or sales.

**FINANCING AVAILABLE**  
**SENIOR DISCOUNTS for 55 and OLDER**  
[www.thvstores.com](http://www.thvstores.com)

Complaint

Exhibit G

**IT'S A GREAT TIME TO REPLACE WINDOWS!**

**Up to 40% FUEL SAVINGS**  
 Composite frame for superior energy performance and savings. Fifty-year warranty. Our fuel pledge is that THV windows will pay for themselves or we will pay you the difference. **GUARANTEED!**

**ALTER-LITE™**  
TRIPLE-pane glass

- Low-E coating
- Tilt-in easy to clean feature
- 50 Year Warranty
- Maintenance-Free

**TAX CREDIT UP TO \$1750**

**FIND OUT IF YOU QUALIFY FOR THE TAX CREDIT. CALL TODAY!**

**TRUCCATING**  
UP TO 50% OFF

**25% OFF**  
**FIRST 25 CALLERS GET FREE INSTALLATION**  
Offer expires 10/31/10. Not valid with any other discounts or offers.

---

**INEXPENSIVE ONE DAY BATH REMODEL**

9am

5pm

**NU-BATH**  
Like a Miracle

Various styles and options for you to choose from. Easy to clean. Installed over your old tub in one day. Professional and affordable.

**\$250 OFF**  
**ANY BATH/SHOWER PKG**  
Offer expires 10/31/10. Not valid with any other discounts or offers.

---

**SIDING**  
 Many colors and styles to choose from. Gives you great curb appeal and added insulation. Maintenance-free.

**ENTRY/PATIO DOORS**  
 Composite core for energy efficiency. Security features. Various colors, styles and hardware to choose from.

**GUTTER PROTECTION**  
 Protect your home's foundation. Stop breeding of mosquitoes. No more ladders.

**33% OFF**  
**ALL OTHER PRODUCTS**  
Offer expires 10/31/10. Not valid with any other discounts or offers.

**CALL TO JOIN A GREAT TEAM NOW HIRING SALES REPS**

---

**\$25,000 Home Improvement**

**ONE LUCKY HOMEOWNER WILL**

**THV Sweepstakes**

**\$15,000 & \$10,000**

in FREE THV HOME IMPROVEMENTS CASH TO SPEND HOW YOU LIKE

**CALL to ENTER TODAY!**

**True Home Value, Inc.** **CALL: FOR YOUR FREE ESTIMATE 800-460-3135** **CLICK: www.thvstores.com** **COME BY: SHOWROOM 130 Walton Ave Bowling Green**

**BUY FEB 2010 PAY JULY 2010**

NO PURCHASE NECESSARY. PURCHASE WILL NOT INCREASE ODDS OF WINNING. Open to homeowners who 21, and legal residents within True Home Value, Inc.'s (THV) service area. Ends 12/31/10. See store for official rules. Void where prohibited. Grand Prize \$15,000. Limit one entry per person/family. For Official Rules, go to www.thvstores.com or write to: Sweepstakes Rules, P.O. Box 28079, Louisville, KY 40228. Sponsor: THV, P.O. Box 18078, Louisville, KY 40227.

Complaint

**Exhibit H**

**WINNING THE WAR  
ON HIGH ENERGY BILLS**

**40% FUEL SAVINGS  
Guaranteed**

Our windows pay for themselves or we pay you the difference!  
**GUARANTEED!**

**LIFETIME WARRANTY**  
**TRU COATING**  
Fourteen Exterior Colors

**WINDOWS • SIDING • DOORS • TUBS  
GUTTER PROTECTION**

**ROLOX**  
HOME CENTER  
A Division of  
**THV**  
True Home Value, Inc.

**FREE ESTIMATE**  
**800-950-3060**  
**www.rolox.com**

**25% OFF**  
**ALL PRODUCTS**  
All offers good for 30 days.  
One offer per household.  
Not valid with any other offer or sales.

Complaint

**Exhibit I**



Our pledge: Your new THV Composit windows will give you an energy savings of 40% on your fuel consumption during the first 12 months after installation or we will pay you the difference!

Issued to: \_\_\_\_\_ Phone # \_\_\_\_\_

\_\_\_\_\_  
 Residence Street Address                      City                      State                      Zip Code

# of Units: \_\_\_\_\_ Pledge/Contract No. \_\_\_\_\_

Effective \_\_\_\_\_ to \_\_\_\_\_

Validated by: \_\_\_\_\_  
 THV Certified Home Remodeler

See reverse side for complete instructions

The THV Pledge is backed by THV Certified Home Remodelers  
 P.O. Box 34749 • Louisville, KY 40232  
 Copyright 2010 THV

THV 0342



**CUSTOMER ACTIVATION RECEIPT**  
 Fill out and return to THV Composit Windows & Doors within 30 days of your completed installation to: THV PO Box 34749, Louisville, KY 40232

Issued To _____	Phone # _____	Number of Units Installed _____	Pledge/Contract No. _____
Residence Street Address _____		Contract # _____	Date _____
City _____	State _____	Zip _____	Effective _____
			Date Installed _____
Purchaser's Signature _____	Date _____	Certified Home Remodeler (Installer) _____	Date _____



**DEALER ACTIVATION RECEIPT**  
 Fill out and return to THV Composit Windows & Doors with copy of approved contract to: THV PO Box 34749, Louisville, KY 40232

Issued To _____	Phone # _____	Number of Units Installed _____	Pledge/Contract No. _____
Residence Street Address _____		Contract # _____	Date _____
City _____	State _____	Zip _____	Effective _____
			Date Installed _____
Signature _____	Date _____		

## Complaint


 TERMS AND CONDITIONS OF THE Complaint Ext  
 40% FUEL PLEDGE

This pledges a savings of 40% on your heating and cooling consumption for this residence at the address shown hereon during the 12 month period beginning with the date of this Pledge. In the event fuel savings are less than 40% of the previous 12 months fuel consumption, the homeowner should notify THV Composit Windows & Doors, who will provide the homeowner with the necessary forms to fill out for benefits under this Pledge. If fuel savings are less than 40% of the previous 12 months fuel consumption, the homeowner will be reimbursed the difference between actual savings and 40% of fuel cost for the previous 12 months.

Notwithstanding anything herein to the contrary, it is hereby agreed and understood that this Pledge only be effective if the homeowner, located at the address shown hereon, has purchased a complete installation of THV Composit Triple Alter-Lite® Glass replacement windows, effective on the dates shown.

This Pledge is based on fuel consumption, not cost. It is subject to the following provisions.

1. This Pledge covers only THV Composit Triple Alter-Lite® Glass replacement windows.
2. Complete installation of THV Composit Triple Alter-Lite® Glass replacement windows is defined as all windows on this residence except basement, attic and porch.
3. THV Composit one inch Double Glass insulated replacement windows may be substituted when window sizes exceed Triple Alter-Lite® Glass.
4. This Pledge covers only single and two family dwellings.
5. Maximum payment under this Pledge is \$1,200.
6. Customer must fill-out and send in the Customer Activation Receipt within 30 days of the completed installation of THV Composit Triple Alter-Lite® Glass replacement windows for Pledge to be activated.
7. Claims under this Pledge must be filled out in writing, with supporting evidence, within 60 days of the 12 month anniversary of this Pledge to THV Composit Windows & Doors. **Failure to make a claim within 60 days of the 12 month anniversary will void the Pledge and any reimbursement due to customer.**
8. Homeowners must properly maintain heating and air conditioning system.
9. An allowance shall be made for any non- heating and cooling utilities included in the utility bill such as, dish washers, refrigerators, lighting, computers, etc. when calculating a claim.
10. Proper allowance for abnormal weather conditions shall be made in adjusting a claim.
11. Reimbursement at rates prevailing at time of window purchase.
12. THV calculations are final and are based on information provided at the activation of this Pledge form.



THV 0343

## Complaint

Dear THV Premium Warranty Customer:

Due to the fluctuating rates for utilities, our energy savings pledge is based on the amount of fuel used, not the cost.

Additionally, our savings pledge states that the fuel use will be adjusted for the weather. To make the adjustment, we rely on statistics published by the National Oceanic and Atmospheric Administration. This agency of the United States Government records the temperature each hour, 24 hours per day and averages these readings to arrive at the average hourly temperature for each day. If the average temperature is 65 degrees F., cooling is required. If the average temperature is below 65 degrees F., heating is required.

Each degree below 65 degrees F., is considered a "heating degree day" meaning one degree is required for one day. Thus, 10 heating degrees could mean one degree of heating for each of ten days, or two degrees of heating for each of five days, etc.

Conversely, cooling degree days apply in the same manner when the average daily temperature is above 65 degrees F.

We use these heating degree days and cooling degree days to compare the relative severity of the weather before and after installation of the windows. Our fuel savings pledge is that you will use less fuel after adjustments are made, up or down, for the change in the weather.

Since both gas and electricity are used for purposes other than heating and cooling your home, we attempt to compute the amount of fuel actually used for the heating and cooling. To do this, we examine your utility statements to determine the consumption during those months when there are no heating or cooling days, then pro-rate that non-heating or non-cooling consumption over the entire year.

The enclosed analysis is based on the above and shows how much more or less was saved on both your gas and electric bills. The cost for this energy is based on the rate charged on the statement nearest the date of installation of your windows.

If you have any additional questions, please give us a call.

## Complaint

Consumption during months with essentially no cooling or heating degree days  $\pm$  1,206 Kwh per month before, and 1973 Mcf after installing the windows.  
Using these averages for 12 months gives the estimated "Non-cooling or non-heating" uses.

Consumption before installation windows:	<u>8,338</u> Kwh
Change in degree day: <u>195</u> to <u>174</u>	<u>-10.77%</u>
Assumed consumption due to weather	<u>7,440</u> Kwh
Assumed consumption less 40%	<u>4,464</u> Kwh
Actual consumption after installing windows	<u>6,971</u> Kwh
Difference	<u>2,507</u> Kwh
Cost at *\$ <u>0.064</u> per Kwh	<u>\$ 160.46</u> \$

\* Rate charged on gas statement nearest date of installation

## Decision and Order

**DECISION AND ORDER**

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondent named in the caption hereof, and the respondent having been furnished thereafter with a copy of a draft of a Complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued, would charge the respondent with violation of the Federal Trade Commission Act; and

The respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondent has violated the Federal Trade Commission Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons pursuant to Section 2.34 of its Rules, now in further conformity with the procedure prescribed in Section 2.34 of its Rules, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent THV Holdings LLC ("THV Holdings") is a Delaware limited liability company with its principal office or place of business at 5611 Fern Valley Road, Louisville, Kentucky 40228.

## Decision and Order

2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondent, and the proceeding is in the public interest.

**ORDER****DEFINITIONS**

For purposes of this order, the following definitions shall apply:

- A. “Clearly and prominently” means
  1. In print communications, the disclosure shall be presented in a manner that stands out from the accompanying text, so that it is sufficiently prominent, because of its type size, contrast, location, or other characteristics, for an ordinary consumer to notice, read and comprehend it;
  2. In communications made through an electronic medium (such as television, video, radio, and interactive media such as the Internet, online services, and software), the disclosure shall be presented simultaneously in both the audio and visual portions of the communication. In any communication presented solely through visual or audio means, the disclosure shall be made through the same means through which the communication is presented. In any communication disseminated by means of an interactive electronic medium such as software, the Internet, or online services, the disclosure must be unavoidable. Any audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. Any visual disclosure shall be presented in a manner that stands out in the context in which it is presented, so that it is sufficiently prominent, due to its size and shade, contrast to the background against which it appears, the length of time it appears on the screen,

## Decision and Order

and its location, for an ordinary consumer to notice, read and comprehend it; and

3. Regardless of the medium used to disseminate it, the disclosure shall be in understandable language and syntax. Nothing contrary to, inconsistent with, or in mitigation of the disclosure shall be used in any communication.
- B. “Close proximity” means on the same print page, web page, online service page, or other electronic page, and proximate to the triggering representation, and not accessed or displayed through hyperlinks, pop-ups, interstitials, or other means.
- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Competent and reliable scientific evidence” shall mean tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results, and that are sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that a representation is true.
- E. “Covered product or service” means any fenestration product, any component thereof, and any product or any service for which respondent makes any claim about energy savings, energy costs, energy consumption, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy.
- F. “Fenestration product” means any window, sliding glass door, or skylight.
- G. “K-value” is a measure of a material’s thermal conductivity.

## Decision and Order

- H. Unless otherwise specified, “respondent” shall mean THV Holdings LLC, its successors and assigns, and its officers, agents, representatives, and employees.
- I. “R-value” is a measure of a material’s resistance to heat flow.
- J. “SHGC” means solar heat gain coefficient, which is the fraction of incident solar radiation admitted through a window, both directly transmitted and absorbed and subsequently released inward.
- K. “U-factor” is a measure of the rate of heat loss.

**I.**

**IT IS ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names that:

- A. Consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or
- B. Respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs;

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction.

## Decision and Order

*Provided, however,* that if respondent represents that consumers who replace their windows with respondent's windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, or if respondent guarantees or pledges up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs under specified circumstances, it must disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge and it must substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region).

**II.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not make any representation, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names:

- A. About the ability of respondent's windows to pay for themselves in energy savings alone within any specific number of years or other time period, when consumers replace their windows with respondent's windows;
- B. That any specific number or percentage of consumers who replace their windows with respondent's windows achieve energy savings or reduction in heating and cooling costs; or
- C. About energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, SHGC, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy of any covered product or service;

## Decision and Order

unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that such representation is true.

**III.**

**IT IS FURTHER ORDERED** that respondent, directly or through any corporation, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any covered product or service in or affecting commerce, shall not provide to others the means and instrumentalities with which to make, directly or indirectly, expressly or by implication, including through the use of endorsements or trade names, any false, unsubstantiated, or otherwise misleading representation of material fact. For the purposes of this Part, “means and instrumentalities” shall mean any information, including, but not necessarily limited to, any advertising, labeling, telemarketing scripts, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any covered product or service, in or affecting commerce.

**IV.**

**IT IS FURTHER ORDERED** that respondent THV Holdings, and its successors and assigns, within thirty (30) days of the issuance of this order, must:

- A. Establish and implement a training program for all principals, officers, directors, managers, employees, agents, and representatives who direct or engage in the promotion or sale of any covered product or service;
- B. Designate a manager to coordinate and oversee the implementation of this training program;
- C. Require all current principals, officers, directors, managers, employees, agents, and representatives who direct or engage in the promotion or sale of any covered product or service to complete the training program within sixty (60) days of the order’s issuance,

## Decision and Order

and require all future principals, officers, directors, managers, employees, agents, and representatives to complete the training program before directing or engaging in the promotion or sale of any covered product or service;

- D. Ensure that the training program addresses:
1. the trainee's duty not to use or make any representation prohibited under this order;
  2. all representations specifically approved by the respondent concerning energy savings, reduction in heating and cooling costs, and any other energy-related attribute of any covered product or service; and
  3. the trainee's duty not to use or make any representation concerning energy savings, reduction in heating and cooling costs, or any other energy-related attribute of any covered product or service unless the respondent has authorized the representation after the order's issuance;
- E. Secure from each participant in this training program, at the conclusion of training, a signed statement acknowledging that he or she has completed the program;
- F. Maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments obtained pursuant to this Part, as well as a copy of all materials used in training pursuant to this Part; and
- G. Regularly evaluate and adjust its training program in light of any material changes to respondent's promotional materials, operations, or any other circumstances that respondent knows or has reason to know may have a material impact on the effectiveness of the training program required pursuant to this Part.

## Decision and Order

**V.**

**IT IS FURTHER ORDERED** that respondent THV Holdings, and its successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation; and
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in its possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

**VI.**

**IT IS FURTHER ORDERED** that respondent THV Holdings, and its successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having supervisory responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondent shall deliver this order to such current personnel within thirty (30) days after the date of service of this order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities. Respondent shall maintain and upon request make available to the Federal Trade Commission for inspection and copying all acknowledgments of receipt of this order obtained pursuant to this Part.

## Decision and Order

**VII.**

**IT IS FURTHER ORDERED** that respondent THV Holdings, and its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. *Provided, however*, that, with respect to any proposed change in the corporation about which respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission in writing, all notices required by this Part shall be emailed to [Debrief@ftc.gov](mailto:Debrief@ftc.gov) or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: “THV Holdings LLC, File No. 112 3057, Docket No. C-4361.”

**VIII.**

**IT IS FURTHER ORDERED** that respondent THV Holdings, and its successors and assigns, within sixty (60) days after the date of service of this order, shall file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of its own compliance with this order. Within ten (10) days of receipt of written notice from a representative of the Commission, it shall submit additional true and accurate written reports.

**IX.**

This order will terminate on May 16, 2032, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any

## Analysis to Aid Public Comment

violation of the order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this order that terminates in less than twenty (20) years;
- B. This order's application to any respondent that is not named as a defendant in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint had never been filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

By the Commission, Commissioner Rosch and Commissioner Ohlhausen not participating.

#### **ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT**

The Federal Trade Commission (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from THV Holdings LLC, a limited liability company (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will

## Analysis to Aid Public Comment

decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves respondent's marketing and sale of replacement windows for use in residences. According to the FTC complaint, respondent represented that its windows likely pay for themselves in energy savings alone within eight years, when consumers replace their windows with THV Compozit windows with Alter-Lite® triple pane glass. The respondent also allegedly represented that consumers who replace their windows with these THV windows are likely to achieve residential energy savings of 40%, save 40% on residential heating and cooling costs, or reduce their energy bills by half. In addition, the respondent allegedly represented that homeowners have saved 35%-55% off their energy bills by replacing their windows with THV windows. According to the complaint, respondent did not possess and rely upon a reasonable basis substantiating these representations when it made them. Many factors determine the savings homeowners can realize by replacing their windows, including the home's geographic location, size, insulation package, and existing windows. Consumers who replace single or double-paned wood or vinyl-framed windows – common residential window types in the United States – with THV replacement windows are not likely to achieve a 40%, 50%, or 35%-55% reduction in residential energy consumption or heating and cooling costs. The complaint also alleges that, by providing its independent dealers and installers with advertising and other promotional materials making the above unsubstantiated representations, respondent provided the means and instrumentalities to engage in deceptive practices. Thus, the complaint alleges that respondent engaged in unfair or deceptive practices in violation of Section 5(a) of the FTC Act.

Some promotional materials challenged in the FTC's complaint include the words "up to" in an apparent attempt to qualify representations that consumers who replace windows with respondent's windows are likely to achieve specified amounts of residential energy savings or reduction in residential heating and cooling costs. In the context of specific ads in this case, the words "up to" do not effectively qualify such representations for replacement windows. The FTC's complaint and the proposed

## Analysis to Aid Public Comment

consent order should not be interpreted as a general statement of how the Commission may interpret or take other action concerning representations including the words “up to” for other products or services in the future.

The proposed consent order contains three provisions designed to prevent respondent from engaging in similar acts and practices in the future. Part I addresses the marketing of windows. It prohibits respondent from making any representation that: (A) consumers who replace their windows with respondent’s windows achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; or (B) respondent guarantees or pledges that consumers who replace their windows with respondent’s windows will achieve up to or a specified amount or percentage of energy savings or reduction in heating and cooling costs; unless the representation is non-misleading and, at the time of making such representation, respondent possesses and relies upon competent and reliable scientific evidence to substantiate that all or almost all consumers are likely to receive the maximum represented savings or reduction. Further, if respondent represents, guarantees, or pledges that consumers achieve such energy savings or heating and cooling cost reductions under specified circumstances, it must: disclose those circumstances clearly and prominently in close proximity to such representation, guarantee, or pledge; and substantiate that all or almost all consumers are likely to receive the maximum represented, guaranteed, or pledged savings or reduction under those circumstances (*e.g.*, when replacing a window of a specific composition in a building having a specific level of insulation in a specific region). The performance standard imposed under this Part constitutes fencing-in relief reasonably necessary to ensure that any future energy savings or reduction claims are not deceptive.

Parts II and III address any product or service for which respondent makes any energy-related efficacy representation. Part II prohibits respondent from making any representation: (A) about the ability of respondent’s windows to pay for themselves in energy savings alone within any specific number of years or other time period, when consumers replace their windows with respondent’s windows; (B) that any specific number or percentage of consumers who replace their windows with respondent’s

## Analysis to Aid Public Comment

windows achieve energy savings or reduction in heating and cooling costs; or (C) about energy consumption, energy savings, energy costs, heating and cooling costs, U-factor, solar heat gain coefficient, R-value, K-value, insulating properties, thermal performance, or energy-related efficacy; unless the representation is non-misleading and substantiated by competent and reliable scientific evidence. Part III prohibits respondent from providing to others the means and instrumentalities with which to make any false, unsubstantiated, or otherwise misleading representation of material fact. It defines “means and instrumentalities” to mean any information, including any advertising, labeling, or promotional, sales training, or purported substantiation materials, for use by trade customers in their marketing of any such product or service.

Parts IV through VIII require respondent to: train personnel who direct or engage in the promotion or sale of any product or service covered by the order not to make representations prohibited by the order; keep copies of advertisements and materials relied upon in disseminating any representation covered by the order; provide copies of the order to certain personnel, agents, and representatives having supervisory responsibilities with respect to the subject matter of the order; notify the Commission of changes in its structure that might affect compliance obligations under the order; and file a compliance report with the Commission and respond to other requests from FTC staff. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the complaint or the proposed order, or to modify the proposed order’s terms in any way.

Complaint

IN THE MATTER OF

**POM WONDERFUL LLC,  
ROLL INTERNATIONAL CORP.,  
STEWART A. RESNICK,  
LYNDA RAE RESNICK,  
AND  
MATTHEW TUPPER**

COMPLAINT AND INITIAL DECISION IN REGARD TO ALLEGED  
VIOLATIONS OF SECTION 5 OF THE FEDERAL TRADE COMMISSION  
ACT

*Docket No. 9344; File No. 082 3122*

*Complaint, September 24, 2010 – Initial Decision, May 17, 2012*

This case addresses POM Wonderful LLC and Roll International Corporation's advertising and promotional materials for POM Wonderful 100% Pomegranate Juice, POMx Pills, and POMx Liquid. The complaint alleged that respondent POM Wonderful LLC ("POM"), its sister company Roll Global LLC, and principals Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper (collectively "Respondents") falsely advertised that POM-branded pomegranate juice could treat prostate cancer and erectile dysfunction or reduce the risk of heart disease. The complaint alleges respondent did not possess and rely upon a reasonable basis substantiating representations of the claimed benefits of using its products. In the Initial Decision the Administrative Law Judge ("ALJ") determined that the advertising claims respondents made regarding their products were false or misleading and unsubstantiated by competent scientific evidence. The ALJ ordered the respondents to cease and desist making claims that their products are effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time; or treat, prevent, or reduce the risk of erectile dysfunction; unless, at the time it is made, the representation is non-misleading and, Respondents possessed and relied upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Respondents appealed the Initial Decision.

## Complaint

*Participants*

For the *Commission*: *Tawana E. Davis, Janet M. Evans, Mary L. Johnson, Elizabeth Nach, Elise Whang, and Andrew Wone.*

For the *Respondents*: *John Graubert, Covington & Burling.*

**COMPLAINT**

The Federal Trade Commission, having reason to believe that POM Wonderful LLC and Roll International Corporation, companies, and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of the companies (“respondents”), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent POM Wonderful LLC (“POM Wonderful”) is a Delaware limited liability company with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. POM Wonderful is wholly owned by the Stewart and Lynda Resnick Revocable Trust, dated December 27, 1988, as amended (“1988 Resnick Trust”). Stewart A. Resnick and Lynda Rae Resnick are the sole trustees and the sole beneficiaries of the 1988 Resnick Trust and have the power to revoke or amend the 1988 Resnick Trust at any time. POM Wonderful is a member-managed company, and the 1988 Resnick Trust is the sole member.

2. Respondent Roll International Corporation (“Roll”) is a Delaware corporation with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. Roll is wholly owned by the 1988 Resnick Trust and is a sister company to POM Wonderful. Roll provides shared services such as legal, consulting, and human resources services to POM Wonderful. Through an in-house advertising agency known as “Fire Station Agency” or “the agency” (“Fire Station”), Roll works with POM Wonderful employees to create content for, and determine placement of, the print, outdoor, direct mail, and online ads for the POM Wonderful products. Fire Station also monitors the effectiveness of the POM Wonderful ad campaigns.

## Complaint

3. Respondent Stewart A. Resnick is the Chairman of POM Wonderful. He also is the Chairman and President of Roll, and a Director of Roll. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the companies, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of the companies.

4. Respondent Lynda Rae Resnick is a co-Director of Roll with respondent Stewart Resnick. She, along with Stewart Resnick, also has authority over POM Wonderful and Roll in her capacity as a trustee and beneficiary of the 1988 Resnick Trust. Individually or in concert with others, she formulates, directs, or controls the policies, acts, or practices of the companies, including the acts or practices alleged in this complaint. Her principal office or place of business is the same as that of the companies.

5. Respondent Matthew Tupper is the President and Chief Operating Officer of POM Wonderful. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of POM Wonderful, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of the companies.

6. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including POM Wonderful 100% Pomegranate Juice (hereinafter "POM Juice"), and POMx Pills and POMx Liquid (hereinafter "POMx"). POM Juice and POMx are "foods" and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

7. POM Wonderful and Roll have operated as a common enterprise while engaging in the deceptive acts and practices alleged below, and individual respondents Stewart A. Resnick and Lynda Rae Resnick have formulated, directed, controlled or had authority to control, or participated in the acts and practices of POM Wonderful and Roll. Because these companies have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below.

## Complaint

8. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act.

**POM JUICE MARKETING**

9. Respondents have disseminated or have caused to be disseminated advertising and promotional materials for POM Juice, including product labeling, print advertising, websites, biogs, banner and flash ads on third-party sites, and video ads. Examples of those ads are attached as Exhibits A through H. These materials contain the following representations or statements, among others:

## a. SUPER HEALTH POWERS!

[Chart comparing antioxidant power of POM Juice and other beverages]

\*For more information, visit [pomwonderful.com/compare](http://pomwonderful.com/compare)

© 2009 POM Wonderful LLC.

**100% PURE POMEGRANATE JUICE.**

It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM Wonderful 100% authentic pomegranate juice. Backed by \$25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!

- POM Juice hang tag, Giant Food, Westbard Shopping Center, Bethesda MD (Sept. 2009) [Exh. A]

## b. Drink to prostate health.

[image of POM Juice bottle]

Sometimes, good medicine can taste great. Case in point: POM Wonderful. A recently published

## Complaint

preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about the results of this study? Visit [pomwonderful.com/prostate](http://pomwonderful.com/prostate). **Trust in POM.**

Pomwonderful.com

- print ad, Prevention magazine (Dec. 2008)  
**[Exh. BJ]**

**c. I'm off to save PROSTATES!**

[image of POM Juice bottle blasting off]

Man by man, gland by gland, The Antioxidant Superpower® is 100% committed to defending healthy prostates. Powered by pure pomegranate juice ... backed by \$25 million in vigilant medical research\* ... there's no telling just how far it will go to improve prostate health in the future.

\* Prostate study details at [http://www.pomwonderful.com/health\\_benefits.html](http://www.pomwonderful.com/health_benefits.html)

\* \* \*

- print ad, Men's Fitness magazine (Feb. 2009) **[Exh. C]**; *see also Exh. D* (print ad, Fitness magazine, Feb. 2009); **Exh. E-4** (POM Wonderful website flash ad, Apr. 30, 2009); **Exh. G** ("Amaze your urologist" internet banner ad, Feb. 14, 2009); **Exh. H** (internet banner ad, Feb. 17, 2009)

**d. The truth about our pomegranates.**

\* \* \*

Complaint



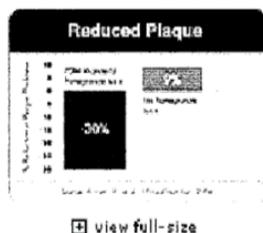
Backed by science.

POM is the only pomegranate juice backed by \$25 million in medical research. To date, numerous published clinical studies have documented the benefits of drinking pomegranate juice, benefits that include improved heart and prostate health and better erectile function. **All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands.... [Read more.](#)**

\* \* \*

- pomegranatetruth.com (Apr. 28, 2009) [Exh. E-1]

e. Real Studies. Real Results.



**Arterial Plaque.**

This pilot research study involved 19 elderly individuals who had atherosclerosis, or hardening of the arteries, where plaque was already built-up to a dangerous level. Ten of the patients drinking just 8 oz. of POM Wonderful 100% Pomegranate Juice a day for one year had **up to a 30% decrease in the thickness of the lining of their carotid artery**, while the control group made up of nine patients that didn't drink POM Wonderful, actually had an increase of 9%. In addition, those who drank the pomegranate juice also had a 21% decrease in their systolic blood pressure. [footnote omitted]



**ACE and Systolic Blood Pressure.**

With hypertension, or high blood pressure, the heart works harder. Arteries are under pressure and the chances of a stroke or heart attack are greater. [footnote omitted] ACE (or angiotensin converting enzyme) is an enzyme that the body produces which may lead to high blood pressure resulting in atherosclerosis. [footnote omitted] In a preliminary research study, ten elderly patients with hypertension drank 8 oz. of POM Wonderful 100% Pomegranate Juice a day for just two weeks. After those two weeks, in those patients drinking POM Wonderful **ACE activity was significantly decreased by 36%**, and, they also saw their **systolic blood pressure drop by 5%**. [footnote omitted]

- pomwonderful.com "Real Studies" page (Apr. 29, 2009) [Exh. E-2]

## Complaint

- f. [video clip opening with image of three adults wearing white lab coats, seated at a table - scientist seated in the center holds a red pomegranate]

[Narrator:] Pomegranate contains powerful antioxidants needed to prevent cancer and diseases. .

[male scientist seated on left tries unsuccessfully to open the pomegranate, while female scientist seated on right effortlessly places a straw into a bottle of POM Juice and slowly drinks]

[Narrator:] POM Juice makes it a little easier.

\* \* \*

- [www.pomwonderful.com](http://www.pomwonderful.com), "Video Gallery" page (Apr. 30, 2009) [Exh. E-3]

- g. \* \* \*

[Interviewer:] Should I take vitamins?

[Lynda Resnick:] I don't know your family history. How's your father?

[Interviewer:] He's in good health. Had a bout of prostate cancer, but that's-

[Lynda Resnick:] You have to be on pomegranate juice. You have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist-your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at UCLA, on 43

Complaint

men ... It arrested their PSA. How old are you, 28?

[Interviewer:] Twenty-six.

[Lynda Resnick:] Get a base line now. *[Pause, wink]* It's also 40 percent as effective as Viagra. Not that you need it. But-- couldn't hoit [sic]!

- Interview with Lynda Resnick, posted on Porn Wonderful Blog page, [http://blog.pomwonderful.com/pom\\_wonderful/2009/03/striking-out-on-your-own.html](http://blog.pomwonderful.com/pom_wonderful/2009/03/striking-out-on-your-own.html) (Mar. 20, 2009) [Exh. F]

#### h. **Backed by Science**

Only POM Wonderful products are backed by \$32 million in medical research. Actually, we are the only pomegranate juice backed by any medical research at all.

There has been a lot of talk lately about the role of pomegranates in promoting heart health, prostate health and proper erectile function....

So what are the medical results on POM Wonderful 100% Pomegranate Juice?

#### **Cardiovascular**

A 2005 study published in the American Journal of Cardiology showed improved blood flow to the heart in patients drinking 8oz [sic] daily of POM Wonderful 100% Pomegranate Juice for 3 months.

Researchers studied a total of 45 patients with coronary heart disease who had reduced blood flow to the heart.

Patients drinking POM Wonderful 100% Pomegranate Juice experienced a 17% improvement in blood flow,

## Complaint

compared to an 18% worsening in patients drinking a placebo.

**Prostate**

A preliminary UCLA medical study, published by The American Association for Cancer Research, found hopeful results for prostate health.

The study tested 45 men with recurrent prostate cancer who drank 8 oz of POM Wonderful 100% Pomegranate Juice daily for two years. **Post- prostate surgery PSA average doubling time increased from 15 to 54 months.** PSA is a protein marker for prostate cancer, and a slower PSA doubling time indicates slower disease progression.

**Erectile Function**

A pilot study released in the International Journal of Impotence Research in 2007 examined 61 male subjects with mild to moderate erectile dysfunction. Compared to participants taking a placebo, **those men drinking 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections.**

\* \* \*

- www.pomwonderful.com, “POM Truth - Backed by Science” web page (Jan. 27, 2010) [Exh. E-5]; *see also* Exh. E-2 (“Health Benefits” web page, Apr. 29, 2009); Exh. E-1 (“Backed by Science” web page, Apr. 28, 2009)

i. \* \* \*

MS. RESNICK: ... But, the Wonderfals are the [pomegranates] ones that we grow because they’re the sweetest and they have the health benefits.

## Complaint

\* \* \*

MS. STEWART: But, the medical benefits even outweigh the mythical benefits?

MS. RESNICK: Oh, they do, they do. I mean, it is the magic elixir of our age and of all ages, and we know that it helps circulation, it helps Alzheimer's, it helps all sorts of things in the body--

MS. STEWART: Antioxidants.

MS. RESNICK: Antioxidants. Polyphenol antioxidants off the chart. MS. STEWART: Right.

MS. RESNICK: And if you know a man that you care about or you are a man, make him drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing/

- Lynda Resnick interview (Nov. 20, 2008), available on YouTube at <http://www.youtube.com/watch?v=t2vRPGH14u4> [Exh. E-6]

j. \* \* \*

MR. TUPPER: With pomegranate, the dose that's been shown to be effective is eight ounces a day. Pomegranate is the one fruit that's actually been tested in human beings by dozens of researchers across the globe.

There's actually been a study published recently on prostate cancer. Men suffering from advanced stages of prostate cancer drinking eight ounces a day saw the progression of the prostate cancer actually slow dramatically. In addition, there have been a number of studies published on cardiovascular disease in which sick patients again consuming eight ounces of pomegranate juice every day saw dramatic improvements in things like atherosclerosis, which is

## Complaint

plaque in the arteries, the amount of blood flow delivered to the heart.

\* \* \*

MR. SULLIVAN: There's a lot of different pomegranate things. How many more products can you put out there, and how much of it is just hooley, ... you know, pomegranate pills, et cetera?

MR. TUPPER: The products that we put into the market, though, all stem from the fundamental science of the pomegranate, and everything that we put into the market, whether it's juice, whether it's tea, whether it's the supplements that we sell, are all backed by an enormous investment in

science. We've actually funded more than \$25 million of scientific research worldwide since we started the business. And, therefore, every product that we sell is backed by that science. Every product that we sell contains those unique antioxidants. We don't do things for scents and flavors. We do them for the health benefits and for the science.

\* \* \*

- Matthew Tupper interview (June 17, 2008), available on YouTube at <http://www.youtube.com/watch?v=Fy2MXbadUr4> [Exh. E-7)

**POMx MARKETING**

10. Respondents have disseminated or have caused to be disseminated advertising and promotional materials for POMx, including labeling, websites, print advertising, and newsletters. Examples of those ads are attached as Exhibits E, and I through N. These materials contain the following representations or statements, among others:

## Complaint

a. \* \* \*

**The power of POM. Now in one little pill.**

All of the antioxidant power of an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice is now available in the convenience of a single calorie- free pill. **Take one daily.**

\* \* \*

**Prostate health.**

Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer. [footnote omitted]

**Time pill.**

Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer. [footnote omitted] According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. [footnote omitted]

83% of those who participated in the study showed a significant decrease in their cancer regrowth rate. [footnote omitted]

\* \* \*

To learn more, visit [pompills.com/research](http://pompills.com/research).

## Complaint

“Basic studies indicate that POMx and POM Wonderful Pomegranate Juice may have the same effects on prostate health.”

*David Heber, MD, PhD, Professor of Medicine and Director, UCLA Center for Human Nutrition*

\* \* \*

“POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits.”

*Dr. Michael Aviram, Lipid Research Laboratory, Technion Faculty of Medicine, Haifa, Israel*

Heart health.

In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily. [footnote omitted]

An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow. Initial studies on POMx share similar promise for heart health, and our research continues. [image of heart]

\* \* \*

- POMx package insert (Monthly and Trial 1<sup>st</sup> Shipment, June 2007) [Exh. I]

b. **Take it daily. Feel it forever.**<sup>TM</sup>

## Complaint

**One POMx Pill= the antioxidant power of an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice**

\* \* \*

**Science, Not Fiction**

- Made from the only pomegranates backed by \$25 million in medical research and the POM Wonderful brand
- Clinically tested

\* \* \*

- Promotes prostate and heart health
  - [www.pompills.com](http://www.pompills.com), POMx Pills home page (Apr. 29, 2009) [**Exh. E-8**]; *see also* **Exh. E-9** (“POMx Pills” web page, Jan. 27, 2010); **Exh. E-8** (“POMx Liquid” web page, Apr. 29, 2009); **Exh. E-9** (“POMx Liquid” web page, Jan. 27, 2010)

**c. Medical Benefits**Research

The antioxidants in POMx are supported by \$32 million in initial scientific research from leading universities, and so far we’ve uncovered encouraging results. [Learn more ...](#)

Heart Health

We have researched the effects of pomegranate juice on cardiovascular health for almost 10 years, and findings suggest that pomegranate juice may help counteract factors leading to arterial plaque build-up, as well as inhibit a number of factors associated with heart disease. Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits to POM

## Complaint

Wonderful Juice, and additional studies are now going on. [Learn more](#)

Prostate Health

A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer who drank an 8oz [sic] glass of pomegranate juice daily. And every POMx capsule provides the antioxidant power of an 8oz glass [sic] of POM Wonderful 100% Pomegranate Juice. [Learn more](#)

- [www.pompills.com](http://www.pompills.com), Health Benefits web page, (Jan. 27, 2010) [**Exh. E-9**]; *see also* **Exh. E-8** (“Health Benefits” web page, Apr. 29, 2009)

**d. The Heart of the Matter****Amaze your cardiologist. Take POMx**

POMx is made from the only pomegranates supported by \$32 million of initial scientific research from leading universities ....

\* \* \*

**Promising results from studies on POM Wonderful Juice.**

One pilot study on 19 patients with atherosclerosis (clogged arteries) at the Technion Institute in Israel demonstrated a reduction in arterial plaque growth. After one year, arterial plaque decreased 30% for those patients who consumed 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily, compared to a 9% worsening for patients who drank a placebo.

A recently published study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily for 3

### Complaint

months experienced 17% improved blood flow; those who drank a placebo experienced an 18% decline.

#### **POMx and heart health.**

Initial research on POMx also shows promise for promoting heart health. In his 2006 POMx study, Dr. Michael Aviram, one of the world's preeminent cardiovascular researchers, remarked that "*POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health.*"

- [www.pompills.com](http://www.pompills.com), Heart Health page, (Jan. 27, 2010) [Exh. E- 9]; see also Exh. E-8 (POMx "Heart Health" web page, Apr. 29, 2009)

#### e. **Pomegranates and Prostate Health**

##### **Prostate Health**

\* \* \*

##### **Promising News**

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. Men who had been treated surgically or with radiation for prostate cancer were given 8oz [sic] of POM Wonderful 100% Pomegranate Juice. A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time.

. . . [A] slower PSA doubling time may reflect slower progression of the disease.

Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8oz [sic] of juice daily, the average

## Complaint

PSA doubling time increased to 54 months. That's a 350% increase. [Learn more.](#)

According to Dr. David Heber, Director of UCLA's Center for Human Nutrition, "*The most abundant and most active ingredients in Pomegranate Juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and Pomegranate Juice have the same effect on prostate health.*"

- [www.pompills.com](http://www.pompills.com), POMx Prostate Health web page (Apr. 29, 2009) [Exh. E-8]; see also Exh. E-9 (POMx "Prostate Health" web page, Jan. 27, 2010)

f. **HEALTHY. ~~WEALTHY.~~ AND WISE.**

**(2 OUT OF 3 IN THIS ECONOMY AIN'T BAD.)**

\* \* \*

**\$32 million in medical research. A sound investment.**

POMx is made from the only pomegranates backed by \$32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.

**Hope for the future. Yours.**

Our POMx pills are made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, '06 [footnotes omitted].

## Complaint

Two additional preliminary studies on our juice showed promising results for heart health. “Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group,” Dr. Dean Omish reported in the *American Journal of Cardiology*, ‘05 [footnotes omitted].

“Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year,” said Dr. Michael Aviram in *Clinical Nutrition*, ‘04 [footnote omitted].

- Washington Post, Parade Magazine (Sept. 27, 2009) [Exh. J]

g. **The antioxidant superpiII.™**

\* \* \*

POMx is made from the only pomegranates backed by \$32 million in medical research. These are the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found *hopeful results for prostate health*. The study reports “statistically significant prolongation of PSA doubling times,” according to Dr. Allen J. Pantuck in Clinical Cancer Research, 2006. [footnotes omitted] Two additional preliminary studies on our juice found *promising results for heart health*. “Stress-induced ischemia decreased in the pomegranate group,” Dr. Dean Omish reported in the American Journal of Cardiology, 2005. [footnotes omitted] “Pomegranate juice consumption resulted in a significant IMT [footnote omitted] reduction by up to 30% after one year,” said Dr. Michael Aviram, referring to reduced arterial plaque in Clinical Nutrition, 2004. [footnotes omitted]

- Washington Post Sunday Circular Free Standing Insert (Jan. 24, 2010) (emphasis in

## Complaint

original) [Exh. K]; *see also* Exh. L (New York Times Magazine, Jan. 6, 2008)

h. \* \* \*

**What's New in the Lab by Dr. Mark Dreher**

\* \* \*

NEW RESEARCH OFFERS FURTHER PROOF OF  
THE HEART- HEALTHY BENEFITS OF POM  
WONDERFUL JUICE

**30% DECREASE IN ARTERIAL PLAQUE**

After one year of a pilot study conducted at the Technion Institute in Israel involving 19 patients with atherosclerosis (clogged arteries) ... those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily saw a 30% decrease in arterial plaque.

**17% IMPROVED BLOOD FLOW**

A recent study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced 17% improved blood flow. Those who drank a placebo experienced an 18% decline.

\* \* \*

- POMx Pills and Liquid Heart Newsletter (Sept. 2007-Feb. 2008) [Exh. M]

## Complaint

i. \* \* \*

**Prostate Cancer Affects****1 Out of Every 6 Men**

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute. Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

\* \* \*

**What's New in the Lab by Dr. Mark Dreher**

POM Wonderful 100% Pomegranate Juice and POMx are backed by a \$25 million dollar investment in world-class scientific research. This includes ten clinical studies published in top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

\* \* \*

In fact, studies funded by POM represent the vast majority of human medical

research ever conducted on pomegranates.

\* \* \*

**NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS**

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. 46 men who had been treated for prostate cancer with surgery or radiation were given

## Complaint

8oz [sic] of POM Wonderful 100% Pomegranate Juice to drink daily.

Patients with prostate cancer showed a prolongation of PSA doubling time, coupled with corresponding lab effects on reduced prostate cancer as well as reduced oxidated stress.

A majority of the patients experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression - extended doubling time may indicate slower disease progression.

Before the study, the mean doubling time was 15 months. After drinking 8oz [sic] of pomegranate juice daily for two years, the mean PSA doubling time increased to 54 months. Testing on patient blood serum showed a 12% decrease in cancer cell proliferation and a 17% increase in cancer cell death (apoptosis).

- POMx Pills and Liquid Prostate Newsletter  
(Fall 2007-Feb. 2008) [Exh. N]

11. As early as May 2007, respondents knew that a large, double-blind, placebo-controlled study, funded by POM Wonderful and led by Dr. Michael Davidson (“the Davidson Study”), showed no significant difference after 18 months between consumption of pomegranate juice and a control beverage in reducing carotid arterial wall thickness. The Davidson Study was published in October 2009. Respondents continue to tout POM Wonderful’s cardiovascular research and benefits despite the negative results of the Davidson Study. *See, e.g.*, **Exh. E-5** (“POM Truth” web page, Jan. 27, 2010); **Exh. E-9** (POMx “Health Benefits” and “Heart Health” web pages, Jan. 27, 2010); **Exh. K** (POMx newspaper circular, Jan. 24, 2010).

## Complaint

**FALSE AND MISLEADING REPRESENTATIONS**

12. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials prove that:

- a. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart; and
- b. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.

13. In truth and in fact, clinical studies, research, and/or trials do not prove that:

- a. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart; and
- b. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.

Among other things, the Davidson Study showed no significant difference between consumption of pomegranate juice and a control beverage in carotid intima-media thickness progression rates after 18 months; two smaller studies funded by POM Wonderful or its agents showed no significant difference between consumption of pomegranate juice and a control beverage on measures of cardiovascular function; and multiple studies funded

## Complaint

by POM Wonderful or its agents did not show that POM Wonderful products reduce blood pressure.

14. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials prove that:

- a. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); and
- b. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT.

15. In truth and in fact, clinical studies, research, and/or trials do not prove that:

- a. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging PSADT; and
- b. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT.

Among other things, at the time the claims were made, the evidence relied on by respondents consisted of results from an unblinded, uncontrolled study; and the study report stated that it is “controversial whether modulation of PSA levels represents an equally valid clinical end point,” and that “further research is needed to ... determine whether improvements in such biomarkers (including PSADT) are likely to serve as surrogates for clinical benefit.”

## Complaint

16. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials prove that:

- a. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
- b. Drinking eight ounces of POM Juice daily treats erectile dysfunction.

17. In truth and in fact, clinical studies, research, and/or trials do not prove that:

- a. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
- b. Drinking eight ounces of POM Juice daily treats erectile dysfunction.

Among other things, a randomized, double-blinded placebo controlled study sponsored by respondents showed that drinking POM Juice provided no statistically significant results on erectile function.

18. Therefore, the representations made in paragraphs 12, 14, and 16 were, and are, false or misleading.

**UNSUBSTANTIATED REPRESENTATIONS**

19. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that:

- a. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart;
- b. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.

## Complaint

- c. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging PSADT;
- d. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT;
- e. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
- f. Drinking eight ounces of POM Juice daily treats erectile dysfunction.

20. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 19, at the time the representations were made.

21. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 19, at the time the representations were made. Therefore, the representation set forth in Paragraph 20 was, and is, false or misleading.

22. Respondents' practices, as alleged in this complaint, constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

**NOTICE**

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3 (2010). A copy of Part 3 of the Commission Rules is enclosed with this complaint, and the Rules are also accessible on the Commission Website at FTC Rules (16 CFR 0-999).

## Complaint

Notice is hereby given that the twenty-fourth day of May, 2011, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Federal Trade Commission an answer to this complaint on or before the 14th day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect.

Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 3.46 of the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and to authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

## Complaint

The Administrative Law Judge will schedule an initial prehearing scheduling conference to be held not later than 10 days after the answer is filed by the last answering respondent in the complaint. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, but in any event no later than five days after the answer is filed by the last answering respondent. Rule 3.31(b) obligates counsel for each party, within five days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

## Complaint

**ORDER****DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

- A. Unless otherwise specified, “individual respondents” shall mean Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of Porn Wonderful LLC (“POM Wonderful”) and Roll International Corporation (“Roll”).
- B. Unless otherwise specified, “respondents” shall mean POM Wonderful and Roll, their successors and assigns; the individual respondents; and each of the above’s officers, agents, representatives, and employees.
- C. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. “Covered Product” shall mean any food, drug, or dietary supplement, including, but not limited to, the POM Products.
- E. “Food” and “drug” shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- F. “Endorsement” shall mean as defined in 16 C.F.R. § 255.0.
- G. “POM Product” shall mean any food, drug, or dietary supplement containing pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.
- H. The term “including” in this Order shall mean “without limitation.”

## Complaint

- I. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

**I.**

**IT IS ORDERED** that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any POM Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); or treat, prevent, or reduce the risk of erectile dysfunction; unless, at the time it is made, the representation is non-misleading and:

- A. the product is subject to a final over-the-counter (“OTC”) drug monograph promulgated by the Food and Drug Administration (“FDA”) for such use, and conforms to the conditions of such use;
- B. the product remains covered by a tentative final OTC drug monograph for such use and adopts the conditions of such use;
- C. the product is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use; or
- D. the representation is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

## Complaint

**II.**

**IT IS FURTHER ORDERED** that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

**III.**

**IT IS FURTHER ORDERED** that respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations under Part I of this Order, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, respondents rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

## Complaint

**IV.****IT IS FURTHER ORDERED** that:

- A. Nothing in Parts II or III of the Order shall prohibit respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and
- B. Nothing in Parts II or III of the Order shall prohibit respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

**V.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging, and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and

## Complaint

- D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

**VI.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

**VII.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and individual respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. *Provided, however,* that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and individual respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and individual respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part

## Complaint

shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at [DEbrief@ftc.gov](mailto:DEbrief@ftc.gov).

**VIII.**

**IT IS FURTHER ORDERED** that each individual respondent, for a period often (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at [DEbrief@ftc.gov](mailto:DEbrief@ftc.gov).

**IX.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

**X.**

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that

## Complaint

the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later: *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

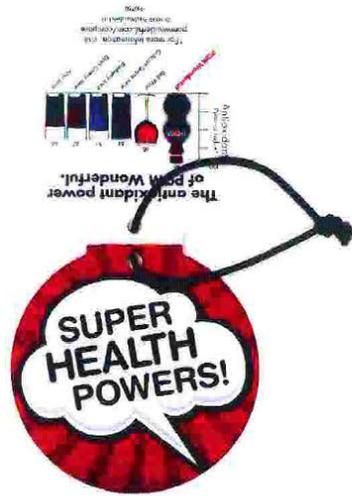
*Provided, further,* that if such complaint is dismissed or a federal court rules that respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, D.C., this twenty-fourth day of September, 2010.

By the Commission.

Complaint

**Exhibit A**



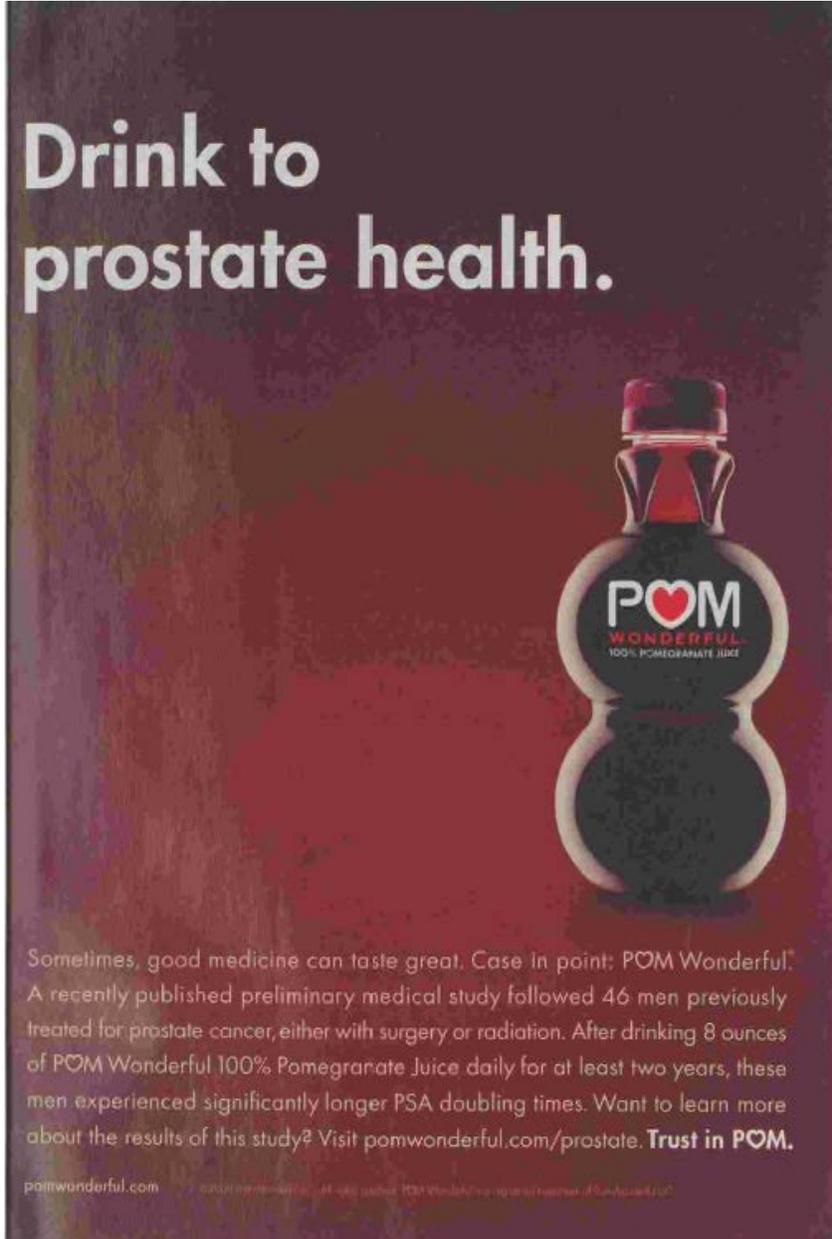
**100% PURE POMEGRANATE JUICE.**

It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM Wonderful 100% authentic pomegranate juice.

Backed by \$25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!

Complaint

**Exhibit B**



**Drink to  
prostate health.**



Sometimes, good medicine can taste great. Case in point: POM Wonderful. A recently published preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about the results of this study? Visit [pomwonderful.com/prostate](http://pomwonderful.com/prostate). **Trust in POM.**

[pomwonderful.com](http://pomwonderful.com) © 2011 POM Wonderful, LLC. All rights reserved. POM Wonderful is a registered trademark of POM Wonderful, LLC.

Complaint

EXHIBIT C

**CITIZEN SAVING SOLUTIONS**  
 Robliner, of *Get a Deal*, up her four last money or 2009.

**BANKS OFF**  
 Deal is to by banking not even a e of dollars and there. clear of that charge thdrawals, or your ce to make our's not ing any a. And if your nt charges monthly fee, h banks.

**OUT OF DEBT**  
 any extra to pay down card bal- e or other interest- lebr. Maybe raid savings over 401(k), h) to do it. ever rate savings are ng, it's prob- iver than your cards varging.

**SAVE**  
 you've zeroed ur credit- balances, at least 10% ur take-home a money et account. ices. If b already g 10%, bump to 15%.

**A ROTH IRA**  
 re already ng your 0) match, e one of your vestments. e mutual companies t you open h for just a month. money will tax free.

**I'm off to save PROSTATES!**

**POM WONDERSFUL**  
 100% POMEGRANATE JUICE

Man by man, gland by gland, The Antioxidant Superpower® is 100% committed to defending healthy prostates. Powered by pure pomegranate juice... backed by \$25 million in vigilant medical research\*... there's no telling just how far it will go to improve prostate health in the future.

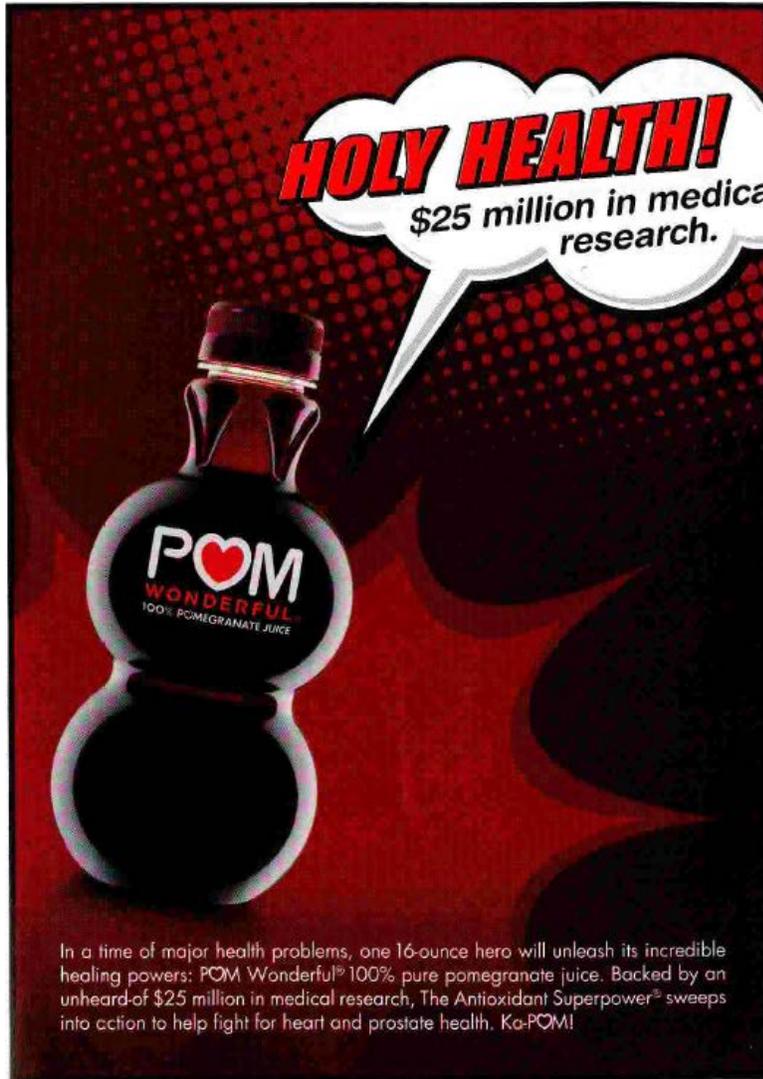
\* Prostate study details at [http://www.pomwonderful.com/health\\_benefits.html](http://www.pomwonderful.com/health_benefits.html)

pomwonderful.com

**The Antioxidant Superpower.®**

Complaint

**EXHIBIT D**



In a time of major health problems, one 16-ounce hero will unleash its incredible healing powers: POM Wonderful® 100% pure pomegranate juice. Backed by an unheard-of \$25 million in medical research, The Antioxidant Superpower® sweeps into action to help fight for heart and prostate health. Ka-POM!

[pomwonderful.com](http://pomwonderful.com)

**The Antioxidant Superpower.®**

Complaint

**EXHIBIT E**

(see enclosed CD with excerpts of several website captures)

Exh E-1 PomegranateTruth

Exh E-2 PomWonderful Health Benefits

Exh E-3 PomWonderful Video Ads

Exh E-4 PomWonderful Products

Exh E-5 POM website excerpt 1.10

Exh E-6 LRR on Martha Stewart Youtube 11.08

Exh E-7 Tupper on Fox News Youtube 6.08

Exh E-8 Pomx Pills website

Exh E-9 PomPills.com 1.10

Complaint

EXHIBIT F

**POM WONDERFUL**

« [Carnish, Same Place with POM Pomegranate Juice](#) | [What's in your juice? Are there any others?](#) »

03/20/2009

● [Striking Out On Your Own](#)

**Newsweek**

Read the latest Lynda Pisciotta interview by [Newsweek's Nick Summers](#). Lynda is the founder of POM and answers the question, is now a good time to start a company? Absolutely...

Posted by POM Wonderful on 03/20/2009 at 09:42 AM | [Permalink](#) | [Digg This](#) | [Save to del.icio.us](#)

**TrackBack**

TrackBack URL for this entry:  
<http://www.typepad.com/blog/2009/03/20/0942101-w620a0v11560a0d0/>

Listed below are links to weblogs that reference [Striking Out On Your Own](#).

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If you have a TypeKey or TypePad account, please [Sign In](#).

(You can use HTML, tags like `<br />` and `<u>` to style your text.)

**Your Information**

(Name and email address are required. Email address will not be displayed with the comment.)

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- [Events, Parties, Picn and POM](#)
- [Food / Drink Recipes Galore](#)
- [Food and Drink](#)
- [Healthy Living with POM](#)
- [Hot off the press](#)
- [POM - International!](#)
- [POM Content Updates!](#)
- [POM's Good Coffee](#)
- [Wonderful World of POM](#)
- [Other Random stuff](#)

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- August 2008

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Exhibit F, Page 1

## Complaint

Striking Out On Your Own | Print Article | Newsweek.com

<http://www.newsweek.com/id/190063/ouput/print>**Newsweek****Striking Out On Your Own****Is now a good time to start a company? Absolutely, says Lynda Resnick, the founder of Fiji Water and POM Wonderful.**Nick Summers  
Newsweek Web Exclusive

When Lynda Resnick brings her own water to an interview, she really brings her own. That is, when she produces a bottle of Fiji, she owns the entire company—as well as POM Wonderful, maker of pomegranate juice and antioxidant supplements. She's a serial entrepreneur who also owns the Teleflora floral service and a number of other ventures. Resnick's new book, [Rubies in the Orchard](#), details a lifetime acquiring businesses and transforming them with a keen eye for value, marketing and community. The writing can be flat—especially compared with how charismatic Resnick is in person—but the ideas are so sound, and the track record so full of success, that the book is still a fun read, and highly instructive to anyone wishing to start a business in these bleak times. Resnick spoke to NEWSWEEK's Nick Summers about the Bush administration's economic legacy, balancing risk with reward and why now is a great time to be running [your own business](#). Excerpts.

**How long were you working on the book?**

Of course it took me my whole life, but six months. I turned in the manuscript, and my editor said it was the cleanest he'd ever seen. I thought, "Is that a compliment?" The corrections took about half an hour; that was it. There was a page and a half that he took out that was a little too strident.

**What was it strident about?**

I get carried away. The Bush administration—I was hysterical during the entire eight years. Beating my chest, crying, screaming at the television. I saw the end. I did. I have a Cassandra complex. Do you know who Cassandra was?

I do!

And do you know what happened when she broke up with Apollo, what he did to her?

I don't.

He gave her the gift of prophesy, but made it so that no one would believe her.

**So you saw the end—of what?**

I didn't see the debacle the way it is today, but I did—every time the stock market went up another 300 points. I would get sick. I was very upset, because I've lived through so many bubbles. I knew that there was no way that this was going to last. You can't expect to make 20 percent a year, year in and year out.

**Why did you write the book? Who was the target audience?**

I wrote it, I hope, for small- to medium-size businesses, although Wall Street could learn a lot from it. But alas, will they? I talk about the tyranny of instant gratification that our country has gone through over the last 20 years. Running companies for quarterly profits is not a long-term game, as we've seen. So my concept is, if you have a product or business or service, you have to make sure you have true intrinsic value in what you're selling. You have to figure out where that value resides—is it your technology, is it some invention that you've made? Is it the fact that your water fell as rain 200 years ago? Is it the fact that your pomegranate has healing properties?

Then communicate that value. You have to have a unique selling proposition, something that sets you apart from the other people in your realm. If you're a dry cleaner, is your front office as pristine as the clothes you're returning? If it's a movie theater, maybe it's an art theater, showing films that they can't get somewhere else?

Community and transparency can level the playing field. Small businesses are not burdened with

## Complaint

Striking Out On Your Own | Print Article | Newsweek.com

<http://www.newsweek.com/id/190063/output/print>

the overhead and the debt of a big business—they can zoom in with their disruptive technology and take over. There was no chance for small business up until recently; it was very hard to come to market with your new idea. Nobody was interested; they wanted to write fancy derivatives and instruments that were going to make it quick on Wall Street. But today there's a real opening, and it's a good day for small business.

**So there's reason for optimism, for entrepreneurs with an idea for a business? And what about taking risks in general?**

What do they have to lose? They may as well go for it. They're not going to see another opening like this. Investing in your own business is what we've always done; we've never been a public company. Who are you going to believe in more than yourself?

Now, I disagree that we should be spending. I'm not, and believe me, I love to. Now I'm very cautious about what I'm buying. I used to buy at the auction houses all the time. We have a big art collection, but I'm not doing it, man. I don't need it. I don't need another thing. Cash is king. If we start saving, we may be able to finance our own future. So it's OK, pull in your belt a little bit.

**What else should entrepreneurs consider about today's economy?**

The wonderful thing about the Internet is that it wasn't there during the last depression. It's the No. 1 thing that I think will save us. Let's say you have a great idea that you've invented: the best mousetrap. How easy it is today to comb the Web and find out if someone else has done that mousetrap. A piece of cake; I could do that in 20 minutes. Then you could go to zoomerang.com, which is a market-research Web site. For \$20 a month, you can find your target market and ask, "How do you feel about this mousetrap? Is this the mousetrap you've longed for? The roach hotel that will make your life easy?" Then, you're ready to go to your patent attorney. And there are also cheap patent attorneys online!

**You write that you despise the phrase "think outside the box."**

Because the answer's inside the box. The answer to your problem is always inside the box, always understanding the intrinsic value again of your product or service. Look there for your marketing answer. Take Fiji Water. Smartwater got Jennifer Aniston to be their spokesperson for millions of dollars. But every celebrity drinks my water. I just take the pictures from Us and Touch, or whatever the hell those magazines are called, and put those on our Web site.

**I hate "think outside the box" too.**

People don't like the obvious—it's like, boring. It's "boring" to think of value, "boring" to think of unique selling proposition, "boring" to think of community and hard work. "We should have this big idea that's just going to transport us to riches!" But it isn't like that, especially now. Hard work is back—with a vengeance.

**That's probably a good lesson for almost everyone.**

I realized after reading [Malcolm Gladwell's] "Outliers" why I did so well when I started [business] at 10. By the time everyone else was graduating from an MBA program, I had been in business for so many years that I was ahead of the pack!

**Do you still have an inner competitiveness to stay on top of the business world? Are you still looking to buy new companies or start new ones?**

Sure, yeah!

**Always? Till you drop dead?**

Well, yeah! I have no plans to retire. You think it's undignified for a woman my age to still be working? There's so much need in this world, how can I not? If I can motivate a person that comes to one of my lectures, that's something. [Coughs, clears throat] Excuse me. My vitamins. I take POMx.

**Should I take vitamins?**

I don't know your family history. How's your father?

**He's in good health. Had a bout of prostate cancer, but that's—**

You have to be on pomegranate juice. You have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist—your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at UCLA, on 43 men ... it arrested their PSA. How old are you, 28?

**Twenty-six.**

Get a base line now. [Pause, wink] It's also 40 percent as effective as Viagra. Not that you need it.

Complaint

Striking Out On Your Own | Print Article | Newsweek.com

<http://www.newsweek.com/id/190063/output/print>

But—couldn't hoit!

URL: <http://www.newsweek.com/id/190063>

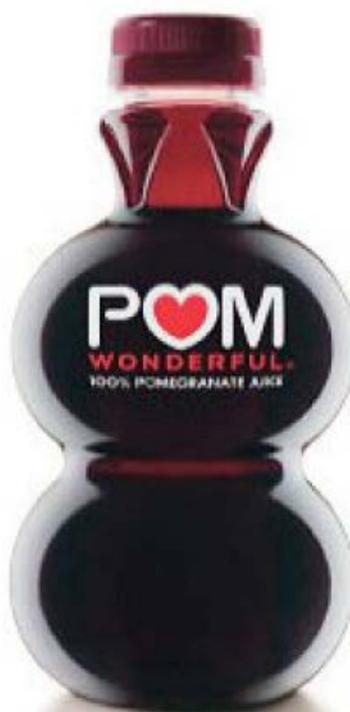
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© 2009

Complaint

**EXHIBIT G**

Amaze your  
**urologist**



The  
**Antioxidant  
Superpower.**

**LEARN MORE ▶**

Complaint

**EXHIBIT H**



**EXHIBIT I**



Complaint

**POMx™ is the first and only pomegranate antioxidant supplement reviewed for safety by the FDA.**

POMx™ is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice. In fact, our method of harnessing astonishing levels of antioxidants is so extraordinary, it's patent-pending.

**The power of POM. Now in one little pill.™**

All of the antioxidant power of an 8oz glass of POM Wonderful 100% Pomegranate Juice is now available in the convenience of a single calorie-free pill. **Take one daily.** Each bottle contains a one-month supply of 30 pills.



Exhibit I, Page 2

**Our antioxidants make other antioxidants feel inferior.**



*fact. 1* More polyphenol antioxidants than any other 100% pomegranate supplement

*fact. 2* The antioxidant power of an 8oz glass of our juice, in a calorie-free pill

*fact. 3* An astonishing 1000mg of natural pomegranate polyphenol extract in every pill

*fact. 4* Made from the same California pomegranates in POM Wonderful 100% Pomegranate Juice

**Why take an antioxidant supplement?**

Let's start with the problem: free radicals. Emerging science tells us these unstable molecules aggressively destroy healthy cells in your body and may be linked to everything from the wrinkles we get as we age to more serious health threats like cancer and heart disease. In fact, scientists have already linked free radicals to as many as 60 different types of diseases.

pesticides and even fried foods. That's where antioxidants come in. Science tells us that pomegranate antioxidants neutralize free radicals, helping to prevent the damage that can lead to disease. In the fight against free radicals, POMx is the Antioxidant Superpill.™

**Not all antioxidants are equal.**

POMx is made from pomegranates only—nothing else. When other supplements add non-pomegranate ingredients or even other antioxidants, they can disrupt the balance of molecules that nature intended the pomegranate to have. The polyphenol antioxidants in POMx are as natural and unadulterated as those in our fresh, California-grown POM Wonderful Pomegranates.

**Fighting free radicals.**

Where do free radicals come from? Everywhere. They're formed by exposure to alcohol, sunlight, tobacco smoke, air pollution,

Exhibit I, Page 3

## Complaint

**"Findings from a small study suggest that pomegranate juice may one day prove an effective weapon against prostate cancer."**

*The New York Times (July 4, 2006)*



**Prostate health.**

Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer.<sup>1</sup>

**Time pill.**

Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer.<sup>2</sup> According to a UCLA study of 46 men age 65 to 70 with

advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%.<sup>3</sup>

83% of those who participated in the study showed a significant decrease in their cancer regrowth rate.<sup>3</sup>

**One small pill for mankind.**

New studies are under way to further investigate the possibilities of POM Wonderful pomegranate antioxidants and their potential ability to slow the rise of PSA levels in patients with prostate cancer.

To learn more, visit [pomfills.com/research](http://pomfills.com/research).

**"The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies indicate that POMx and POM Wonderful Pomegranate Juice may have the same effects on prostate health."**

*David Hoher, MD, PhD, Professor of Medicine and Director,  
UCLA Center for Human Nutrition*

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.  
\*American Cancer Society. 11/04. Copyright reserved, UCLA HealthCenter, April 2007. 1pomfills.com/research. © 2006 by POM

**Exhibit I, Page 4**

**"POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits."**

*Dr. Michael Aviram, Lipid Research Laboratory,  
Technion Faculty of Medicine, Haifa, Israel*

**Heart health.**

In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for those patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily.<sup>2</sup>

An additional study at the University of California, San Francisco included 45 patients with impaired blood flow to the heart. Patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced a 17% improvement in blood flow.<sup>3</sup> Initial studies on POMx share similar promise for heart health, and our research continues.



Fig. 1 THE HEART

**The POMx Difference**

**Ultra-Potent:**

- 1000mg of natural pomegranate polyphenol extract in every pill
- More antioxidants than any other pomegranate supplement
- One POMx pill = the antioxidant power of 8oz of POM Wonderful 100% Pomegranate Juice
- Your daily antioxidants in a single pill
- A full spectrum of pomegranate polyphenol antioxidants

**Natural:**

- Made from pomegranates and nothing else

- No synthetic or other antioxidants added
- No sugar, artificial colors or preservatives
- Calorie-free, vegan, kosher

**Science, Not Fiction:**

- Made from the only pomegranates backed by \$20 million in medical research and the POM Wonderful brand
- Promotes heart and prostate health
- Guards your body against free radicals<sup>4</sup>
- Proven to be easily absorbed<sup>5</sup>
- Clinically tested on adults<sup>6</sup>

To access the original published studies mentioned, visit [pomfills.com/research](http://pomfills.com/research).

**Exhibit I, Page 5**

Complaint

EXHIBIT J

HEALTHY. ~~WEALTHY.~~ AND WISE. (2 OUT OF 3 IN THIS ECONOMY AIN'T BAD.)

Antioxidants are a necessity. Not a luxury.

Emerging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body. Taking one POMx pill a day will help protect you from free radicals and keep you at your healthy best. Even when you're going through the worst.



The Antioxidant Superpill.™

Hope for the future. Yours.

Our POMx pills are made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, '06.<sup>1,2,3</sup>

Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05.<sup>12,4</sup>

"Pomegranate juice consumption resulted in significant reduction in IMT<sup>5</sup> (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram in *Clinical Nutrition*, '04.<sup>10,5,6</sup>



The antioxidant power of our 8oz juice.

\$32 million in medical research. A sound investment.

POMx is made from the only pomegranates backed by \$32 million in medical research at the world's leading universities.

Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.



Recession-proof your health with POMx.

POMx is an all-natural, ultra-potent antioxidant extract. Containing a full spectrum of pomegranate polyphenols, POMx is so concentrated that a single capsule has the antioxidant power of a full glass of POM Wonderful® 100% Pomegranate Juice.

Try POMx Monthly FREE for ONE MONTH. We'll even pay for the shipping.



Order Now: 888-766-7455 or [pompills.com/ph](http://pompills.com/ph) Use discount code: PH30

\*SIGN UP FOR POMx MONTHLY AND WE'LL SEND YOUR FIRST BOTTLE FREE AFTER THAT YOU'LL CONTINUE TO RECEIVE MONTHLY SHIPMENTS FOR \$49.95 WITH COMPLIMENTARY SHIPPING. Offer ends 10/31/09 and applies only to the purchase price for the first bottle of POMx Monthly. Following months will be \$79.95 per bottle. One discount per customer. Cannot be combined with other offers. No substitutions, transfer rights or cash refunds. We reserve the right to discontinue this promotion, change product and/or shipping charge at any time. Valid only at [pompills.com/ph](http://pompills.com/ph) or 1-888-766-7455. Not valid on POMx Trial or other POMx products.



Yonagida.com research \*\*These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease. Ask your doctor with regard to diet therapy. Drink 100% pomegranate juice daily for two years. \*\*In patients with coronary heart disease and myocardial infarction drink 100% pomegranate juice daily for three months. Study measured intima-media thickness (IMT). \*\*In patients aged 60-75 years with severe atherosclerosis drink 100% pomegranate juice daily for one year. ©2009 Pom Wonderful LLC. All rights reserved. POM Wonderful, POMx and Antioxidant Superpill are trademarks of Pom Wonderful LLC. PWC102



Complaint

EXHIBIT L

PX7565\_P111PrintAds\_MYT0108\_F.qxd 12/18/07 5:13 PM Page 1
New York Times Magazine
Issue: January 6<sup>th</sup>, 2008
In Home: 1/6/08



The easy, portable, calorie-free way to get your daily antioxidants.

The power of POM, in one little pill.

Antioxidant Superpill™ Not all antioxidants are created equal. POMx™ fights free radicals with a mighty 1000mg in every pill. That's more concentrated antioxidants than any other pomegranate antioxidant supplement. There are antioxidants, and then there are POMx antioxidants.

Peace of Mind in a Pill. POMx is a highly concentrated, powerful blend of polyphenol antioxidants made from the very same pomegranates as POM Wonderful® 100% Pomegranate Juice. The same pomegranates we grow exclusively in California, where they're hand-picked on site.

Safe and Natural. POMx is made from pure pomegranates. So there are no added sugars, preservatives or any other ingredients - just 100% pomegranate polyphenol antioxidants. So naturally, POMx is absorbed safely into your body. In fact, POMx is the first and only antioxidant supplement reviewed for safety by the FDA.

Backed by Science. POMx is made from the only pomegranates supported by \$23 million in medical research. Emerging science suggests that free radicals aggressively destroy healthy cells in your body - contributing to premature aging and even disease. The good news is POM Wonderful pomegranate antioxidants neutralize free radicals. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found hopeful results for prostate health. "Pomegranate juice delays PSA doubling time in humans," according to AJ Pantuck, et al. in Clinical Cancer Research 2006.™ Two additional preliminary studies on our juice showed promising results for heart health. "Pomegranate juice improves myocardial perfusion in coronary heart patients," per D. Ornish, et al. in the American Journal of Cardiology, 2005.™ "Pomegranate juice pilot research suggests anti-atherosclerosis benefits," according to M. Aviram, et al. in Clinical Nutrition, 2004.™



One a Day, For Life. Ready to take on free radicals? A daily POMx pill is all you need. Invest in your health and order your 30-day supply today. Call now to get your first monthly shipment.

Call 1-888-POM-PILL (766-7455) or visit pom-pills.com/nb and enter NB30 at checkout.



The antioxidant power of just 8 oz. juice.



Reviewed for Safety by the FDA.



100% Natural Pomegranate Extract.

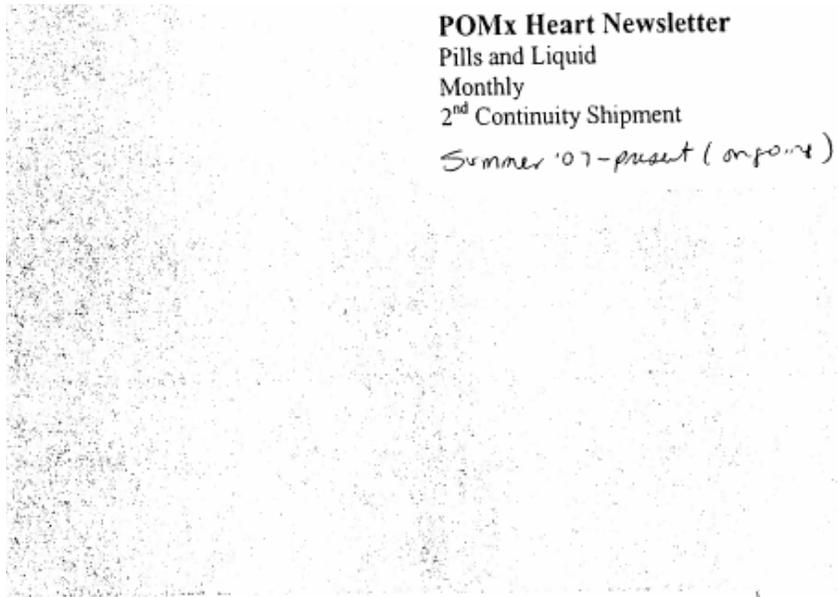
Try POMx for one month - FREE!

We'll even pay for the shipping. Visit pom-pills.com/nb or call 1-888-POM-PILL. Use discount code: NB30

Sign up for POMx Monthly and we'll send your first bottle free. After that, you'll continue to receive monthly shipments for \$29.95 with complimentary shipping. One month only \$1.99. The first month free plus free shipping offer applies only to the purchase price for the first month. Shipping handles will be \$29.95 per bottle. This discount can only be used on POMx products. One discount per customer. Cannot be combined with other offers. No substitutions. Limited rights. All US quantities will be given. We reserve the right to modify or discontinue this promotion at any time. We reserve the right to change product price or shipping charge at any time. Offer valid only at pom-pills.com/nb or 1-888-766-7455. Payment made in full at time of purchase.

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Complaint

**EXHIBIT M****POMx Heart Newsletter**

Pills and Liquid

Monthly

2<sup>nd</sup> Continuity Shipment*Summer '07-present (ongoing)*

**POMx YOUR PARTNER IN PROMOTING LIFELONG HEALTH**

VOLUME 1, ISSUE 1: FOR YOUR HEART

**What's New in the Lab  
by Dr. Mark Dreher**



Mark Dreher, PhD  
Chief Science Officer  
POMWonderful, LLC

Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health. Welcome to Your First Issue of the POMx Newsletter! There's more to come, so please stay tuned in the coming months for:...

Future newsletters will contain content derived from these questions and reader feedback. We look forward to hearing from you!



**Enjoy Your Life With  
a Healthy Heart**

According to the American Heart Association (AHA), at least 58.8 million Americans suffer from some form of heart disease. Maintaining a healthy heart by reducing your risk for cardiovascular disease should be at the core of every lifetime.

Complaint



VOLUME 1, ISSUE 1: FOR YOUR HEART

**What's New in the Lab**  
by Dr. Mark Dreher



Mark Dreher, PhD  
Chief Science Officer  
POMWonderful, LLC

Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health. Welcome to Your First Issue of the POMx Newsletter! There's more to come, so please stay tuned in the coming months for....

- POM Wonderful's latest research
- Health tips
- Pomegranate facts
- New product information

There's a strong pipeline of research supporting initial findings that POM Wonderful 100% Pomegranate Juice and its counterpart, POMx, are successfully fulfilling their promise for promoting heart health. We are committed to continually testing our products, not only prior to market

**Did You Know?**

**POLYPHENOLS**

Polyphenols are antioxidants that naturally occur in pomegranates. These antioxidants neutralize free radicals, helping to prevent the cell and tissue damage that can lead to disease. The heart health benefits associated with California grown, Wonderful variety pomegranates are due to their very high levels of polyphenols.

release but at every step in their evolution. Various patient studies across a wide variety of health concerns are in the works, and we look forward to sharing the results of this research with you.

At POM Wonderful, we aim to be your partner in the promotion of good health that lasts a lifetime. It is our commitment to you and our mission as a company. If you have any questions and/or concerns please send them directly to me at: [chiefscienceofficer@pomwonderful.com](mailto:chiefscienceofficer@pomwonderful.com)

Future newsletters will contain content derived from these questions and reader feedback. We look forward to hearing from you!



**Enjoy Your Life With a Healthy Heart**

According to the American Heart Association (AHA), at least 58.8 million Americans suffer from some form of heart disease. Maintaining a healthy heart by reducing your risk for cardiovascular disease should be at the core of every lifelong wellness plan. A nutrient-rich diet and active lifestyle are the best weapons you have for combatting heart disease and enhancing your vitality at any age.

The AHA recommends eating plenty of fruits and vegetables loaded with the vitamins, minerals and fiber your body requires, without the extra calories it doesn't need. But even though you may be eating enough of the right foods, your body still may not be getting all the nutrients it needs to keep you heart truly healthy.

**ANTIOXIDANTS: YOUR ALLY IN FIGHTING HEART DISEASE**

In order to keep your body in tip-top shape and your heart beating to the rhythm of all you wish to do in life, you need help in the prevention of cell and tissue damage that can lead to disease.

Science tells us that antioxidants neutralize the free radicals that can aggressively destroy healthy cells in your body. But not all antioxidants are equal – some are better at neutralizing free radicals than others. And because your body may not always produce enough of the antioxidants required to neutralize all the free radicals that can lead to cell damage, we have developed POMx to harness and deliver the most potent antioxidants around.

**THE FREE RADICAL FIGHTER**

Pomegranates contain polyphenols – powerful antioxidants that are important as part of a balanced diet. Published research has shown that the unique polyphenol antioxidants

(please turn to back)



## Complaint

VOLUME 1, ISSUE 1: FOR YOUR HEART

Healthy Heart (from fruit) in POMx and POM Wonderful 100% Pomegranate Juice are superior fighters in the battle against free radicals. Each dose of POMx contains the same amount of antioxidant polyphenols found in 8oz of POM Wonderful 100%

**The antioxidants in POMx are supported by \$20 million in initial scientific research**

Pomegranate Juice, and POMx is the most concentrated source of pomegranate polyphenol antioxidants available.

POM Wonderful is committed to understanding the effects of POM Wonderful Pomegranate Juice on cardiovascular health. To date, our scientists have found that pomegranate juice may help counteract factors leading to arterial plaque build up, as well as inhibit a number of factors associated with heart disease.

**NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE**

**30% DECREASE IN ARTERIAL PLAQUE**

After one year of a pilot study conducted at the Technion Institute in Israel involving 19 patients with atherosclerosis (clogged arteries),

In his 2006 POMx study, Dr. Michael Aviram, one of the world's pre-eminent cardiovascular researchers from the Technion Institute in Israel, remarked that "POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health."

these patients who consumed 8oz of POM Wonderful 100% Pomegranate Juice daily saw a 30% decrease in arterial plaque.

**17% IMPROVED BLOOD FLOW**

A recent study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8oz of POM Wonderful 100% Pomegranate

Juice daily for three months experienced 17% improved blood flow. Those who drank a placebo experienced an 18% decline.

**PROMOTES HEALTHY BLOOD VESSELS**

An in vitro study at the University of California, Los Angeles (UCLA) showed that pomegranate juice uniquely possesses enough antioxidant activity to protect nitric oxide (an important bio-chemical that helps maintain healthy blood vessels for proper blood flow) against oxidative destruction thereby enhancing its biological activity. In other words, pomegranate juice by protecting nitric oxide promotes healthy blood flow.

**THE POWER OF POMx**

The antioxidants in POMx are supported by \$20 million in initial scientific research from leading universities and so far we've uncovered encouraging results.

**POMx supplements your diet without adding calories, allowing you to more easily maintain a healthy weight while still getting the necessary antioxidants**

Due to this promising information, our studies on POMx and heart health continue. It is our mission to deliver the latest information on our research to you in this newsletter as soon as studies are completed. At POM Wonderful we are committed to learning all we can about the health benefits of this miraculous fruit and sharing them with you.



**NEXT ISSUE: PROSTATE HEALTH**

One out of every six men will get prostate cancer, but only one out of 34 will die from the disease. In our newsletter next month, we will discuss preventative measures all men need to know to manage their prostate health.

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Complaint

**EXHIBIT N**

**POMx Prostate Newsletter**

Pills and Liquid

Monthly

3<sup>rd</sup> Continuity Shipment

*Fall '07 - present (ongoing)*



VOLUME 1, ISSUE 2: PROSTATE HEALTH

**Prostate Cancer Affects  
1 Out of Every 6 Men**

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute. Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

**Prostate cancer  
is the second  
leading cause of**

fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or  
*(continued on back)*

**What's New in the Lab  
by Dr. Mark Dreher**



**Mark Dreher, PhD  
Chief Science Officer  
POMWonderful, LLC**

Research studies like the ones discussed in this newsletter and

## Complaint

**POMx YOUR PARTNER IN  
PROMOTING LIFELONG HEALTH**

VOLUME 1, ISSUE 2: PROSTATE HEALTH

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**Prostate cancer  
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Cancer Institute**

Since the early 1990's, prostate cancer incidence and deaths have been declining, but the American Cancer Society estimates that there will still be about 218,890 new cases of prostate cancer and 27,050 deaths in the United States in 2007.

According to the American Cancer Society, some of the risk factors for prostate cancer include:

**Age** – Growing older raises a man's risk of prostate cancer. About two of every three prostate cancers are found in men over the age of 65.

**Family History** – Men with close family members (father or brother) who have had prostate cancer are more likely to get it themselves, especially if their relatives were young when they got the disease.

**Diet** – One risk factor that can be changed is diet. The National Cancer Institute's research suggest that obesity and weight gain is linked to increased prostate cancer mortality.

Men who eat a lot of red meat or high-fat dairy products seem to have a greater chance of getting prostate cancer. These men also tend to eat fewer

fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or  
*(continued on back)*

**What's New in the Lab  
by Dr. Mark Dreher**

**Mark Dreher, PhD**  
Chief Science Officer  
POM Wonderful, LLC

Research studies like the ones discussed in this newsletter and conducted by UCLA (my alma mater) serve to validate the many reasons I am proud to be affiliated with POM Wonderful and POMx.

POM Wonderful 100% Pomegranate Juice and POMx are backed by a \$25 million dollar investment in world-class scientific research. This includes ten clinical studies published in top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

Working at POM Wonderful gives me the unique opportunity to really make a difference in the world. That's what gets me up every morning! I get to work with renowned scientists, including a Nobel Laureate, at leading

**Studies funded by  
POM represent the  
vast majority of  
medical research  
ever conducted  
on pomegranates.**

universities around the world. In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates. No other company that I know of is as dedicated as POM in pursuing the truth and keeping our customers informed.

At POM Wonderful, we aim to be your partner in the promotion of good health that lasts a lifetime. It is our commitment to you, our mission as a company.

Complaint

VOLUME 1, ISSUE 2: PROSTATE HEALTH

Prostate Cancer (from front) more servings of vegetables and fruits rich in antioxidants and to eat less red meat and high-fat foods.

**EARLY DETECTION SEEN AS KEY TO INCREASING SURVIVAL RATES\***

The prostate-specific antigen (PSA) test and rectal exam can be used to detect the presence of prostate cancer when no symptoms are present. They may help catch the disease at an early stage when treatment is more effective.

During a PSA test, a small amount of blood is drawn and the level of PSA (a protein produced by the prostate) is measured to determine the level of risk. When prostate cancer is found and treated, the PSA test may also measure the potential risk for the cancer to return.

\*Please talk to your doctor for more specific prostate cancer information.

**NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS**

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. 46 men who had been treated for prostate cancer with surgery or radiation were given Boz of POM Wonderful 100% Pomegranate Juice to drink daily. A

**Patients with prostate cancer showed a prolongation of PSA doubling time, coupled with corresponding lab effects on reduced prostate cancer as well as reduced oxidated stress.**

majority of the patients experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression – extended doubling time may indicate slower disease progression.

Before the study, the mean doubling time was 15 months. After drinking Boz of pomegranate juice daily for two years, the mean PSA doubling time increased to 54 months. Testing on patient blood serum showed a 12% decrease in cancer cell proliferation and a 17%

increase in cancer cell death (apoptosis).

In another study, in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death.

Based on the promising results of these preliminary studies, two additional studies are underway to more fully investigate the potential of POMx to extend PSA doubling time.

According to Dr. David Heber, Director of UCLA's Center for Human Nutrition, "The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and pomegranate juice may have the same effects."

**SEND US YOUR QUESTIONS AND COMMENTS**

We encourage you to participate in our commitment to a lifetime of good health by sending your questions and/or concerns to [chiefscienceofficer@pomfills.com](mailto:chiefscienceofficer@pomfills.com). Future newsletters will contain content derived from these questions and reader feedback. We look forward to hearing from you!



**NEXT ISSUE: POMEGRANATE SUPPLEMENT COMPARISONS**

How does POMx compare with other pomegranate supplements for antioxidant potency?



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Initial Decision

**INITIAL DECISION****I. INTRODUCTION****A. Summary of Complaint and Answer**

The Complaint, issued September 24, 2010, alleges that Respondents POM Wonderful LLC, Roll Global LLC, Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper (“Respondents”) disseminated advertising and promotional materials representing that the consumption of eight ounces of POM Juice, one POMx Pill, or one teaspoon of POMx Liquid (the “POM Products”) daily “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 9, 10, 19. Because, according to the Complaint, Respondents represented that they possessed and relied upon, but in fact did not possess or rely upon a reasonable basis substantiating such claims, Respondents’ representations were false or misleading. Complaint ¶¶ 19-21.

The Complaint further alleges that Respondents disseminated advertising and promotional materials representing that “clinical studies, research, and/or trials prove” that consuming the POM Products “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 9, 10, 12, 14, 16. The Complaint further asserts that these representations are false or misleading because, in fact, clinical studies, research, and/or trials do not prove that consuming the POM Products, “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 13, 15, 17, 18.

The Complaint concludes that the foregoing acts and practices of Respondents constitute unfair or deceptive acts or practices, and false advertising, in violation of sections 5(a) and 12 of the Federal Trade Commission Act. Complaint ¶ 22.

Respondents filed their Answer to the Complaint on October 18, 2010. While admitting that they disseminated the advertising and promotional materials attached as exhibits to the Complaint, they denied that such materials make the claims alleged. Answer ¶¶ 9, 10, 12, 14, 16, 19. Respondents also deny making false or

## Initial Decision

misleading claims, and further aver that “there is substantial scientific research indicating the health benefits of [the POM Products] and substantiating their advertising and promotional materials.” Answer ¶¶ 13, 15, 17, 18, 21, 22.

**B. Procedural History**

The administrative hearing (also referred to herein as the “trial” or “administrative trial”) in the instant case began on May 24, 2011 and concluded on November 4, 2011. By Order dated November 18, 2011, the hearing record was closed. The hearing record is voluminous. Nearly 2000 exhibits were admitted. Among these exhibits are the advertisements and promotional materials upon which Complaint Counsel relies to prove that Respondents made the representations alleged in the Complaint. These consist of: 27 print advertisements, some of which comprise multiple pages; 2 multi-page newsletters; 7 separate “web captures” of Respondents’ 3 websites, recorded at multiple points in time; 2 internet “banner” advertisements; 4 press releases; and 4 television interviews (the “Challenged Advertisements”); *see* Complaint Counsel’s Post-Hearing Brief, Appendix A. Also included in the exhibits are more than 46 scientific studies sponsored by Respondents and offered on the issue of substantiation, numerous consumer surveys, and 14 expert reports. In addition, 24 witnesses testified, either live or by deposition, including 14 expert witnesses, and there are 3,273 pages of trial transcript. The parties submitted 3,929 proposed findings of fact (1,130 by Complaint Counsel and 2,799 by Respondents). The parties’ proposed findings of fact and conclusions of law, replies to proposed findings of fact and conclusions of law, post-trial briefs, and reply briefs total 3,396 pages.

Commission Rule 3.51(a) states that the Administrative Law Judge (“ALJ”) shall file an initial decision within 70 days after the filing of the last filed initial or reply proposed findings of fact, conclusions of law and order pursuant to Commission Rule 3.46 and that the Administrative Law Judge may extend this time period by up to 30 days for good cause. 16 C.F.R. § 3.51(a). The parties filed concurrent post-trial briefs and proposed findings of fact on January 7, 2012. The parties filed replies to the other’s proposed findings and briefs on February 7, 2012. Pursuant to

## Initial Decision

Commission Rule 3.41(b)(6), closing arguments were held on March 6, 2012.<sup>1</sup>

Seventy days from the last filed reply proposed findings and conclusions and briefs was April 17, 2012 and, absent an order pursuant to Rule 3.51, the Initial Decision was to be filed on or before April 17, 2012. Based on the voluminous and complex record in this matter and other grounds, an Order was issued on April 16, 2012 finding good cause for extending the time period for filing the Initial Decision by 30 days. Accordingly, issuance of this Initial Decision on May 17, 2012 is in compliance with Commission Rule 3.51(a).

### C. Evidence

This Initial Decision is based on a consideration of the whole record relevant to the issues, including the exhibits properly admitted into evidence, deposition transcripts, and the transcripts of testimony at trial, and addresses the material issues of fact and law. The briefs and proposed findings of fact and conclusions of law, and the replies thereto, submitted by the parties were thoroughly reviewed. Proposed findings of fact submitted by the parties, but not included in this Initial Decision were rejected, either because they were not supported by the evidence or because they were not dispositive or material to the determination of the allegations of the Complaint or the defenses thereto. The Commission has held that Administrative Law Judges are not required to discuss the testimony of each witness or all exhibits that are presented during the administrative adjudication. *In re Amrep Corp.*, No. 9018, 102 F.T.C. 1362, 1670, 1983 FTC LEXIS 17, \*566-67 (Nov. 2, 1983). Further, administrative adjudicators are “not required to make subordinate findings on every collateral contention advanced, but only upon those issues of fact, law, or discretion which are ‘material.’” *Minneapolis & St. Louis Ry. Co. v. United States*, 361 U.S. 173, 193-94 (1959); *accord Stauffer Labs., Inc. v. FTC*, 343 F.2d 75, 82 (9th Cir. 1965). *See also Borek Motor Sales, Inc. v. National Labor*

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<sup>1</sup> Although Commission Rule 3.41(b)(6) states that “[e]ach side shall be permitted to make a closing argument no later than 5 days after the last filed proposed findings,” by Order dated January 26, 2012, good cause was found for moving the closing arguments to March 6, 2012.

## Initial Decision

*Relations Bd.*, 425 F.2d 677, 681 (7th Cir. 1970) (holding that it is adequate for the Board to indicate that it had considered each of the company's exceptions, even if only some of the exceptions were discussed, and stating that "[m]ore than that is not demanded by the [Administrative Procedure Act] and would place a severe burden upon the agency").

Under Commission Rule 3.51(c)(1), "[a]n initial decision shall be based on a consideration of the whole record relevant to the issues decided, and shall be supported by reliable and probative evidence." 16 C.F.R. § 3.51(c)(1); see *In re Chicago Bridge & Iron Co.*, No. 9300, 138 F.T.C. 1024, 1027 n.4, 2005 FTC LEXIS 215, at \*3 n.4 (Jan. 6, 2005). Under the Administrative Procedure Act ("APA"), an Administrative Law Judge may not issue an order "except on consideration of the whole record or those parts thereof cited by a party and supported by and in accordance with the reliable, probative, and substantial evidence." 5 U.S.C. § 556(d). All findings of fact in this Initial Decision are supported by reliable, probative, and substantial evidence. Citations to specific numbered findings of fact in this Initial Decision are designated by "F."<sup>2</sup>

Pursuant to Commission Rule 3.45(b), several orders were issued in this case granting *in camera* treatment to material, after

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2 References to the record are abbreviated as follows:

CX – Complaint Counsel's Exhibit  
PX – Respondents' Exhibit  
JX – Joint Exhibit  
Tr. – Transcript of testimony before the Administrative Law Judge  
Dep. – Transcript of Deposition  
CCB – Complaint Counsel's Post-Trial Brief  
CCRB – Complaint Counsel's Post-Trial Reply Brief  
CCFF – Complaint Counsel's Proposed Findings of Fact  
CCRRFF – Complaint Counsel's Reply to Respondent's Proposed Findings of Fact  
RB – Respondents' Post-Trial Brief  
RRB – Respondents' Reply Brief  
RTB – Respondent Matthew Tupper's Post-Trial Brief  
CCRRTB – Complaint Counsel's Reply to Respondent Matthew Tupper's Reply Brief  
RFF – Respondents' Proposed Findings of Fact  
RRCCFF – Respondents' Reply to Complaint Counsel's Proposed Findings of Fact

## Initial Decision

finding, in accordance with the Rule, that its public disclosure would likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment. 16 C.F.R. § 3.45(b). Commission Rule 3.45(a) allows the Administrative Law Judge “to grant *in camera* treatment for information at the time it is offered into evidence subject to a later determination by the [administrative] law judge or the Commission that public disclosure is required in the interests of facilitating public understanding of their subsequent decisions.” *In re Bristol-Myers Co.*, Nos. 8917-19, 90 F.T.C. 455, 457, 1977 FTC LEXIS 25, at \*6 (Nov. 11, 1977). As the Commission later reaffirmed in another leading case on *in camera* treatment, since “in some instances the ALJ or Commission cannot know that a certain piece of information may be critical to the public understanding of agency action until the Initial Decision or the Opinion of the Commission is issued, the Commission and the ALJs retain the power to reassess prior *in camera* rulings at the time of publication of decisions.” *In re General Foods Corp.*, No. 9085, 95 F.T.C. 352, 356 n.7; 1980 FTC LEXIS 99, at \*11 n.7 (March 10, 1980). Thus, in instances where a document had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not in fact require *in camera* treatment, such material is disclosed in the public version of this Initial Decision, pursuant to Commission Rule 3.45(a) (the ALJ “may disclose such *in camera* material to the extent necessary for the proper disposition of the proceeding”). This Initial Decision does not contain any material that requires *in camera* treatment.

**D. Summary of Initial Decision**

The preponderance of the evidence shows that some of the Challenged Advertisements disseminated by Respondents would reasonably be interpreted by consumers to contain an implied claim that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and further, as to some of these advertisements, that these effects were clinically proven, as alleged in the Complaint. These advertisements are attached to this Initial Decision as an Appendix. As to other Challenged Advertisements disseminated by Respondents, the preponderance of the evidence fails to demonstrate that such advertisements would reasonably be interpreted by consumers as containing such claims.

## Initial Decision

The evidence further shows that the appropriate level of substantiation for claims that a product treats, prevents, or reduces the risk of a disease is competent and reliable scientific evidence. The evidence also demonstrates that where such claims are made in connection with a food, or food-derived product, that is safe, and that is not being offered as a substitute for medical treatment, double-blind, randomized, placebo-controlled clinical trials, such as those required by the Food and Drug Administration, are not required. However, for claims that a food or food-derived product treats, prevents, or reduces the risk of a disease, experts in the relevant fields would agree that competent and reliable scientific evidence must include clinical studies, although not necessarily double-blind, randomized, placebo-controlled clinical trials, that are adequate to show that the product did treat, prevent, or reduce the risk of disease.

Notwithstanding the fact that double-blind, randomized, placebo-controlled clinical trials are not required to substantiate Respondents' implied claims for the POM Products, the evidence demonstrates that Respondents' substantiation was, nevertheless, inadequate. Regardless of whether competent and reliable scientific evidence existed to substantiate highly qualified or generalized health claims about the POM Products, the weight of the persuasive expert testimony demonstrates that there was insufficient competent and reliable scientific evidence to support the implied claims in some of the Challenged Advertisements disseminated by Respondents, that the POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, or were clinically proven to do so. Whether or not Respondents' substantiation was adequate to support the express language of the advertisements is not the material issue. Because Respondents' substantiation was inadequate to support the implied claims, such claims were false or misleading within the meaning of Section 12 of the Federal Trade Commission Act ("FTC Act"), as interpreted by applicable case law. The evidence further shows that such health-related efficacy claims are material to consumers. Accordingly, the preponderance of the evidence supports the conclusion that Respondents violated Sections 5 and 12 of the FTC Act.

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Pursuant to Section 5(b) of the FTC Act, a cease and desist order is entered herewith (the “Order”), the provisions of which will serve to prevent Respondents from engaging in deceptive advertising practices in the future, are reasonably related to the unlawful acts or practices found to exist, and are sufficiently clear and precise. The Order is binding upon the corporate Respondents as well as the individual Respondents, and covers any food, drug or dietary supplement that may be advertised by Respondents in the future. Neither applicable law nor the evidence in this case supports Complaint Counsel’s proposed provision prohibiting Respondents from making any disease claim in the future, unless the claim has received prior approval from the Food and Drug Administration in accordance with Food and Drug Administration statutes and regulations.

**II. FINDINGS OF FACT****A. The Respondents****1. POM Wonderful LLC**

1. POM Wonderful (“POM Wonderful” or “POM”) is a limited liability company organized under the laws of the State of Delaware. (Complaint ¶ 1; CX1367 at 0002 (S. Resnick, Welch’s Dep. at 8); CX1437; Answer ¶ 1).
2. POM Wonderful’s principal office or place of business is at 11444 West Olympic Boulevard, Los Angeles, California 90064. (Complaint ¶ 1; Answer ¶ 1).
3. POM Wonderful is wholly owned by the Stewart and Lynda Resnick Revocable Trust, dated December 27, 1988 (the “Resnick Trust”). (Complaint ¶ 1; Answer ¶ 1; CX1384 at 0008).
4. Respondent POM Wonderful is a member-managed company, and the Resnick Trust is the sole member. (Complaint ¶ 1; Answer ¶ 1).
5. In 2002, POM first launched POM Wonderful 100% Pomegranate Juice, a premium, all-natural pomegranate

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juice made from pomegranates grown from POM's orchards. (L. Resnick, Tr. 145-46).

6. POM Wonderful is currently in the business of selling fresh pomegranates and pomegranate-related products, including 100% pomegranate juice ("POM Juice") and pomegranate extract products known as POMx pills and POMx liquid ("POMx") ("the POM Products"). (S. Resnick, Tr. 1630-31; CX1364 at 0005 (Tupper, Coke Dep. at 20); CX1374 (Tupper, Ocean Spray Dep. at 26); CX1363 at 0012 (S. Resnick, Coke Dep. at 45-46)).

## **2. Respondent Roll Global LLC**

7. Roll International Corporation is a separate corporation organized under the laws of the State of Delaware. (Complaint ¶ 2; Answer ¶ 2).
8. Roll International Corporation was reorganized at the end of 2010 and is currently known as Roll Global ("Roll"). (S. Resnick, Tr. 1629).
9. Roll is wholly owned by the Resnick Trust. (Complaint ¶ 2; Answer ¶ 2).
10. Roll is a privately held corporation. (S. Resnick, Tr. 1630).
11. POM Wonderful, FIJI Water, Suterra, Paramount Farms, Paramount Citrus, Teleflora, Neptune Shipping, Paramount Farming, and Justin Winery are among the separate operating businesses under Roll's ownership umbrella (hereafter "affiliated companies"). (CX1364 at 0004-05 (Tupper, Coke Dep. at 16-17); CX1374 (Tupper, Ocean Spray Dep. at 36); Perdigao, Tr. 593-94).
12. Stewart and Lynda Resnick are the sole owners of Roll and its affiliated companies, including POM Wonderful. (S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15); CX1376 (S. Resnick, Ocean Spray Dep. at 13-14)).

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13. Roll's affiliated companies pay Roll for certain provided services. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 89; CX1359 (L. Resnick, Dep. at 26); Perdigao, Tr. 616-17).
14. Fire Station acts as Roll's in-house advertising agency. Fire Station bills POM and other Roll affiliated companies separately. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 88-89; CX1359 (L. Resnick, Dep. at 26); Perdigao, Tr. 616-17).

**3. Respondents Stewart and Lynda Resnick**

15. POM Wonderful is owned solely by Stewart and Lynda Resnick ("the Resnicks"). (S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15).
16. The Resnicks have been, and currently are, the sole trustees and beneficiaries of the Resnick Trust. (Complaint ¶ 1; Answer ¶ 1; CX1421 at 0002-03; CX1384 at 0008).
17. The Resnick Trust had owned Roll International Corporation and POM. (JX0001 ¶¶ 10-11, 18; Complaint ¶¶ 1-2; Answer ¶¶ 1-2).
18. The Resnicks are the sole owners of Roll Global, the successor-in-interest to Roll International Corporation, and its affiliated companies, including POM. (JX0003 ¶ B.2; S. Resnick, Tr. 1629; CX1360 (S. Resnick, Dep. at 15); CX1376 (S. Resnick, Ocean Spray Dep. at 13)).
19. Stewart Resnick ("Mr. Resnick") is, and at all times relevant to this action has been, the Chairman and President of Roll. (JX0001 ¶¶ 12, 18; S. Resnick, Tr. 1629; Complaint ¶ 3; Answer ¶ 3; CX1384 at 0008; CX1363 at 0014 (S. Resnick, Coke Dep. at 54-55)).
20. Mr. Resnick is, and at all times relevant to this action has been, the Chairman of POM Wonderful. (Complaint ¶ 3; Answer ¶ 3).

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21. Mr. Resnick is the Chief Executive Officer of POM. (S. Resnick, Tr. 1869).
22. Mr. Resnick's responsibilities include making final decisions about POM's investments and corporate expansion. (S. Resnick, Tr. 1631; CX1360 (S. Resnick, Dep. at 20-21); *see also* CX1357 (Kuyoomjian, Dep. at 154-56) (testifying that Mr. Resnick's participation in POM's business included involvement in strategic planning and financial decisions as well as providing feedback on POM's advertising)).
23. Mr. Resnick spends the second greatest amount of his time on the POM business and, among other activities, sets the overall budgets for POM, including the marketing and advertising and medical research budgets. He has been intimately involved in the development of POM's scientific research program. (S. Resnick, Tr. 1631-32; CX 1363 at 0014 (S. Resnick, Coke Dep. at 56); CX1367 at 0014 (S. Resnick, Welch Dep. at 55)).
24. Mr. Resnick's authority includes "any decisions made with respect to what . . . [POM] talk[s] about, [and] how . . . [POM] talk[s] about it," including "authority for advertising the benefits of POM." (Tupper, Tr. 2975).
25. Mr. Resnick leaves the marketing of POM mostly to Mrs. Lynda Resnick. He considers himself ultimately responsible for whether advertising should or should not go out, although he delegated day-to-day responsibility to Mr. Matthew Tupper. (Tupper, Tr. 2975; S. Resnick, Tr. 1869-70).
26. When Mrs. Lynda Resnick has chosen to involve him, Mr. Resnick has been involved at a high level with POM's advertising and marketing campaigns, including on occasion seeing headlines before advertisements were disseminated. (CX1376 (S. Resnick, Ocean Spray Dep. at 140-42); CX1360 (S. Resnick, Dep. at 50-51)).
27. Lynda Resnick ("Mrs. Resnick") was, at all times relevant to this action, a director and was Vice Chairman of Roll

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International Corporation. (JX0001 ¶ 18; Complaint ¶ 4; Answer ¶ 4; L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25)).

28. Mrs. Resnick is Vice Chairman of Roll Global. (L. Resnick, Tr. 287; CX1359 (L. Resnick, Dep. at 24-25)).
29. Mrs. Resnick is involved in POM's marketing, branding, public relations, and product development. (CX1363 at 0011 (S. Resnick, Coke Dep. at 41); CX1364 at 0007 (Tupper, Coke Dep. at 27); CX1347 (Glovsky, Dep. at 36)).
30. Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010, although Mrs. Resnick reduced her day-to-day involvement in POM's business beginning in 2007 (L. Resnick, Tr. 86, 93, 157-58; *see also* CX1375 (L. Resnick, Tropicana Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 22, 108)).
31. As of 2011, Mrs. Resnick was still the chief marketing person at POM. (L. Resnick, Tr. 289), and this was also her role in 2010 and 2009. (CX1375 (L. Resnick, Tropicana Dep. at 24); CX1362 (L. Resnick, Coke Dep. at 47, 77-78)).
32. Mrs. Resnick commissioned, helped develop, and used consumer and marketing research for POM's business. (CX1359 (L. Resnick, Dep. at 76-78)).
33. Mrs. Resnick has worked with POM's marketing department and Roll's advertising agency, Fire Station, along with scientists and public relations personnel, to implement creative concepts for POM marketing pieces and campaigns. It was a team approach. (L. Resnick, Tr. 87-89; *see also* CX0409; CX0410; CX1359 (S. Resnick, Dep. at 70)).
34. Mrs. Resnick has the "final say" with respect to POM's marketing and advertising content and concepts. (CX1368

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at 0003 (L. Resnick, Welch's Dep. at 9); L. Resnick, Tr. 93).

35. According to Mrs. Resnick, when it comes to marketing and creative issues, everyone has a "dotted line" to her, meaning she is in a position of authority even though she may not have day-to-day responsibilities for each employee. (CX1375 (L. Resnick, Tropicana Dep. at 24); L. Resnick, Tr. 287-88).

#### **4. Respondent Matthew Tupper**

36. Respondent Matthew Tupper ("Mr. Tupper") joined Roll in May 2001 as Vice President of strategy. (JX0003 ¶ B.5).
37. Mr. Tupper joined POM as a full-time employee in 2003, as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).
38. In 2005, his title at POM changed to President, but his responsibilities did not change from those in his position as Chief Operating Officer. (JX0001 ¶¶ 12, 18; Tupper, Tr. 886-87).
39. Mrs. Resnick considers Mr. Tupper as having been her "partner at POM since 2003." (CX0001 at 0037; L. Resnick, Tr. 230).
40. Mr. Tupper retired from POM at the end of the 2011. (Tupper, Tr. 2973).
41. Mr. Tupper will not be working for Roll Global or any other company owned by the Resnicks after his retirement from POM. (Tupper, Tr. 2974).
42. In his capacity as an officer of POM, Mr. Tupper, together with others, formulated, directed, or controlled the policies, acts, or practices of POM. (Complaint ¶ 5, Answer ¶ 5).
43. Mr. Tupper reported to the Resnicks. Mr. Tupper reported directly to Mr. Resnick. Mr. Tupper had a "dotted line"

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reporting to Mrs. Resnick. (CX1367 at 0014 (S. Resnick, Welch Dep. at 53); CX1364 at 0007, 0027 (Tupper, Coke Dep. at 27-28, 107); CX1375 (L. Resnick, Tropicana Dep. at 23-24)).

44. Mr. Tupper was responsible for managing the day-to-day affairs of POM, which employs roughly 350 people worldwide, including management of the day-to-day operations of the POM marketing team. (JX0003 ¶ B.6; Tupper, Tr. 2974; CX1363 at 0011 (S. Resnick, Coke Dep. at 42)).
45. Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. (Tupper, Tr. 903-04, 912-13; CX0606 at 0003).
46. Mr. Tupper's activities included hiring and firing POM employees, including the head of POM's marketing department, on his own, or, depending on the situation, in consultation with either Mr. or Mrs. Resnick. (Tupper, Tr. 902-03; *see also* CX1360 (S. Resnick, Dep. at 22-23); CX1359 (L. Resnick, Dep. at 41, 45); CX1353 (Tupper, Dep. at 24-25)).
47. At POM, nine or ten people have directly reported to Mr. Tupper, including the Vice President of Marketing (including former Senior Vice President of Marketing, Diane Kuyoomjian, ("Ms. Kuyoomjian"), the Vice President of Clinical Development (currently Bradley Gillespie ("Dr. Gillespie")), and the head of the Operations Department. (Tupper, Tr. 888-89, 2974; CX1353 (Tupper, Dep. at 24-25); CX1378 at 0008 (Kuyoomjian, Ocean Spray Dep. at 27)).
48. Mark Dreher, Ph.D. ("Dr. Dreher"), POM's former Vice President of Scientific and Regulatory Affairs, reported to Mr. Tupper. (Dreher, Tr. 527, 529; L. Resnick, Tr. 249).
49. Fiona Posell ("Ms. Posell"), former Vice President of Corporate Communications at Roll and POM, reported to Mr. Tupper and Mrs. Resnick. (Posell, Tr. 299, 321, 325).

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50. The head of POM's Marketing department reported to Mr. Tupper, as did the departments with sales responsibilities. (Tupper, Tr. 891).
51. Mr. Tupper's responsibilities within POM included implementing POM's direction with regard to health benefit advertising and the use of science in connection with the advertising. With respect to this advertising, Mr. Tupper was the "connecting piece" between the marketing vision and the communication of the science. It was Mr. Tupper's job to work with all parts of the POM team, including marketing, scientists, and lawyers, to make sure that the advertising was done in "the right way." (Tupper, Tr. 2975-76).
52. One of Mr. Tupper's responsibilities was to be a liaison between the marketing staff of POM and the researchers in studies sponsored by POM, to help the marketing team "wade through" the science, of which Mr. Tupper had some understanding. (L. Resnick, Tr. 261; Tupper, Tr. 899, 914).
53. Mr. Tupper had a significant degree of involvement in the research aspects of POM's business, and his responsibilities included discussing which research areas are appropriate for funding, participating in the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. (Tupper, Tr. 895-96, 906; *see also* CX0770; CX0779; CX0800; CX0919; CX0920 (showing Tupper's participation in managing POM's medical and scientific research)).

**B. The POM Products****1. Description of the POM Products**

54. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed products to the public, including POM Juice, POMx Pills, and POMx Liquid. (Answer ¶ 6; Complaint ¶ 6).

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55. The Complaint in this case challenges Respondents' advertisements with respect to three products: POM Juice, POMx Pills, and POMx Liquid. (Complaint ¶¶ 6, 9, 10).
56. Respondents also manufacture, advertise, and sell other products containing pomegranate, including various POM Juice blends, Lite POM Juice, POMx bars, POMx iced tea and iced coffee, and a POMx sports recovery beverage. (JX0003 ¶ B.8).

**a. POM Juice**

57. POM Juice is a 100% juice product derived from whole pomegranate fruits. (PX0353 (Heber, Dep. at 124); CX1362 (L. Resnick, Dep. at 85-86); CX1363 (S. Resnick, Dep. at 46-47)).
58. POM Juice is produced by pressing whole pomegranates, including the arils and peels. (CX0967 at 0014, *in camera*). The subsequent cloudy juice is filtered and/or enzyme treated before concentrating. (CX0537 at 0003).
59. The concentrate from POM Juice is stored in 52-gallon drums. (CX1369 (Tupper, Welch Dep. at 22)).
60. To make it ready for sale, the concentrate is reconstituted with water to make "100 percent pomegranate juice," pasteurized, and bottled for sale. (JX0003 ¶ B.9; CX1369 (Tupper, Welch Dep. at 19-23)).
61. The final POM Juice product contains "85.4% water, 10.6% total sugars, 1.4% pectin, 0.2-1.0% polyphenols, and organic acids." (CX0537 at 0003).
62. POM Juice does not contain dietary fiber or vitamin C. (CX0537 at 0014; CX0716 at 0041).
63. POM Juice contains a variety of polyphenols, including 80 to 90% ellagitannins and gallotannins, 8 to 15% anthocyanins and 2 to 5% ellagic acid. (CX0163 at 0007).
64. A single serving of POM Juice is eight ounces. (CX1379 at 0008, *in camera*). A serving of POM Juice provides

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140 calories and 34 grams of sugar. (CX1306 (Weidner, Decl. at 0020)).

65. POM Juice is sold in the refrigerated produce section of the grocery store. (CX1367 (S. Resnick, Welch Dep. at 122); CX1374 (Tupper, Ocean Spray Dep. at 56-57)). Consumers must go to the fresh produce aisle of a store to purchase any POM Juice product. (CX1362 (L. Resnick, Coke Dep. at 135-36)).
66. POM Juice is not sold in the “drug” or “over the counter” section of any establishment. (CX1362 (L. Resnick, Coke Dep. at 135-36); CX1367 (S. Resnick, Welch Dep. at 122; CX1374 (Tupper, Ocean Spray Dep. at 56-57)).

**b. POMx Liquid**

67. POMx Liquid “is the product of the pressed whole fruit after most of the juice is extracted and the polyphenols are concentrated by filtering and concentrating using juice processing.” (CX0096 at 0014, *in camera*).
68. Consumers can purchase POMx Liquid via the company website or through a telephone call center. (JX0003 ¶ B.14).
69. POM’s website states that the company’s recommended daily serving of POMx Liquid is one teaspoon and recommends consumers take one teaspoon of POMx Liquid daily. (CX1379 at 0008-09, *in camera*).

**c. POMx Pills**

70. POMx is an extract from the pomegranate, made through a process by which POMx Liquid is first derived from the whole fruit, and then POMx is extracted from the POMx Liquid. (CX1363 (S. Resnick, Dep. at 46-47)).
71. POMx was created to use up the “tens of thousands of tons of discarded, mashed-up pomegranates left over from the juicing process.” (CX0001 at 0013; CX0967 at 0014).

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72. Consumers can purchase POMx Pills via the company website or through a telephone call center. POMx Pills also are available through a few U.S. Retail outlets that sell dietary supplement products. (JX0003 ¶ B.14).
73. Pomegranate extracts, because of the production process, contain no anthocyanins. (CX1352 (Heber, Dep. at 358); *see also* CX1258 at 0003 (POMx has only “trace” anthocyanins)).
74. Mrs. Resnick stated “[m]y marketing team and I were eager to learn if we could produce a pomegranate extract that could deliver the power of eight ounces of POM juice in a capsule.” (CX0001 at 00013).
75. POMx caters to those consumers who want the benefits of the juice, without the calories or sugar to get, “The Power of POM, in one little pill.” (CX0169 at 0001).
76. POM’s website recommends consumers take one POMx Pill daily, preferably with eight ounces of water and food. (CX1379 at 0008, *in camera*).

**2. Safety of the POM Products**

77. Pomegranates have been safely consumed as nutritious food by humans for thousands of years. (PX0192 (Heber Expert Report at 0013, 0018)).
78. Pomegranate juice and pomegranate extract have a “high degree of safety.” (PX0192 (Heber Expert Report at 0013)).
79. Pomegranate juice is safe for human consumption if consumed within the nutritional range. (PX0192 (Heber Expert Report at 0018)).
80. POMx is safe for human consumption if consumed within the nutritional range. (PX0192 (Heber Expert Report at 0018)).
81. Unlike some drugs, pomegranate juice has no adverse side effects. (PX0192 (Heber Expert Report at 0042)).

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82. The FDA maintains a list of substances that are identified by the FDA as generally regarded as safe (“GRAS”). (Heber, Tr. 2008-09).
83. Before a substance can be GRAS identified, the FDA reviews the scientific literature and the traditional intake of the substance. (Heber, Tr. 2009).
84. Both pomegranate juice and pomegranate extract are GRAS identified. (Heber, Tr. 2009, 2032; 21 C.F.R. § 182.20).
85. There have been no reported cases of persons being harmed by eating a pomegranate or drinking pomegranate juice. (Heber, Tr. 1947-48).
86. There have been no reported cases of toxicity where pomegranates or pomegranate juice have been consumed in nutritional amounts. (Heber, Tr. 1948).
87. In all the studies that have been conducted on pomegranate juice and pomegranate extract, there have never been any reports of any material harm caused to the subjects by consuming the products. (Heber, Tr. 2007-08; PX0353 (Heber, Dep. at 115)).
88. None of the clinical studies conducted on pomegranate juice and pomegranate extract found any serious risk to human health from consuming the products. (PX0192 (Heber Expert Report at 0018)).
89. Pomegranate juice is a food. (PX0192 (Heber Expert Report at 0011)).
90. Pomegranate extract is a food-based dietary supplement that has substances found in pomegranate juice at levels within the nutritional range. (PX0192 (Heber Expert Report at 0011)).
91. In 2007, in a peer-reviewed study titled, “*Pomegranate Juice Does Not Impair Clearance of Oral or Intravenous Midazolam, a Probe for Cytochrome P450-3A Activity*:

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*Comparison With Grapefruit Juice,”* by Farkas D, Oleson L, Zhao Y, Harmatz, J, Zinny M, Court M, and Greenblatt D (J Clin. Pharmacol 2007; 47:286-294), Dr. Greenblatt and his colleagues examined the effect of POM Juice and grapefruit juice on inhibiting enteric cytochrome P450-3A activity in healthy human volunteers. The study showed POM Juice did not cause drug interaction in humans. (PX0136 at 0008).

92. In 2007, in a peer-reviewed study titled, “*Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals With Increased Waist Size,*” by Heber D, Seeram N, Wyatt H, Henning S, Zhang Y, Ogden L, Dreher M, and Hill J (J Agric. Food Chem. 2007; 55:-10050-10054), Dr. Heber and his colleagues examined the safety in humans of consuming POMx Pills. The study reported: Although there were 11 minor adverse events reported by 9 of the 64 subjects, none of these minor adverse effects were deemed to be related to POMx Pills. The study further reported: no adverse events related to the POMx Pill consumption or changes in blood count, serum chemistry, or urinalysis were observed in the subjects. (PX0139 at 0001, 0003, 0004).
93. Complaint Counsel’s expert, Dr. Sacks, testified that the issue of the safety of the POM Products was not within the scope of his assignment in this case, that his expert report contains no opinions on the safety of the POM Products, and that he has “no opinion about whether [the POM Products are] safe or not.” (PX0361 (Sacks, Dep. at 74, 76); CX1291 (Sacks Expert Report at 0008-09)).
94. Complaint Counsel’s expert, Professor Meir Stampfer, admitted that there are no safety concerns with consuming pomegranate juice apart from “the usual harm that comes with fruit juice, sugary beverages . . . but that is not specific to pomegranate juice.” (PX0362 (Stampfer, Dep. at 195-96)).

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**3. Sales of the POM Products**

95. Respondents began selling POM Juice in 2002. POM Juice is sold in supermarkets nationally and is a major seller in the premium juice category. (CX0967 at 0014, *in camera*).
96. POM's U.S. Sales of 100% Juice, from September 2002 to November 2010, totaled approximately \$247,739,776. (JX0001 ¶ 15).
97. For the 52 weeks ending July 20, 2008, the weighted average base price per unit for POM Juice was \$2.93 for an 8-ounce bottle or \$4.29 for a 16-ounce bottle. (CX0221 at 0007).
98. In 2007, POM began selling POMx Pills and POMx Liquid. (CX1347 (Glovsky, Dep. at 29-30)).
99. POM's Total POMx Pill Gross Revenue, from May 2007 to November 2010, totaled approximately \$4,017,681. (JX0001 ¶ 16).
100. POM's Total POMx Liquid Gross Revenue, from May 2007 to November 2010, totaled approximately \$209,820. (JX0001 ¶ 17).
101. If bought directly from POM's website, POM charges \$29.95 (excluding shipping) for a 30-count bottle of POMx Pills and \$77.85 (excluding shipping) for a 90-count bottle of POMx Pills. (CX1379 at 0009-10, *in camera*).
102. If bought directly from POM's website, POM charges \$29.95 (excluding shipping) for a five-ounce bottle of POMx Liquid. (CX1379 at 0010-11, *in camera*).

**C. Background Facts****1. History of POM and science program****a. Overview**

103. In 1987, the Resnicks acquired farmland containing over 100 acres of mature pomegranate trees. (CX0105 at 0002).
104. Between 1989 and 2001, Paramount Farming Company, one of the Roll affiliated companies (F. 11), continued to acquire and plant additional pomegranate acreage, bringing the total to 6,000 acres by 2001. (CX0105 at 0002-08).
105. In 1998, the Resnicks began collaborating with researchers to determine whether, and to what extent, there was any truth to the folklore surrounding the health properties of the pomegranate. (L. Resnick, Tr. 150; CX1363 at 0016-17 (S. Resnick, Coke Dep. at 61-66); CX0105 at 0003; CX1362 at 0018 (L. Resnick, Coke Dep. at 71-72); S. Resnick, Tr. 1853-56); CX1359 (L. Resnick, Dep. at 82); CX1360 (S. Resnick, Dep. at 84-85); CX1372 (S. Resnick, Tropicana Dep. at 32-33; CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram, Dep. at 4); CX1367 at 0004(S. Resnick, Welch's Dep. at 15); PX0004).
106. In 2000, the Resnicks formed Paramount Juice Company and, shortly thereafter, in 2001, changed the name to POM Wonderful LLC. (CX1418 at 0001-03).
107. By spring 2001, the yield from the Resnicks' 6,000 acres of pomegranates "ha[d] progressed exponentially . . . making it essential to immediately begin a marketing program for the POM Juice product." (CX0004 at 0001).
108. POM began bottling, selling, and marketing POM Juice on a regional basis in the fall of 2002, and in national markets in 2003. (CX1353 (Tupper, Dep. at 41-42); CX1395 at 0003).

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109. Currently, the Resnicks own approximately 18,000 acres of pomegranate orchards and are the largest growers of pomegranates in the United States. (CX1374 (Tupper, Ocean Spray Dep. at 29-30)).
110. According to Mrs. Resnick, when Respondents went about creating a market for pomegranate juice, “only about one in ten Americans said they were familiar with pomegranates, and fewer than half of that group said they had eaten one in the past year.” (PX0370 at 2).
111. According to Mr. Resnick, a primary part of POM’s messaging to consumers is about the health benefits of its products. (S. Resnick, Tr. 1653; CX1372 (S. Resnick, Tropicana Dep. at 31-32)).
112. Mrs. Resnick has stated her belief that POM juice is “health in a bottle” and that this is part of POM Juice’s unique selling proposition. (CX0001 at 0006; L. Resnick, Tr. 77-78).
113. POM uses the results of studies it has sponsored for marketing purposes, as part of “[POM’s] unique selling proposition.” At least part of the reason for sponsoring studies was for marketing and public relations purposes. (CX1375 (L. Resnick, Tropicana Dep. at 87); CX1372 (S. Resnick, Tropicana Dep. at 74-75; CX0003 at 0001)).

**b. Early research**

114. POM began its pomegranate research under the direction of POM’s former Medical Director, and the Resnicks’ personal friend and family physician, Dr. Leslie Dornfeld (“Dr. Dornfeld”), a professor of Internal Medicine at the University of California, Los Angeles (UCLA). (L. Resnick, Tr. 150; CX1350 (Liker, Dep. at 29); CX0105 at 0003).
115. In 1998, Respondents and Dr. Dornfeld collaborated with Dr. Michael Aviram, the Head of the Technion Lipid Research Laboratory at the Rambam Medical Center in Haifa, Israel, known for his work exploring the antioxidant

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properties of red wine, to understand the antioxidant effect and potential cardiovascular benefits of pomegranate juice. (CX1374 (Tupper, Ocean Spray Dep. at 87); CX1358 (Aviram, Dep. at 4); CX1363 at 0016-17 (S. Resnick, Coke Dep. at 61-66); CX1367 at 0004 (S. Resnick, Welch Dep. at 15); CX0001 at 0010-11; L. Resnick, Tr. 150; PX0004). Dr. Aviram's initial research paper showed that pomegranates possess antioxidative and antiatherosclerotic properties. (CX1358 (Aviram, Dep. at 7); PX0004).

116. Dr. Dornfeld initially oversaw the development of POM's research program until he was no longer able to do so for health-related reasons. In 2001, Dr. Dornfeld recruited Dr. Harley Liker ("Dr. Liker"), a physician and faculty member at UCLA, to be his successor as POM's Medical Director. Dr. Dornfeld and Dr. Liker worked together until 2002, when Dr. Liker became POM's Medical Director. (Liker, Tr. 1873, 1877; CX1350 (Liker, Dep. at 15, 27-28); S. Resnick, Tr. 1858).
117. Dr. Liker also became the Resnicks' personal physician and company wellness coordinator and wellness director in 2001. (Liker, Tr. 1876-77).
118. Respondents hired Risa Schulman, who was POM's Director of Research and Development from approximately 2002 to 2005. POM subsequently hired Dr. Mark Dreher ("Dr. Dreher") in 2005 as Vice President of Scientific and Regulatory Affairs. (CX0105 at 0016; Dreher, Tr. 527).
119. After identifying an area of scientific interest, Dr. Liker works with Mr. Tupper and Mr. Resnick to determine the leading experts in that scientific field and contacts them to conduct research for Respondents. (Liker, Tr. 1878-80).
120. Dr. Dreher's duties primarily entailed exploratory research, which was looking at new products such as POMx and developing clinical and basic science for new applications for POM products. "Basic science" refers to test-tube, animal studies, and preclinical research. Dr.

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Dreher also arranged for contracts and funding of research with universities and contract research organizations, provided the materials for testing, and helped to organize the objectives for the studies and for carrying out the studies. (Dreher, Tr. 528).

121. Dr. Dreher reported to Mr. Tupper and also reported, to a certain extent, to Dr. Liker, to help Dr. Liker manage the logistics associated with some of the larger studies. Dr. Dreher and Dr. Liker met weekly for the first two-and-a-half to three years Dr. Dreher was at POM, and then less frequently in the last year of his employment. (Dreher, Tr. 529-30).
122. After Dr. Dreher left, POM hired Dr. Bradley Gillespie in 2009 as its Vice President of Clinical Development. (CX1349 (Gillespie, Dep. at 10-11); CX1353 (Tupper, Dep. at 28)).
123. POM has also hired scientific consultants, including Dr. Aviram and Dr. David Heber. (CX1380 at 0005; CX1349 (Gillespie, Dep. at 264-65); Heber, Tr. 1941; S. Resnick, Tr. 1637).

**c. Relevant studies**

124. Respondents' studies have explored the effect of POM products on many different areas of health, including the cardiovascular system, immunity, athletic performance, erectile health, prostate cancer, skin care, cognitive function, dental health, and urinary tract health. (CX1353 (Tupper, Dep. at 48-52); Tupper, Tr. 2979-81).
125. Respondents' research efforts branch in various directions in order to examine the role that oxidation and inflammation play in many seemingly unrelated diseases and conditions. (CX1353 (Tupper, Dep. at 47-49); Tupper, Tr. 2979-81; Heber, Tr. 1957, 2112-13, 2185).
126. The results of five POM-sponsored studies have been referred to in the Challenged Advertisements. The studies are:

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- a. A study by Dr. Aviram, published in 2001 titled, *Pomegranate Juice Consumption Inhibits Serum Angiotensin Converting Enzyme Activity and Reduces Systolic Blood Pressure* (“Aviram ACE/BP Study”). The Aviram ACE/BP Study, conducted on ten patients, examined the effect of POM Juice consumption on angiotensin converting enzyme (“ACE”). (CX0542; *see e.g.*, CX0013 at 0003; CX0031; CX0473 (Compl. Ex. E-2 at 00:30, 1:25)).
- b. A study by Dr. Aviram, published in 2004 titled, *Pomegranate Juice Consumption for 3 Years by Patients with Carotid Artery Stenosis Reduces Common Carotid Intima-Media Thickness, Blood Pressure and LDL Oxidation* (“Aviram CIMT/BP Study”). The Aviram CIMT/BP Study, conducted on 19 patients, examined the effect of POM Juice consumption on carotid intima-media thickness (“CIMT”). (CX0611; *see, e.g.*, CX0029; CX0280 CX0328/CX0331/CX0337; CX0473 (Compl. Ex. E-2 at 00:24)).
- c. A study by Dr. Dean Ornish, published in 2005 titled, *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease* (“Ornish MP Study”). The Ornish MP Study, examined the effect of POM Juice consumption on 45 patients with coronary heart disease. (CX1198; *see, e.g.*, CX0351; CX0355; CX0473 (Compl. Ex. E-2 at 00:30)).
- d. A study by Dr. Allan Pantuck, published in 2006 titled, *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer* (“Pantuck Study”). The Pantuck Study examined the effect of POM Juice consumption on 46 men previously treated for prostate cancer by radiation therapy or surgery. (CX0815; *see, e.g.*, CX0351; CX0355; CX0314 at 0004; CX0372 at

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0002; CX0379 at 0002; CX0380 at 0002; CX0473 (Compl. Ex. E-2 at 00:24)).

- e. A Study by Dr. C.P. Forest and Dr. H. Padma-Nathan, published in 2007 titled, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* (“Forest/Padma Nathan Study”). The Forest Erectile Dysfunction Study (2007) examined the effect of POM Juice consumption on 53 men with mild to moderate erectile dysfunction. (CX1193; see, e.g., CX0351; CX0355; CX0473 (Compl. Ex. E-2 at 00:24)).
127. POM also sponsored a study by Dr. Michael Davidson titled, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, published in 2009 (“Davidson CIMT Study”). The Davidson CIMT Study (2009) tested the effect of POM Juice on CIMT progression rates in 289 subjects at moderate risk for moderate coronary heart disease. (CX1065).
  128. In over a decade, Respondents sponsored over 100 studies at 44 different institutions. (Liker, Tr. 1887-88).
  129. Of the studies POM had conducted as of 2010, approximately 40 percent were performed at UCLA or by Dr. Aviram at the Technion Faculty of Medicine. (See CX1241; CX1360 (S. Resnick, Dep. at 113-17)).
  130. More than 70 of the studies sponsored by the Respondents have been published in peer-reviewed scientific journals. Seventeen of these published studies are human clinical trials. (Liker, Tr. 1888; CX0611; CX0908; PX0004; PX0005; PX0014; PX0060; PX0061; PX0020; PX0021; PX0023; PX0073; PX0074; PX0075; PX0127; PX0136; PX0139; PX0146 (Trombold JR, Barnes JN, Critchley L, and Coyle EF, *Ellagitannin Consumption Improves*

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*Strength Recovery 2-3 d after Eccentric Exercise, Med. Sci. Sports Exerc.*, Vol. 42, No. 3, pp. 493-98, 2010)).

131. Respondents continue to sponsor medical research to determine the benefits of their pomegranate products. Respondents have invested over 35 million dollars in their research program. (S. Resnick, Tr. 1752, 1861-64; CX1363 (S. Resnick, Coke Dep. at 74)).
132. Respondents currently have ongoing research in the areas of cardiovascular health and prostate health. (Tupper, Tr. 984-85, 994; PX0014; PX0023; PX0060; PX0061).

**2. Advertising process****a. Overview**

133. Roll has a full-service internal advertising agency called Fire Station. (JX0001 ¶ 18; L. Resnick, Tr. 88-89; Leow, Tr. 493; Perdigao, Tr. 593-94).
134. George Michael Perdigao (“Mr. Perdigao”) is the president of Roll’s advertising agency, Fire Station, and Roll’s corporate communications department, and reports to the Resnicks. (CX1376 (S. Resnick, OS Dep. at 145); JX0001 ¶ 18; Perdigao, Tr. 590, 594).
135. Elizabeth Leow Hendry (“Ms. Leow”) has been a creative director at Roll since 2005, with POM as one of her clients. Ms. Leow is currently the creative director for Fire Station, one of Roll’s companies. She has continued to work on POM’s advertising. (Leow, Tr. 415; CX1356 (Leow, Dep. at 16-18, 22)).
136. Prior to Fire Station’s creation in approximately January 2008, Roll provided advertising services to its affiliated companies through advertising personnel employed by Teleflora, another Roll affiliate. (F. 11; Perdigao, Tr. 592).

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137. This group of advertising professionals at Teleflora and later Fire Station has also been known as “The Agency.” (Perdigao, Tr. 592; L. Resnick, Tr. 88-89).
138. POM uses Fire Station for all or virtually all of its domestic advertisement agency needs. (Tupper, Tr. 920-21).
139. Generally, Fire Station would be responsible for coming up with specific creative ideas or media plans, and POM’s marketing department would help guide the process and provide input. (CX1357 (Kuyoomjian, Dep. at 88-89)).
140. The creation of POM marketing and advertising was a collaborative effort between Fire Station and POM that entailed coming up with ideas for print, outdoor, or television campaigns, as well as writing copy, creating graphics, and putting the ideas together for a final execution. (Leow, Tr. 420-21; Tupper, Tr. 920).

**b. Development of advertising**

141. Mrs. Resnick held regular creative meetings with the senior in-house representatives of POM and Roll, including representatives of POM’s marketing department (“POM Marketing”), Roll’s public relations department, and Roll’s advertising agency, Fire Station. Staff members at POM and Roll informally refer to these meetings with Mrs. Resnick as “LRR Meetings.” (JX0003 ¶ A.12; L. Resnick, Tr. 87-88, 92)).
142. In addition to Mrs. Resnick, Mr. Tupper and employees from POM’s marketing and scientific departments, Fire Station employees and someone from Roll’s Corporate Communications department regularly attend LRR meetings. (Rushton, Tr. 1366; Perdigao, Tr. 624-25; Tupper, Tr. 929-30; L. Resnick, Tr. 249; CX1351 (McLaws, Dep. at 33-34)).
143. At LRR Meetings and during other interactions with POM Marketing and Fire Station, Mrs. Resnick would approve a general direction for POM’s advertising and also approved

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the lion's share of POM's advertising concepts. (CX1362 at 0008 (L. Resnick, Coke Dep. at 30-31); *see also* Perdigao, Tr. 604, 628 (agreeing that it is fair to say that Mrs. Resnick has final authority on advertising campaigns); Rushton, Tr. 1369-71 L. Resnick, Tr. 99-100, 186-87; Leow, Tr. 470; CX0023 at 0001 (stating that "LRR is going to take a more active role in writing copy[]" and that "[i]f [Mrs. Resnick] writes it, it will be approved"); CX1351 (McLaws, Dep. at 23-24) (stating that the "decision to either move forward or make adjustments [on marketing on advertising] came from Lynda"))).

144. Mr. Tupper attended most of the LRR Meetings, at which the highest-level executives involved in marketing discussed how to better market POM's products. (Perdigao, Tr. 624-25).

**c. Creative briefs**

145. The first step in the creative process for POM advertising is a "creative brief," prepared by POM's marketing department and provided to Fire Station. (L. Resnick, Tr. 123; Loew, Tr. 451; CX1368 at 0024 (L. Resnick, Welch Dep. at 95)).
146. The creative brief was the document used to formally initiate an advertising project. (Perdigao, Tr. 616-17).
147. A creative brief is an outline of the assignment, with the purpose of providing an overview of the assignment. A creative brief might include information on the key message(s) to be conveyed, a suggested target audience for the advertisement, demographics, and media. (Leow, Tr. 451-52; L. Resnick, Tr. 123; *see* CX0409 (creative briefs ranging from January 2004 to October 2009); *see also* CX0129 to CX0131 (2007 creative briefs for POMx print advertisements)).
148. The creative brief outline addresses matters such as "Objective," "Target Audience," "Insights," "Main

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Message,” “Benefit” or “Benefits,” and “Tonality,” among other matters. (CX0409).

149. Creative briefs are developed for new marketing campaigns that POM undertakes. (Tupper, Tr. 921).
150. POM’s online marketing department prepares creative briefs for online components of POM’s marketing initiatives. Such briefs are then submitted to Fire Station. (Rushton, Tr. 1353-54, 1391-92).
151. A creative brief is a concept document, to give the advertising agency (Fire Station) insight on how to start a campaign. The substance of a creative brief may or may not ultimately be reflected in an advertisement. (Tupper, Tr. 921; Leow, Tr. 484-85).
152. By their nature, creative briefs were brief and general, and there would be one or more follow-up meetings to discuss the project. (Rushton, Tr. 1396; Perdigao, Tr. 618).
153. The creative process is a collaborative process in which participants share and mold concepts, thoughts and ideas. “It’s not like . . . you get a creative brief, a guy goes in a room, and then comes out with an ad. It’s not quite that simple.” (Perdigao, Tr. 621-22).
154. Mr. Tupper participated in discussions with the marketing department about individual parts or elements of creative briefs. (Tupper, Tr. 924).
155. Once the creative brief was received by Fire Station, it would be assigned to appropriate personnel at the agency, depending on the project. (Leow, Tr. 452-53).
156. The creative team(s) at Fire Station would then work together to start creating advertisement concepts, which would be reviewed first by Ms. Leow, then by Mr. Perdigao, and finally by POM Marketing. It is a fluid process, including multiple revisions. Depending on the assignment, the concepts were sometimes also reviewed by Mr. Tupper. These reviews at the concept stage

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involved the general creative direction, look, tone, and idea of the advertising, rather than body copy. (Leow, Tr. 457-60).

157. Advertising concepts would include the graphics and headlines. A headline is the main message of an advertisement and usually appears in larger type. Body copy is the smaller print usually appearing at the bottom of an advertisement. (Leow, Tr. 462-63, 467).
158. After the creative concepts were approved, the creative team at Fire Station would draft body copy with direction from POM Marketing, using the creative brief as an outline and including any additional input marketing might add. (Leow, Tr. 462-64).
159. There are no scientists or technical writers on Fire Station's staff. Therefore, if the body copy of an advertisement were to contain information on studies and POM Marketing wanted specific wording, it would be provided by POM Marketing. (Leow, Tr. 464-65).
160. After the copy of an advertisement was drafted, it would go to the head of marketing for approval, and sometimes, depending on the project, to Mr. Tupper and Mrs. Resnick for approval. (Leow, Tr. 463-64; L. Resnick, Tr. 187-188).
161. Once the concepts for a big advertising campaign were approved, they would ultimately go to Mrs. Resnick for approval. Fire Station presented advertising concepts to Mrs. Resnick during LRR Meetings. (Leow, Tr. 461; Perdigao, Tr. 623-25; Rushton, Tr. 1358).
162. In addition to approving the body copy, POM Marketing would also thereafter provide final review of the completed advertisement, and depending on the project, Mr. Tupper might approve it as well. (Leow, Tr. 464-66).
163. After proofreading by Fire Station personnel, POM's advertisement would be sent to Fire Station's production department to create the "mechanical" – the completed

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advertisement in final electronic form that is ready to be sent to publications. (Leow, Tr. 466-67).

164. The process POM uses to connect the science to the advertising includes a “checklist of individuals who need to review and sign off on those ads, ultimately culminating in the legal review.” (Tupper, Tr. 2977-78).
165. POM approves final executions of advertisements created by Fire Station before dissemination. (Leow, Tr. 466; Perdigao, Tr. 637).
166. Mrs. Resnick would sometimes review finished advertisements. (Leow, Tr. 466).
167. Mrs. Resnick’s participation in the creative process included briefing POM Marketing, as well as meeting with POM and Fire Station personnel to review proposed creative pieces developed by Fire Station. (CX1368 at 0003 (L. Resnick, Welch Dep. at 9-10)).
168. Mrs. Resnick has reviewed and provided detailed edits and suggestions for POMx Pill advertisements (CX0126 at 0002) and the POM Wonderful website (CX0024 at 0009-38); approved designs and headlines for advertisements in various media (CX0247 at 0002; CX0248 at 0002); and suggested and reviewed concepts for new advertisements (CX0266 at 0002-03; CX0320 at 0002).

### **3. Target audience for POM Products advertising**

169. The POM Juice print advertisements at issue in this case were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: the *Chicago Tribune* (CX0016), *Prevention* (CX0029, CX0034, CX0260), *Details* (CX0031), *Rolling Stone* (CX0033, CX0036), *Health* (CX0103, CX0251), *InStyle* (CX0109), *Town and Country* (CX0109) *Men’s Health* (CX0192, CX0260), and *Men’s Fitness* (CX0274). See also CX0474; CX0371 (declarations describing capture of print advertisements and dissemination information).

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170. The POMx Pills print advertisements at issue in this case were disseminated in a wide variety of locally and nationally distributed publications, including but not limited to: *Fortune* (CX0120), the *New York Times* (CX0169, CX0337), *Discover* (CX0122), *Men's Health* (CX0348), *Popular Science* (CX0348), *Time* (CX0350) and *Playboy* (CX0355, CX0470 at 0002; Leow Tr. 496).
171. The POM Products have been advertised in print advertisements in magazines, freestanding inserts ("FSIs") in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors' offices, advertising on prescription drug bags, Internet websites, online banner advertisements, medical outreach, radio, television, and press releases. (L. Resnick, Tr. 81-82 (radio), 186 (FSIs); Leow, Tr. 426-28, 457 (out of home, health clubs, banner ads, television); Perdigao, Tr. 597-98 (press releases), 608-09 (prescription drug bags); Tupper, Tr. 927 (magazine wraps); CX1375 (L. Resnick, Trop. Dep. at 167 (medical outreach)); CX1357 (Kuyoomjian, Dep. at 85-86 (posters in doctors' offices)), 122 (radio)).
172. POM placed advertising in such magazines as *Health Magazine*, *Men's Health*, and *Men's Fitness*, because these publications are geared toward the health-conscious consumer. (Leow, Tr. 425-26).
173. POM has purchased online banner advertisements on websites, including specific websites with audiences interested in personal health, fitness, and physical well-being such as *Men's Health*, *ESPN*, *Livestrong*, and *WebMD*. (Rushton, Tr. 1397-98; CX0463; CX0466; CX0468; Leow, Tr. 428-29).
174. Current POM Juice buyers tend to be in their forties, possibly older, and are sophisticated to some extent about their health. (L. Resnick, Tr. 127-28).
175. For purposes of a creative brief (*see* F. 145-151) "target audience" refers to the audience to whom the advertisement would appeal. (Leow, Tr. 451-52).

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176. Seven creative briefs for POM Juice advertising projects, dating between January 2004 and July 2006, described the “target audience” for the subject advertisement as: “Hip Gen X 25-39. Skews female (60/40) likely to be affluent, professional, college grads who are very health-conscious (hypochondriacs) and live in urban areas. Either single or married without kids.” (CX409 at 0001; *see also* CX0409 at 0003, 0005, 0006, 0008, 0010, and 0022). In July 2006, this description was prefaced with the comment, “same as general POM consumer.” (CX409 at 0022)
177. Two creative briefs dated June 28, 2006 and July 13, 2006, which stated that they were to be used for all future POMx Pill projects, identified the target audience for POMx Pills as “Age and Gender: 25-64 year old men and women (50/50 split) Psychographic: (1) Core POM Consumer, (2) Consumer who won’t drink the juice or tea but who is seeking a natural cure for current ailments or to maintain health and prevent future ailments[.]” These creative briefs further noted, under “tonality,” in part, “catchy headlines but serious copy that reflects the fact that antioxidants are important for health. The pill form is more medicinal by nature and attracts consumers that are looking for health benefits but won’t drink the juice or tea.” (CX0409 at 0016, 0018).
178. A creative brief for POMx Pills, dated September 1, 2006, referred to “a handful of different creative approaches targeting different consumers that include men, seniors and young health conscious females.” Under target consumer audience,” this creative brief stated: “Age & Gender: Start with men 40+, HH income \$75K+, primarily men who are scared to get prostate cancer . . . Two other targets based on this plan include seniors 55+ who are heavy supplement users (AARP & Readers’ Digest) and young health conscious women (Oprah, More, Health) – both of whom will benefit from the antioxidants (cardiovascular, anti-aging, etc.)” (CX0409 at 0023).
179. In a creative brief for the “Health Benefits” section of the POM Wonderful website, from June 2008, the “target audience” was described as “General population (35+,”

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60% Female): Consumers . . . Who are looking for general information about Pomegranate Health, Antioxidant, Polyphenol or related topics and want to learn more . . . or find out the truth about Pomegranates[,] Who have seen articles about pomegranates or antioxidants[,] With an ailment that pomegranates have been rumored to help[.]” The “target audience” for the website was also identified to include “Health Care Professionals” including “Primary care physicians[,] Urologists[,] Dieticians[,] Nutritionalists[,] Other healthcare industry professionals.” (CX0200 at 0002).

180. Ms. Leow, a creative director for Roll, expressed her opinion that scientific information in advertising and marketing material helps sell the products, because the scientific information provides the consumer with a “reason to believe.” (Leow, Tr. 512-13).
181. A creative brief attached to an email from Michael Perdigao to Lynda Resnick dated June 25, 2008, noted that the “primary target consumer” for an unidentified referenced POM Juice campaign “should be the 30-something health conscious (hypochondriac?) who is educated and affluent.” (CX0211 at 0002).

**D. Testifying Experts****1. Complaint Counsel’s experts****a. Dr. Meir Stampfer**

182. Dr. Meir J. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. (Stampfer, Tr. 689-91; CX1293 (Stampfer Expert Report at 0001)). He teaches epidemiology, advanced epidemiology, and preventive medicine. (CX1293 (Stampfer Expert Report at 0001)). Epidemiology is the study of the determination and distribution of disease in humans. (Stampfer, Tr. 691).

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183. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cancer and cardiovascular disease (“CVD”), and their precursors. (CX1293 (Stampfer Expert Report at 0003-04)). These include: Nurses’ Health Study (started 1976, 121,700 women, cancer prevention, CVD, diabetes, and other health issues); Nurses’ Health Study II (started 1989, 116,800 women, same as Nurses’ Health Study); Physicians’ Health Study (started 1982, 29,000 men, multivitamin supplements, and aspirin, and beta carotene for prevention of CVD and cancer); and Health Professionals Follow-up Study (started 1986, 51,529 men, nutritional factors as related to cancer, including prostate cancer, and heart disease). (CX1293 (Stampfer Expert Report at 0003-04); Stampfer, Tr. 692-94). Additionally, he has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer and conducted randomized clinical trials involving nutrition and health, including dietary interventions to reverse atherosclerosis. (Stampfer, Tr. 698-700).
184. Dr. Stampfer has published more than 850 articles in medical journals, including the *New England Journal of Medicine*, *American Journal of Epidemiology*, *Epidemiology*, and *Journal of American Medical Association*. (CX1293 (Stampfer Expert Report at 0002)). Over 300 of these articles relate to the relationship between nutrition and the prevention or treatment of CVD or prostate cancer. (Stampfer, Tr. 701; *see also* CX1293 (Stampfer Expert Report at 0002)).
185. In 2003, the Institute for Scientific Information identified Dr. Stampfer as the most cited researcher in clinical medicine and epidemiology in the world during the past 20 years. (CX1293 (Stampfer Expert Report at 0002)). In 2005, the Institute for Scientific Information identified him as the most cited researcher in clinical medicine over the previous decade. (CX1293 (Stampfer Expert Report at 0002)).

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186. Dr. Stampfer currently is an editor for leading medical journals, including the *Journal of the American College of Nutrition*, *American Journal of Epidemiology*, *American Journal of Medicine*, and *Clinical Chemistry*. Dr. Stampfer also had editorial positions on the *American Journal of Clinical Nutrition*, *New England Journal of Medicine*, and *American Journal of Medicine*. (Stampfer, Tr. 701; CX1293 (Stampfer Expert Report at 0001-02)). Dr. Stampfer is a member of professional organizations relating to epidemiology, cancer, and CVD, including the Society of Epidemiological Research, the American College of Nutrition, the American Heart Association, and the American Association for Cancer Research. (Stampfer, Tr. 701-03). He also has consulted for the government on the U.S. Dietary Guidelines. (Stampfer, Tr. 703).
187. Dr. Stampfer was accepted as an expert on: 1) epidemiology; 2) nutrition, including its relation to the prevention and treatment of CVD and prostate cancer; and 3) clinical testing related to the prevention of prostate cancer and CVD. (Stampfer, Tr. 704-05; *see also* CX1293 (Stampfer Expert Report at 0005)).
188. Dr. Stampfer was asked to evaluate, from his perspective as an expert in the fields of epidemiology, nutrition, and clinical testing, whether the following claims were supported by the materials submitted by the Respondents:
- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;
  - tests prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart;

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- drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); and
- tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging “PSADT.”

(CX1293 (Stampfer Expert Report at 0005-06)).

189. To form his opinions, in addition to drawing upon his own expertise, Dr. Stampfer reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analyses from Respondents’ sponsored research, information about ingredients contained in the POM Products, and deposition transcripts of researchers who conducted studies for Respondents and related deposition exhibits and reports. Dr. Stampfer also reviewed materials he found through his independent literature search. (CX1293 (Stampfer Expert Report at 0006-07); Stampfer, Tr. 734-36; CX1294).
190. Dr. Stampfer opined that the materials relied upon by Respondents do not provide competent and reliable scientific evidence to support claims that: (1) drinking eight ounces of POM Juice or taking a daily serving of POMx is clinically proven to treat, prevent, or reduce the risk of heart disease or prostate cancer; (2) a daily eight ounce serving of POM Juice or a serving of POMx treats, prevents, or reduces the risk of heart diseases, including by prolonging PSADT (defined *infra* F.1042); or (3) a daily eight ounce serving of POM Juice or a serving of POMx treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1293 (Stampfer Expert Report at 0007)).

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**b. Dr. Frank Sacks**

191. Dr. Frank M. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. (Sacks, Tr. 1411-12; CX1291 (Sacks Expert Report at 0001)). He has taught pharmacology, epidemiology, and nutrition courses related to human disease, CVD, biochemistry, or preventative medicine. (Sacks, Tr. 1412-13; CX1291 (Sacks Expert Report at 0002)).
192. Dr. Sacks has researched CVD and coronary heart disease (“CHD”) and their risk factors, including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential risk-modifying diets, foods, food components, and drugs. (CX1291 (Sacks Expert Report at 0002); Sacks, Tr. 1415-18). He is the principal investigator of several National Institute of Health studies focusing on dietary nutrients and weight loss, carbohydrate amount and type affecting risk of CVD and diabetes, and dietary fat and high-density lipoprotein (“HDL”) metabolism in humans. (CX1291 (Sacks Expert Report at 0005-06)).
193. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. (Sacks, Tr. 1412-13, 1424-25; CX1291 (Sacks Expert Report at 0002-04)). Dr. Sacks has also written over 60 reviews, reports, editorials, and book chapters, addressing CVD, CHD, and the relationship between nutrition and these diseases or their risk factors. (CX1291 (Sacks Expert Report at 0004)).
194. Through his professional memberships and activities, Dr. Sacks keeps current on new developments and research in the areas of nutrition, CVD, cholesterol disorders, and hypertension. (Sacks, Tr. 1424). He served as an editor for the *American Journal of Clinical Nutrition*, *Journal of Clinical Lipidology*, a *Nutrition Journal (BioMed Central)*, and *The Journal of Lipid Research*. (CX1291 (Sacks Expert Report at 0006)). In these positions, he

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reviewed the adequacy of the design, the conduct of clinical research, and the appropriateness and accuracy of the statistical methodology in hundreds of papers submitted for publication. (Sacks, Tr. 1424-25; CX1291 (Sacks Expert Report at 0006)).

195. Dr. Sacks serves as a chair of the Nutrition Committee of the American Heart Association (AHA), which advises the AHA on matters of science and public policy and devises guidelines and advisory statements to the government, health professionals, and the public on nutrition. (Sacks, Tr. 1426; CX1291 (Sacks Expert Report at 0006-07)). Dr. Sacks is also a member of the National Cholesterol Education Program of the National Heart, Lung and Blood Institute of NIH, which revises national guidelines on prevention and treatment of CVD. (CX1291 (Sacks Expert Report at 0007); Sacks, Tr. 1426).
196. Dr. Sacks was accepted as an expert in the areas of nutrition, CVD, CHD, cholesterol disorders, hypertension, and analysis of clinical studies. (Sacks, Tr. 1429-30; CX1291 (Sacks Expert Report at 0008)).
197. Dr. Sacks was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; and (2) clinical studies, trials, and/or tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease. (CX1291 (Sacks Expert Report 0008-09)).
198. To form his opinions, in addition to drawing upon his own expertise in nutrition and CVD treatment, Dr. Sacks reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data, and data analysis from Respondents' sponsored research, information about ingredients contained in the POM Products, and deposition

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transcripts of researchers who conducted studies for Respondents and related deposition exhibits. Dr. Sacks also reviewed materials he found through an independent literature search. (Sacks, Tr. 1447-49; CX1291 (Sacks Expert Report at 0008-09); CX1292, Apps. 2, 3, 4).

199. Dr. Sacks opined that: (1) the materials relied upon by Respondents do not support claims that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents, reduces the risk of, or treats heart disease, including by decreasing arterial plaque, lowering blood pressure and/or improving blood flow to the heart; and (2) clinical studies, research, and/or trials do not prove that drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx liquid, daily, prevents or reduces the risk of or treats heart disease, including by, decreasing arterial plaque, lowering blood pressure and/or improving blood flow to the heart. (CX1291 (Sacks Expert Report at 0010)).

**c. Dr. James Eastham**

200. Dr. James A. Eastham is the Chief of Urology in the Department of Surgery at Memorial Sloan-Kettering Cancer Center in New York. He serves as the Director of Clinical Research, Urology and chairs the protocol review committee for clinical trials in the Department of Surgery. (CX1287 (Eastham Expert Report at 0001); Eastham, Tr. 1207-08). He is a board-certified urological surgeon who has treated more than 2,000 patients with prostate cancer, including some who experienced a rise in prostate-specific antigen (“PSA”) after receiving initial therapy. (CX1287 (Eastham Expert Report at 0002); Eastham, Tr. 1206, 1225-28, 1233).
201. Dr. Eastham has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. (Eastham, Tr. 1215-17). As a member of the Data Safety Monitoring Board for the Selenium and Vitamin E Cancer Prevention Trial, he is familiar with the design and performance of the largest

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prevention trials studying antioxidants and prostate cancer. (CX1287 (Eastham Expert Report at 0002-03); Eastham, Tr. 1210-11).

202. Dr. Eastham is a member of several professional associations, including the American Urological Association, the Society of Urologic Oncology, and the National Comprehensive Cancer Network (“NCCN”) Prostate Cancer Guidelines Committee. He regularly attends and speaks at national and international meetings of professional societies that specialize in urology and prostate cancer. (CX1287 (Eastham Expert Report at 0003); Eastham, Tr. 1211-13).
203. Dr. Eastham has peer-reviewed numerous papers involving randomized, double-blinded, controlled human clinical studies that were submitted to medical journals, such as *Urology*, *Journal of Urology*, and *Journal of Clinical Oncology*. (CX1287 (Eastham Expert Report at 0003); Eastham, Tr. 1224-25). Dr. Eastham has published over 200 peer-reviewed articles in scientific journals, as well as dozens of book chapters or reviews pertaining to urology and the treatment of prostate cancer. (CX1287 (Eastham Expert Report at 0003-04); CX1288, Ex. A; Eastham, Tr. 1214-15).
204. Dr. Eastham was accepted as an expert in the areas of: (1) urology specializing in prostate cancer, including the prevention and treatment of prostate cancer; and (2) clinical testing related to the prevention and treatment of prostate cancer. (Eastham, Tr. 1234; CX1287 (Eastham Expert Report at 0004)).
205. Dr. Eastham was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); and (2) tests prove that drinking eight ounces of POM Juice, or taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats or prevents prostate cancer,

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including by prolonging PSADT. (CX1287 (Eastham Expert Report at 0004-05)).

206. To form his opinions in addition to drawing upon his own expertise in the field of urology, specializing in prostate cancer, including the prevention and treatment of prostate cancer, and clinical testing relating to the treatment and prevention of prostate cancer, Dr. Eastham reviewed the materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, data and data analysis from Respondents' sponsored research, and information about ingredients contained in the POM Products. Dr. Eastham also reviewed materials he found through an independent literature search. (CX1287 (Eastham Expert Report at 005); Eastham, Tr. 1287-88; CX1288, Ex. B).
207. Dr. Eastham provided the following opinion: the materials relied upon by Respondents do not provide reliable scientific evidence that POM Juice, POMx Pills, or POMx Liquid effectively prevents, reduces the risk of, or treats prostate cancer or are clinically proven to do so. (CX1287 (Eastham Expert Report at 006, 012)).

**d. Dr. Arnold Melman**

208. Dr. Arnold Melman is a Professor and Chairman of the Department of Urology at Albert Einstein College of Medicine and Montefiore Medical Center in New York. (Melman, Tr. 1072-73). Dr. Melman is a board-certified, practicing clinical urologist at Montefiore Medical Center and has treated thousands of patients with erectile dysfunction. (Melman, Tr. 1071-73).
209. Dr. Melman has extensive experience in designing and reviewing protocols for well-designed clinical trials. As an editor of *Sexuality and Disability*, the *Journal of Urology*, and the *International Journal of Impotence Research*, Dr. Melman reviewed hundreds of articles involving erectile dysfunction by evaluating, among other factors, the design, data collection and reporting, and statistical analysis of clinical studies. (Melman, Tr. 1075-

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77; CX1289 (Melman Expert Report at 0002)). Furthermore, Dr. Melman was a principal investigator on two National Institutes of Health research grants relating to erectile dysfunction. (Melman, Tr. 1079-80; CX1289 (Melman Expert Report at 0002-03)).

210. Dr. Melman was chairman of the U.S. Food and Drug Administration's Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, and was a member of the National Institutes of Health's Urology Special Emphasis Panel. (Melman, Tr. 1077-78; CX1289 (Melman Expert Report at 0001-02)). Dr. Melman is a member of several professional organizations, including the American Federation for Clinical Research, Society of University Urologists, American Urological Association, American Association of Clinical Urologists, International Society of Urology, and International Academy of Sex Research; and has spoken at national and international meetings of professional societies that specialize in urology and erectile dysfunction. (Melman, Tr. 1077-79; CX1289 (Melman Expert Report at 0001-02)). Dr. Melman has published more than 200 peer-reviewed articles relating to urology in scientific journals. Many of these published articles relate to erectile dysfunction. (Melman, Tr. 1076-77; CX1289 (Melman Expert Report at 0002)).
211. Dr. Melman was accepted as an expert in: (1) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; and (2) clinical testing involving erectile dysfunction. (Melman, Tr. 1080-81).
212. Dr. Melman was asked to determine whether the materials he reviewed were sufficient to support claims that: (1) drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction; and (2) clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice, daily, prevents, reduces the risk of, or treats erectile dysfunction. (CX1289 (Melman Expert Report at 0003)).

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213. To form his opinions, in addition to relying on his expertise in urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction, and clinical testing involving erectile dysfunction, Dr. Melman reviewed materials submitted by Respondents and affiliated researchers, including published and unpublished study reports, protocols, and data and data analyses from Respondents' sponsored research. (CX1289 (Melman Expert Report at 0003); Melman, Tr. 1083). Dr. Melman also reviewed articles he found through his independent research of peer-reviewed journals. (Melman, Tr. 1083; CX1289 (Melman Expert Report at 0003)).
214. Dr. Melman opined that POM Wonderful pomegranate juice has not been proven to prevent, reduce the risk of, or treat erectile dysfunction. (CX1289 (Melman Expert Report at 0005)).

**2. Respondents' experts****a. Dr. Denis Miller**

215. Dr. Denis R. Miller is a board certified pediatrician and pediatric hematologist and oncologist licensed to practice medicine in the state of New Jersey. (PX0206 (Miller Expert Report at 1); PX0354 (Miller, Dep. at 16)). He directs one of the largest pediatric oncology/ hematology programs in the world and holds an endowed chair. (PX0206 (Miller Expert Report at 3)).
216. Dr. Miller has, for over 40 years, directed clinical care, education, laboratory and clinical research, and administration, and led departments at some of the most prestigious hospitals in the world. (PX0206 (Miller Expert Report at 2); Miller, Tr. 2190). Dr. Miller has designed, managed, and directed many different research studies calculated to develop new anti-cancer agents. (PX0206 (Miller Expert Report at 2-3)).
217. Dr. Miller has authored or co-authored over 300 book chapters, peer-reviewed articles, and abstracts mostly on

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cancer and blood disorders. (PX0206 (Miller Expert Report at 4); Miller, Tr. 2191).

218. Complaint Counsel has retained Dr. Miller on several matters, and he testified for Complaint Counsel previously in the matter of *Daniel Chapter One*. (PX0206 (Miller Expert Report at 5, 18)).
219. Dr. Miller was accepted as an expert in the design of clinical research protocols and asked to testify on the areas of the applicable standards of substantiating evidence for fruit and fruit juice or food products in general as opposed to the standard that is applicable to drugs. (Miller, Tr. 2192, 2218).
220. Dr. Miller provided the following opinions: pomegranates are a food that have been eaten for thousands of years and its consumption as a food is without known risks; the appropriate level of scientific substantiation regarding the health benefit claims of pomegranates should be flexible and consider several factors (including risk of harm) with the desirability of getting information to the public; the standard for substantiating foods that are clearly safe need not be as rigorous as that for a new drug or anticancer agent, but should be based on reliable and competent scientific data; and POM Wonderful is not being put forth as a substitute or alternative to conventional and approved drug therapies and medical care. (PX0206 (Miller Expert Report at 15)).

**b. Dr. David Heber**

221. Dr. David Heber received his Ph.D. in Physiology from UCLA, an MD from Harvard Medical School, and a B.S. in Chemistry from UCLA. (PX0192 (Heber Expert Report at 0005)). Dr. Heber is the founding director of the UCLA Center for Human Nutrition, which is a center for clinical research, education, and public health endeavors. (Heber, Tr. 1937).
222. Dr. Heber is a treating physician with patients, and has been a member of the faculty of UCLA Medical School

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for 33 years. He is currently a Professor of Medicine in Public Health. (Heber, Tr. 1937; CX1407 (Heber, Tropicana Tr. 76)).

223. Dr. Heber has co-authored over 200 peer-reviewed publications in the field of nutrition and its relation to various diseases and written 25 chapters in other scientific texts. (Heber, Tr. 1939-40). He was the editor-in-chief of the leading text on nutritional oncology and has written a book on the importance of diet in maintaining health and resisting diseases. (Heber, Tr. 1939).
224. Dr. Heber was accepted as an expert in the relationship between nutrition and various diseases, including coronary heart disease and prostate cancer, as well as other diseases. (Heber, Tr. 1941).
225. Dr. Heber was asked to testify on Dr. Stampfer's expert report and provide opinions on issues related to pomegranate juice and extract, including: (1) antioxidants found in pomegranates, their potency, and how they act in the body (their mechanisms of action); (2) the health and safety effects; and (3) nutritional research methodology relating to the evaluation of scientific research on health benefits. (PX0192 (Heber Expert Report at 0004)).
226. Dr. Heber provided the following opinions: it is not appropriate to require the use of double-blind placebo-controlled studies for evaluating the health benefits of foods; translational nutritional science looks at the best available evidence, as a totality, rather than just one type of clinical study; and the body of research on pomegranate juice and extract, revealing how they act in the body, provides support for potential benefits for heart disease and prostate cancer. (PX0192 (Heber Expert Report at 0013-15)).

**c. Dr. Dean Ornish**

227. Dr. Dean Ornish is a medical doctor and Clinical Professor of Medicine at the University of California at San Francisco. (Ornish, Tr. 2314).

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228. Dr. Dean Ornish is the Founder and President of the Preventative Medicine Research Institute (“PMRI”) in Sausalito, CA. (PX0025 (Ornish Expert Report at 0001)).
229. For over 34 years, Dr. Ornish directed clinical research on the relationship between diet and lifestyle and coronary heart disease. He was the first to prove by a series of RCTs that heart disease could be reversed by making changes in diet and lifestyle. (Ornish, Tr. 2316-17).
230. Dr. Ornish has written six published books on the subject of the effect of diet and lifestyle on heart disease and other diseases. (Ornish, Tr. 2318). Dr. Ornish’s research has been reported in many prestigious journals, and he has written numerous articles for distinguished peer-reviewed journals. (Ornish, Tr. 2318-19).
231. Dr. Ornish was accepted as an expert in the relationship between the heart and nutrition and in cardiovascular disease and its relationship to nutrition and nutrients. (Ornish, Tr. 2321-22).
232. Dr. Ornish was asked to evaluate: (1) whether drinking eight ounces of POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid may be beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease; and (2) whether basic science, clinical studies, research, and/or trials show that the consumption of POM Juice, POMx Pill, or POMx Liquid may be beneficial in maintaining cardiovascular health and lessening the risk of cardiovascular disease. Dr. Ornish was further asked to review the report titled, “Expert Report of Frank M. Sacks” and to evaluate the claims and statements made in that document. (PX0025 (Ornish Expert Report at 0004-05)).
233. Dr. Ornish provided the following opinion: the scientific evidence from basic science studies, animal research, and clinical trials in humans indicates that pomegranate juice in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pill, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is

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likely to reduce the risk of cardiovascular disease. (PX0025 (Ornish Expert Report at 0005)).

**d. Dr. Arthur Burnett**

234. Dr. Arthur Burnett is a Professor of Urology serving on the faculty of the Department of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2241). Dr. Burnett holds a faculty appointment in the Cellular and Molecular Medicine Training Program of the Johns Hopkins University School of Medicine and is the Director of the Basic Science Laboratory in Neuro-urology of the James Buchanan Brady Urological Institute and Director of the Male Consultation Clinic/Sexual Medicine Division of the Department of Urology at Johns Hopkins. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2241).
235. Dr. Burnett obtained his medical degree from the Johns Hopkins University School of Medicine in Baltimore, Maryland and completed his internship, residency and fellowship at the Johns Hopkins Hospital. (PX0149 (Burnett Expert Report at 0001); Burnett, Tr. 2240-41).
236. Dr. Burnett has authored and published over 180 original peer-reviewed articles and 40 book chapters. (PX0149 (Burnett Expert Report at 0003)).
237. Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. (Burnett, Tr. 2244).
238. Dr. Burnett has conducted world renowned research on nitric oxide ("NO"). (PX0149 (Burnett Expert Report at 0003)).
239. Dr. Burnett was accepted as an expert in the field of urology and sexual medicine to offer opinions on: (1) the science of nitric oxide biology; (2) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health, erectile function and treatment of erectile dysfunction; (3) the impact of

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pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (4) scientific studies involving erectile function and dysfunction. (PX0149 (Burnett Expert Report at 0001-07); Burnett, Tr. 2243-44, 2249-51, 2255-56, 2270-74; PX0349 (Burnett, Dep. at 23-25, 103, 112, 116-118, 137)).

240. Dr. Burnett was asked to provide expert testimony regarding POM's basic science and clinical study, as well as pomegranate juice's effect on the nitric oxide regulatory mechanism, the vascular system/function, and on erectile health, erectile function and erectile dysfunction. (PX0149 (Burnett Expert Report at 0004-07); PX0349 (Burnett, Dep. at 103, 112, 116-118); Burnett, Tr. 2243-44, 2255-56, 2270-74).
241. To form his opinions, Dr. Burnett reviewed studies on erectile function and nitric oxide, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007) and a few *in vitro* and animal studies. (PX0149 (Burnett Expert Report at 0004)). Dr. Burnett relied upon his "education, experience, and knowledge of developments in the fields of urology and sexual medicine, including the promotion of erectile health and treatment of erectile dysfunction." (PX0149 (Burnett Expert Report at 0004)).
242. Dr. Burnett provided the following opinion: pomegranate juice possesses potent anti-oxidative endothelial NO mechanisms in vasculature. These mechanisms serve potential beneficial effects on vascular blood flow and promote vascular biologic health. Basic scientific and clinical evidence supports the probable benefit of pomegranate juice on the vascular structures involved in penile erection. (PX0149 (Burnett Expert Report at 0005-06)).

**e. Dr. Irwin Goldstein**

243. Dr. Irwin Goldstein is a sexual medicine physician who has been practicing medicine since 1976 and has been involved in sexual medicine clinical practice, clinical

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research and basic science research since 1980. (PX0189 (Goldstein Expert Report at 0001-02); PX0352 (Goldstein, Dep. at 14)).

244. Dr. Goldstein has been certified by the American Board of Urology since 1982. He was a Professor of Urology and Professor of Gynecology at the Boston University School of Medicine from 1990 to 2005 and 2002 to 2005, respectively. (PX0189 (Goldstein Expert Report at 0001-03)).
245. Dr. Goldstein has published over 250 original peer-reviewed manuscripts in male and female sexual medicine. (PX0189 (Goldstein Expert Report at 0002-03)).
246. Dr. Goldstein was part of the original advisory board to Pfizer that engaged in an extensive drug development plan that developed sildenafil (Viagra), and was also on the advisory boards of Bayer and Eli Lilly for the development of vardenafil (Levitra) and tadalafil (Cialis). (Goldstein, Tr. 2590-91).
247. Dr. Goldstein was accepted as an expert in the field of sexual medicine, the studies that have been done on sexual medicine and the impact of pomegranate juice and antioxidants and nitric oxide on erectile function and dysfunction. (Goldstein, Tr. 2592). Dr. Goldstein was asked to provide testimony on: (1) sexual medicine; (2) the study, design, and treatment of men with sexual health problems; (3) the studies that have been done on sexual medicine particularly regarding the promotion of erectile health and treatment of erectile dysfunction; (4) the mechanisms by which nitric oxide is formed and acts in penile erection and in the promotion of erectile health and treatment of erectile dysfunction; (5) urology as it relates to the treatment, prevention, and reduction of risk of erectile dysfunction; (6) the impact of pomegranate juice and antioxidants and nitric oxide on erectile health, erectile function and erectile dysfunction; and (7) scientific testing involving erectile health, erectile function and erectile dysfunction. (PX0352 (Goldstein, Dep. at 19-

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22, 37-42); PX0189 (Goldstein Expert Report at 0003-15); Goldstein, Tr. 2592, 2600-05, 2611, 2620).

248. To form his opinions, Dr. Goldstein reviewed studies on erectile function, nitric oxide, and the Mediterranean diet, including POM-sponsored studies such as the Forest Erectile Dysfunction Study (2007), an article titled, *Recreational Use of Phosphodiesterase Type 5 Inhibitors by Healthy Young Men* (2010), and several *in vitro* and animal studies. (PX0189 (Goldstein Expert Report at 0005); PX0352 (Goldstein, Dep. at 125)).
249. Dr. Goldstein offered the following opinions: (1) the available body of scientific literature, including *in vitro*, and preliminary clinical trials, strongly suggests that consuming pomegranate juice promotes erectile health; and (2) the use of pomegranate juice to promote erectile health is a separate and distinct concept from the use of a neutraceutical as a safe and effective treatment for the medical condition of erectile dysfunction such as with a PDE5 inhibitor. (PX0189 (Goldstein Expert Report at 0004-05)). Dr. Goldstein concluded that reasonable and competent scientific evidence shows that pomegranate produced a definite benefit to proper and effective erectile function. (Goldstein, Tr. 2605).

**f. Dr. Jean deKernion**

250. Dr. Jean deKernion is a practicing urologist certified by both the American Board of Surgery and the American Board of Urology. He obtained his medical degree in 1965 from Louisiana State University School of Medicine in New Orleans, Louisiana and did his residencies in surgery and urology at the university hospitals of Cleveland and the National Cancer Institute. (deKernion, Tr. 3039-40, 3127; PX0161 (deKernion Expert Report)).
251. Dr. deKernion was, from 1981 until his retirement in 2011, Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs (2001-2011) at the David Geffen UCLA School of Medicine. Dr. deKernion's responsibilities included the urological

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clinical and research education of students, residents, and fellows at all levels; a busy practice in urologic oncology, primarily related to prostate cancer but also bladder and kidney cancer; growth and oversight of large and diverse research programs; and administration of programs for the Dean's office and hospital. (deKernion, Tr. 3039; PX0161 (deKernion Expert Report at 0001)).

252. During Dr. deKernion's tenure as Chair of the Department of Urology at UCLA, he built a multidisciplinary research portfolio, which ranks among the largest and best in the United States. (PX0161 (deKernion Expert Report at 0003)).
253. Dr. deKernion's career in urologic oncology has involved both clinical and basic/translational research. (PX0161 deKernion Expert Report at 0001)).
254. Dr. deKernion co-authored the first book on urologic oncology and has co-authored 133 chapters since. His research has involved both basic laboratory research and clinical research publishing 228 papers to date in peer-reviewed journals and many other invited manuscripts. For six years, Dr. deKernion was the associate editor of the Journal of Urology and has been a reviewer for approximately 20 other peer-reviewed journals. (PX0161 (deKernion Expert Report at 0002); deKernion, Tr. 3041-43).
255. Dr. deKernion has served on a number of national committees and was a founding member of the Society of Urologic Oncology, was elected as a trustee of the American Board of Urology, and numerous committees of national urological societies and was appointed to the National Cancer Advisory board by President Bush. (deKernion, Tr. 3040; PX0161 (deKernion Expert Report at 0002)).
256. Dr. DeKernion was accepted as an expert in the field of urology and prostate health to offer opinions on research done on pomegranate juice and POM Products as they relate to the prostate. He was also asked to provide

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expert opinions on the validity of PSA doubling time in assessing response to POM Products and on the strength of the science supporting the role of POM in prostate health and prostate cancer. In addition, Respondents asked Dr. DeKernion to rebut the opinions in Dr. Eastham's expert report. (deKernion, Tr. 3043-44; 3108-09; PX0161 (deKernion Expert Report at 0003)).

257. To form his opinions, Dr. deKernion reviewed the expert reports of Dr. Eastham and Dr. Miller, the FTC depositions of Dr. Pantuck and Dr. Carducci, protocols for the Pantuck Phase II Prostate Cancer Study (2006), the Carducci Dose Study, and the Pantuck Phase III Study, articles cited in Dr. Eastham's report, scientific articles found by conducting a literature search, and marketing materials. (PX0351 (deKernion, Dep. at 6-8, 27-29); PX0351a04; PX0351a05).
258. Dr. de Kernion provided the following opinions: (1) based on the data available, it is reasonable to state that POM products have shown an effect on prostate cancer with little or minimal toxicity; (2) given the current evidence, Dr. deKernion would suggest to patients and friends who have early prostate cancer that they consider taking POM, among other measures such as exercise, restrict intake of fatty foods, and weight control, to improve their probability for prevention or control of a tumor. (PX0161 (deKernion Expert Report at 0011-12)).

**g. Dr. Ronald Butters**

259. Dr. Ronald Butters is Professor Emeritus at Duke University and has been on faculty at Duke for over 40 years. He served as the Chairman of the Linguistics Department at Duke and Chairman of Duke University's English Department. (Butters, Tr. 2812).
260. Dr. Butters is a member of the advisory board of the New Oxford American Dictionary and has served as editor and co-editor of multiple prestigious scientific and academic publications. He participates in numerous professional associations and is the past president of the International

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Association of Forensic Linguistics. (Butters, Tr. 2812-13).

261. Dr. Butters has written textbooks and other books on the subjects of linguistics, which is the study of all forms of human language: semantics and semiotics. (Butters, Tr. 2814-15).
262. Dr. Butters was accepted as an expert in linguistics, including the meaning of language and symbols and the context in which they appear. (Butters, Tr. 2816, 2954-55).
263. Dr. Butters offered his opinions as a linguistics expert on the meanings of Respondents' advertisements. (Butters, Tr. 2816-17).
264. Dr. Butters concluded that Respondents' advertisements do not convey, either expressly or by implication: that scientific research proves that the use of certain recommended amounts, in recommended frequencies, of Pom Wonderful products successfully treats, prevents, or reduces: (1) the risk of heart disease, including decreasing arterial plaque, lowering blood pressure, and/ or improving blood flow to the heart; (2) the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and (3) the risk of erectile dysfunction. (PX0158 (Butters Expert Report at 0002-03)).
265. Dr. Butters also opined that Respondents' advertisements convey that (1) pomegranate juice is a healthy beverage and (2) Pom Wonderful products contain "antioxidants," for which there has been preliminary scientific research regarding their potential beneficial properties, and (3) readers and hearers are generally encouraged to investigate scientific research and draw their own conclusions. (PX0158 (Butters Expert Report at 0002-03)).

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**h. Dr. David Reibstein**

266. Dr. David Reibstein is a tenured Professor of Marketing at the University of Pennsylvania in The Wharton School. Dr. Reibstein has taught courses in marketing management, marketing strategy and marketing metrics to MBA Program and Executive MBA Program students; marketing research courses to MBA Program students; and other marketing courses to undergraduate students. Many of these courses involve the use and design of surveys. (Reibstein, Tr. 2482; PX0356a01 at 0002-03).
267. Dr. Reibstein has been a visiting professor at Stanford Business School, Harvard Business School and Purdue University where he taught marketing courses. Dr. Reibstein has taught courses in marketing strategy and advanced industrial marketing strategy at INSEAD, a top business school in Europe. (Reibstein, Tr. 2483; PX0356a01 at 0002, 0003).
268. Dr. Reibstein received his Doctor of Industrial Administration from the Herman C. Krannert Graduate School of Industrial Administration at Purdue University with a major in marketing and a minor in behavioral science. (Reibstein, Tr. 2481). Dr. Reibstein's doctoral dissertation was titled, "*An Empirical Study of Brand Choice and Switching Behavior.*" (PX0356a01 at 0001). Dr. Reibstein attended the Master of Business Administration Program at the Graduate Business School at Tulane University. (Reibstein, Tr. 2480-81; PX0356a01 at 0001). Dr. David Reibstein received a B.S. in Business Administration and a B.S. in Statistics and Political Science from the University of Kansas. (Reibstein, Tr. 2480; PX0356a01 at 0001). Dr. Reibstein has been awarded an Honorary Master of Science by The Wharton School at the University of Pennsylvania. (PX0356a01 at 0001).
269. Dr. Reibstein was the Executive Director for the Marketing Science Institute, an organization of 72 company-members. The Marketing Science Institute works closely with its members to identify the major

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marketing issues confronting them. The Marketing Science Institute prepares reports on various marketing issues which are disseminated to its members and the general business community. The Marketing Science Institute sets the research agenda for marketing academia globally. (Reibstein, Tr. 2483-84; PX0356a01 at 0002).

270. Dr. Reibstein has published extensively in prestigious peer-reviewed marketing journals, including many articles on marketing and marketing research. Those journals include, among others, the Journal of Consumer Research, Journal of Marketing Research, Marketing Science and the Harvard Business Review. (Reibstein, Tr. 2484; PX0356a01 at 0004-07).
271. Dr. Reibstein has written over seven books and numerous chapters in books on marketing and marketing research. (Reibstein, Tr. 2484; PX0356 (Reibstein, Dep. at 14; (PX0356a01 at 0007, 0008)). Dr. Reibstein authored the book “Marketing Metrics: 50+ Metrics Every Executive Should Master (2006)” which was named as the “Best Business Book: Marketing” by Strategy & Business in 2007. (PX0356a01 at 0004).
272. Dr. Reibstein has provided management education in the field of marketing to more than 300 companies. He has designed, executed, and supervised hundreds of market research studies for over 30 years, including surveys concerning consumer behavior. (Reibstein, Tr. 2485-86).
273. Dr. Reibstein has performed consulting research for a variety of companies where his work focuses on understanding the reasons that customers buy, what motivates customers to buy, and the interface with customer behavior and a company’s marketing activities, price, product, place, and promotion. (Reibstein, Tr. 2484-85; PX0356 (Reibstein, Dep. at 14-15)). Dr. Reibstein’s consulting work for companies involves collecting and processing information to better inform the company about what has or might influence customers to make the purchase decisions they do, and in the manner they do to reduce uncertainty in the decisions they make.

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Dr. Reibstein's consulting work also involves determining the messages consumers take from certain advertising. (PX0356 (Reibstein, Dep. at 16)). Dr. Reibstein has also provided extensive management education in the field of marketing to more than 300 companies over his career. (Reibstein, Tr. 2485).

274. Dr. Reibstein serves on the board of the Marketing Accountability Standards Board. This board sets the standards on what are the most important marketing metrics and how to measure them both in the United States and globally. (Reibstein, Tr. 2485).
275. Dr. Reibstein was accepted as an expert witness in marketing and marketing research. (Reibstein, Tr. 2485).
276. Dr. Reibstein prepared for Respondents a survey analysis titled, Survey of POM Wonderful 100% Pomegranate Juice Users ("Reibstein Survey") to understand the underlying motivations that consumers had for purchasing pomegranate juice and what those motivations might have been. (PX0356 (Reibstein, Dep. at 11, 39); Reibstein, Tr. 2487).
277. As stated in the Reibstein Survey, the primary objective of the survey was to evaluate the main factors driving the purchasing decision for POM Wonderful 100% Pomegranate juice buyers, including whether and to what extent POM Wonderful 100% Pomegranate juice buyers purchase the product based on their belief that the product cures or prevents a particular disease. Dr. Reibstein's finding and opinion is that there is a very small percentage of people that bought, would buy again, or would recommend to a friend POM Wonderful Pomegranate Juice because they believed it was beneficial to any disease. (PX0223 at 0003).
278. Dr. Reibstein also reviewed the Bovitz Survey and the OTX Attitudes & Usages ("A&U") Study. (*See* Section II.J, *infra*). Dr. Reibstein opined that these studies have methodological flaws, cannot be relied on, and do not

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invalidate the results of the Reibstein Survey. (Reibstein, Tr. 2517; PX0223 at 0003).

**3. Complaint Counsel's rebuttal experts****a. Dr. Michael Mazis**

279. Dr. Michael Mazis is a Professor Emeritus of Marketing at the Kogod School of Business, American University. (PX0296 (Mazis Expert Report at 0002); Mazis Tr. 2653). He was a Professor of Marketing at American University from 1981 to 2008, serving ten years as chair of the Department of Marketing. (PX0296 (Mazis Expert Report at 0002); Mazis, Tr. 2653).
280. Dr. Mazis has served as a paid consultant for numerous federal government agencies, including the FTC, FDA, Consumer Product Safety Commission, Department of Justice, Federal Deposit Insurance Corporation, Bureau of Alcohol, Tobacco and Firearms and U.S. Mint. (Mazis, Tr. 2656, 2697).
281. Dr. Mazis was employed by the FTC from July 1977 through August 1979. During that time, he was Chief of Marketing and Consumer Research in the Office of Policy and Planning. In addition, Dr. Mazis was employed by the FTC one day per week for a period of five or six years, beginning in the mid-1990's. He has also served as the FTC's principal marketing witness in several cases. Dr. Mazis has been a testifying expert witness in at least 24 legal proceedings during the last four years. (PX096a001 at 0001; Mazis, Tr. 2653, 2696-98; PX0296 (Mazis Expert Report at 0002-03, 0012); PX0359 (Mazis, Dep. at 22-24)).
282. Dr. Mazis is a former director of the Association for Consumer Research. He was Editor of the Journal of Public Policy & Marketing from 1992 to 1995 and Associate Editor of The Journal of Consumer Affairs from 1998 to 2001. (PX0296 (Mazis Expert Report at 0002); Mazis, Tr. 2654). Among his duties as an editor and associate editor, Dr. Mazis would review and critique

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survey research. (Mazis, Tr. 2655-56). Dr. Mazis has conducted hundreds of surveys and research studies, including over one hundred surveys for use in legal proceedings. (Mazis, Tr. 2657).

283. Dr. Mazis was called as an expert rebuttal witness in marketing and marketing research to rebut the expert testimony of Dr. Reibstein. (Mazis, Tr. 2659; CX1297 (Mazis Expert Report at 0002)).
284. Dr. Mazis opined that the Reibstein Survey contains substantial defects in its design and interpretation and that, as a result of these flaws, no reliable conclusions can be drawn from the Reibstein Survey, with regard either to the materiality of any of the challenged claims or to whether any of the challenged advertisements communicate any of the challenged claims. (CX1297 (Mazis Expert Report at 0004)).

**b. Dr. David Stewart**

285. Dr. David W. Stewart is a full Professor of Marketing in the A. Gary Anderson Graduate School of Management, University of California at Riverside, where he served as dean of the business school for four years before being asked to step down. (PX0295a01 at 0002, 0041; Stewart, Tr. 3161, 3224-25; CX1295 (Stewart Expert Report at 0002)). During his academic career, Dr. Stewart has taught a variety of graduate and undergraduate level courses related to advertising, consumer behavior, marketing research, and marketing strategy. (PX0295a01 at 0050-51; Stewart, Tr. 3160-61; CX1295 (Stewart Expert Report at 0003-04)).
286. Dr. Stewart has authored or co-authored eight books on advertising related issues and has written over 125 articles which have been accepted in peer-reviewed academic journals. (Stewart, Tr. 3162-63; PX0295a01 at 0002, 0005, 0008-17; CX1295 (Stewart Expert Report at 0002)). Dr. Stewart has served as the editor, associate editor, or member of the editorial board of numerous academic journals. (PX0295a01 at 0043-47; CX1295 (Stewart

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Expert Report at 0002); Stewart, Tr. 3161). Dr. Stewart has served as the President of the Academic Council of the American Marketing Association and chairman of the Section on Statistics in Marketing of the American Statistical Association. (Stewart, Tr. 3161-62; PX0295a01 at 0002, 0043). He is a past president of the Society of Consumer Psychology of the American Psychological Association. (Stewart, Tr. 3162; PX0295a01 at 0002, 0045; CX1295 (Stewart Expert Report at 0003)).

287. Dr. Stewart was accepted as an expert in advertising, marketing, consumer behavior, and survey methodology. (Stewart, Tr. 3168).
288. Dr. Stewart was called as a rebuttal witness to respond to Respondents' expert, Dr. Butters. (Stewart, Tr. 3168).
289. Dr. Stewart opined that Dr. Butters' conclusions are inconsistent with the extant literature on consumer response to advertising, POM Wonderful's own internal planning documents, and empirical evidence, and thus Dr. Butters' conclusions have no merit with regard to the determination of what claims are communicated by any challenged POM Wonderful advertisement. (CX1295 (Stewart Expert Report at 0017-18)).

**E. Alleged Advertising Claims****1. Facial analysis****a. Alleged "clinically proven" claims****i. Print advertisements****(a) CX0016 ("Drink and be healthy" print advertisement)**

290. CX0016 is a POM Juice advertisement with a headline "Drink and be healthy." CX0016 is reprinted in the Appendix to this Initial Decision. (Appendix at 1). (CX0016 at 0001).

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291. CX0016 ran once in the Chicago Tribune on October 12, 2003. (CX0016 at 0002).
292. CX0016 ran in 2003 as part of the original launch of the POM Juice product and has not been disseminated since 2003. It was one of the first advertisements Respondents ever ran. (Tupper, Tr. 2995; L. Resnick, Tr. 157).
293. Based on the overall, common-sense, net impression of the advertisement, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0016 to contain the message that it is clinically proven that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease, by reducing arterial plaque. (CX0016 at 0002; F. 294-296).
294. CX0016 draws a clear and direct connection between consumption of POM Juice and prevention or reduction of risk for heart disease by juxtaposing statements and representations that (a) POM Juice has more antioxidants than other drinks, (b) antioxidants protect against free radicals, (c) free radicals can cause “heart disease,” (d) “medical studies have shown” that consumption of POM Juice “minimizes factors that lead to atherosclerosis,” which the advertisement defines for the reader as “plaque buildup in the arteries,” and (e) such plaque buildup is “a major cause of heart disease.” (CX0016 at 0001).
295. The statement in the advertisement that “[m]edical studies have shown that drinking 8 oz. of POM Wonderful pomegranate juice daily minimizes factors that lead to atherosclerosis (plaque buildup in the arteries), a major cause of heart disease” uses definitive and unambiguous language. This language draws a clear and direct connection between the referenced proof and the claimed effect on heart disease. (CX0016 at 0001 (emphasis added)).
296. In the context of CX0016, the elements of the advertisement communicating that POM is a food product, including the large image of the pomegranate fruit, the

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reference to POM Juice as “delicious” and “refreshing,” and the reference to POM being “[i]n the refrigerated produce section of your grocer[,]” do not materially alter the message conveyed, described in F. 293. (CX0016 at 0001).

**(b) CX0029 (“10 OUT OF 10 PEOPLE DON’T WANT TO DIE” print advertisement)**

297. The advertisement for POM Juice identified as CX0029 is a POM Juice advertisement with a headline “10 OUT OF 10 PEOPLE DON’T WANT TO DIE” that ran in *Prevention* magazine in or about November 2004 and January 2005. The advertisement also ran in *Martha Stewart Living* magazine in or about May 2005. (CX0029 at 0001-03).
298. CX0029 is reprinted in the Appendix to this Initial Decision. (Appendix at 2-3).
299. Based on the overall, common-sense, net impression of the advertisement, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0029 to contain the message that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, and is clinically proven to do so, by reducing arterial plaque. (CX0029 at 0001-02; F. 300-305).
300. There are elements in CX0029 that weigh against the interpretation described in F. 299. These include an irreverent and/or humorous headline, “10 OUT OF 10 PEOPLE DON’T WANT TO DIE,” the bold notation on the first page indicating that POM Juice is found “in the refrigerated produce section of your grocer,” the image of the pomegranate, the reference to a study as a “pilot” study, and the language in the last paragraph which refers to keeping “your heart healthy” with regular exercise and a healthy diet, in addition to drinking POM Juice. (CX0029 at 0001-02).

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301. Notwithstanding the elements described in F. 300, other elements in CX0029 dominate the communication, and result in the overall net impression that consuming POM Juice prevents, reduces the risk of, or treats heart disease, and is clinically proven to do so by reducing arterial plaque. These elements include statements and representations that: (1) free radicals “lead to” “heart disease”; (2) antioxidants “neutralize” free radicals; (3) “scientific research shows” that POM Juice has a superior ability to prevent LDL oxidation and a “clinical pilot study shows that” consuming an “8 oz. glass” of POM Juice “daily” “reduces plaque in the arteries up to 30%” with a footnoted citation to a study by Dr. Aviram published in *Clinical Nutrition* in 2004; (4) “heart attacks are due to . . . plaque in the arteries”; and (5) “heart disease” is America’s number one killer. The language used is affirmative and non-qualified. (CX0029 at 0001-02).
302. Interspersed with the language described in F. 301 are an image of a human heart and an image of a graph asserting POM Juice’s superior abilities to prevent oxidation of LDL, which the advertisement defines as “bad cholesterol” that “clogs arteries.” In the context of this advertisement, these images reinforce the message conveyed by the language described in F. 301. (CX0029 at 0001-02).
303. Through the language and images described in F. 301 and F. 302, the advertisement draws a clear connection between the consumption of POM Juice and prevention, treatment or reduction of the risk of heart disease. The advertisement also draws a clear connection for the reader between reduced arterial plaque, as shown by the referenced study, and prevention of heart disease. (CX0029 at 0001-02).
304. Notwithstanding the irreverent or humorous headline, “10 OUT OF 10 PEOPLE DON’T WANT TO DIE,” the overall tone of the advertisement is serious. In addition, the advertisement resembles a news article. (CX0029 at 0001-02).

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305. In the context of the language and images described in F. 301 and F. 302, the fact that the advertisement pertains to a food product does not materially alter the message conveyed. (CX0029 at 0001-02).

**(c) CX0314; CX0372; CX0379; CX0380  
("Magazine Wrap" Advertisements)**

306. A "magazine wrap" is a type of advertisement that covers, or wraps, the actual magazine cover. (CX1357 at 87 (Kuyoomjian, Dep. at 86)).
307. POM disseminated a *New York Times* "magazine wrap" advertisement, identified as CX0314, in fall 2008, which included the headline, "Drink to prostate health[]" with an image of the POM Juice bottle on the cover. (CX0314 at 0003).
308. CX0372, CX0379, and CX0380 are *Time* magazine wraps, disseminated in August 2009 (CX0379) and September 2009 (CX0372 and CX0380). The cover of each of these magazine wraps uses the image of the POM bottle "speaking" the headline, "Lucky I have super Health Powers!" The body copy of each advertisement, CX0372, CX0379, and CX0380, is virtually identical to the body copy of CX0314. (CX0372 at 0001-04; CX0379 at 0001-04; CX0380 at 0001-06).
309. CX0314, CX0372, CX0379 and CX0380 are reprinted in the Appendix to this Initial Decision. (Appendix at 4-26).
310. Based on the overall, common-sense, net impression of these advertisements, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0314, CX0372, CX0379, and CX0380 to contain the message that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of prostate cancer, by slowing PSA doubling times, and that these effects have been demonstrated in clinical testing. (CX0314; CX0372; CX0379; CX0380; F. 307-308, 311-319).

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311. The text on the inside front cover of each of these magazine wrap advertisements describes the results of a published study involving POM Juice, which “followed 46 men previously treated for prostate cancer . . . .” “After drinking eight ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly slower” “PSA doubling times.” The text then draws for the viewer a clear link between PSA levels and prostate cancer by immediately informing the viewer that “PSA (Prostate-Specific Antigen) is a biomarker that indicates the presence of prostate cancer. ‘PSA doubling time’ is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease.” (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).
312. CX0314 further states: “In addition, in-vitro testing using blood serum from the patients who drank pomegranate juice showed a 17% increase in prostate cancer cell death and a 12% decrease in cancer cell growth.” This language does not materially detract from the overall net impression that the efficacy of POM Juice has been demonstrated in clinical testing; however, the language does represent that the degree of clinical proof is not fully conclusive. (CX0314 at 0004).
313. The magazine wrap further states: “Backed by Science. Only POM is backed by \$25 million in medical research conducted at the world’s leading universities.” The page on which these claims appeared was titled, “The proof is in the POM.” In the context of this advertisement, these statements contribute to and reinforce an overall net impression that efficacy for prostate cancer has been demonstrated by clinical testing. (CX0314 at 0005).
314. The text on the inside front cover of each of these magazine wrap advertisements quotes Dr. Allan Pantuck, “lead author” of the study referenced in F. 311, as stating: “This is a big increase.” This language bolsters the strength and authoritative nature of the study referenced in

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the advertisements. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

315. The inside front cover of each of the magazine wraps states in part, “Results from this study were so promising that many of the original patients continued to drink pomegranate juice daily, and their PSA doubling times remained suppressed.” This statement further bolsters the strength of the referenced PSA study. Moreover, the additional statements in this paragraph that the “[r]esearch [c]ontinues” and that “[t]hree more clinical studies are now underway to further investigate the effects of POM on prostate health” do not materially detract from the overall net impression that the claimed efficacy of POM Juice for prostate cancer is based upon clinically testing. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).
316. Amid the text on the inside front cover of each of these magazine wrap advertisements is the “caduceus” symbol, showing snakes curling around a staff. In the context of this advertisement, the symbol, considered to be a symbol of medicine or medical practice, creates a “medical” tone and contributes to the overall net impression described in F. 310. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002; *see also* F. 541).
317. The overall tone of each of the magazine wraps is serious. With respect to the relationship between POM Juice and prostate cancer, the language of the advertisements is clear and affirmative, and not meaningfully qualified. (CX0314; CX0372; CX0379; CX0380).
318. The italicized statements in the middle of the inside front cover of each magazine wrap, that “[p]rostate cancer is the most commonly diagnosed cancer in men in the United States. After lung cancer, it’s the second leading cause of cancer death in men,” further reinforce the already serious tone of the advertisement. (CX0314 at 0004; CX0372 at 0002; CX0379 at 0002; CX0380 at 0002).

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319. There are elements of these magazine wraps which, in a different context, could militate against the message described in F. 310. These include: (1) generalized references to “health,” “prostate health,” and (2) general descriptions of POM’s antioxidant characteristics and relationship to free radicals. In the context of these advertisements, however, these elements do not materially detract from the message described in F. 310. Similarly, in the context of these advertisements, the reference to POM Juice being “available in your supermarket produce section” does not materially alter the overall net impression described in F. 310. (CX0314 at 0004-05; CX0372 at 0002-03; CX0379 at 0002-03; CX0380 at 0002-03).
320. In the context of these advertisements, the use of humor and/or hyperbole, such as (1) the image of the POM bottle dressed as a caped superhero (CX0314 at 0006); and (2) the POM bottle announcing “Lucky I have super HEALTH POWERS!” “HOLY HEALTH” and “100% PURE pomegranate juice to the rescue!” (CX0372 at 0001-02, 0004; CX0379 at 0001- 02; CX0380 at 0001-02, 0005-06) does not materially detract from the message described in F. 310.

**(d) CX0351/CX0355 (“The Only Antioxidant Supplement Rated X” print advertisement)**

321. The advertisements identified as CX0351 and CX0355, with the headline, “The Only Antioxidant Supplement Rated X,” were disseminated, respectively, in the publication the *Advocate* on or about June 1, 2010, and in *Playboy* magazine on or about July 1, 2010. (CX0351 at 0001-02; CX0355 at 0001-02). These advertisements are reprinted in the Appendix to this Initial Decision. (Appendix at 27-28).
322. The imagery and advertisements in CX0351 and CX0355 are substantially identical to each other. (CX0351 at 0001; CX0355 at 0001).

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323. These advertisements state and represent (1) antioxidants keep you healthy by protecting against free radicals, which “emerging science suggests” can damage the body; (2) POMx Pills give you in supplement form “super-potent,” and the best available, antioxidants, that are the same antioxidants contained in POM Juice; (3) POMx is “backed by” millions of dollars in research, showing unique and superior antioxidant power and also revealing “promising results for” “prostate, cardiovascular and erectile health.” (CX0351 at 0001; CX0355 at 0001).
324. These advertisements further state that “[i]n a preliminary study on erectile function, men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo. ‘As a powerful antioxidant, enhancing the actions of nitric oxide in vascular endothelial cells, POM has potential in the management of ED . . . further studies are warranted’. *International Journal of Impotence Research*, ‘07.” (CX0351 at 0001; CX0355 at 0001).
325. Based on the overall, common-sense net impression of CX0351 and CX0355, a significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as claiming that a clinical study has shown that taking one POMx Pill daily treats, prevents or reduces the risk of, erectile dysfunction. The advertisements specifically reference “improved erections” and “ED” and draw a direct connection between taking POMx Pills and “improved erections” and “managing” “ED.” (CX0351 at 0001; CX0355 at 0001; F. 323-324).
326. In the context of these advertisements, the use of the phrase “erectile health” or “erectile function,” rather than the express term, “erectile dysfunction” is insufficient to alter the overall net impression that the advertisement is conveying a message about erectile dysfunction. (CX0351 at 0001; CX0355 at 0001; *see also* F. 537).
327. The headline (F. 321), and the sub-headlines “[a]lways use protection,” “[s]uper-potent just like you” and “[w]e’re not

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just playing doctor,” although humorous or irreverent, in the context of these advertisements, fail to detract from the overall, net impression described in F. 325. (CX0351 at 0001; CX0355 at 0001).

**(e) CX1426 at 00038-42/Compl. Ex. I  
(POMx “Antioxidant Superpill” Package  
Insert)**

328. CX1426 at 0038-0042 (POMx “Antioxidant Superpill” package insert), which is attached to the Complaint in this matter as Exhibit I, is a brochure that was disseminated by Respondents as a package insert for shipment with POMx Pills, in or about June 2007. (CX1426 at 0038-42 (Compl. Ex. I); Answer ¶ 10; L. Resnick, Tr. 177-78; CX1356 at 180 (Leow, Dep. at 179)).
329. The package insert consists of five pages of text and images. (CX1426 at 0038-42 (Compl. Ex. I)).
330. The package insert is reprinted in the Appendix to this Initial Decision. (Appendix at 29-33).
331. Based on the overall, common-sense, net impression of CX1426 at 0038-42, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret the package insert to contain a claim that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents, or reduces the risk of prostate cancer, by slowing PSA doubling times, and that these effects have been demonstrated in clinical testing. (CX1426 at 0041 (Compl. Ex. I); F. 332, 334-336).
332. The first page of the package insert features the POMx bottle, with the headline “Antioxidant Superpill” and the sub-headline, “POM in a Pill.” The second page of the package insert represents that POMx is safe, has been reviewed for safety by the FDA, and that POMx has the same “polyphenol antioxidants” contained in POM Juice. The third page of the package insert then clearly represents a link between consuming the antioxidants

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provided by the POM products and prevention or reduction of the risk of disease, specifically including heart disease and cancer, by stating or representing: (1) POMx contains the same antioxidant power as POM Juice; (2) antioxidants fight free radicals, which “emerging science tells us” destroy healthy cells and “may be linked to . . . serious health threats like cancer and heart disease”; and (3) antioxidants “neutralize” free radicals, thereby “helping to prevent the damage that can lead to disease.” (CX1426 at 0038-40 (Compl. Ex. I)).

333. The fourth page of this package insert begins with a headlined quotation attributed to the July 4, 2006 *New York Times* that findings from a small study suggest that pomegranate juice “may one day prove” an effective weapon against prostate cancer and statements that “new studies are under way to further investigate.” This headline does not materially detract from the overall net impression that the efficacy of POMx has been demonstrated in clinical testing; however, the headline does indicate that the degree of clinical proof is not fully conclusive. (CX1426 at 0041 (Compl. Ex. I)).
334. The fourth page of the package insert states or represents that (1) “Prostate cancer is the most commonly diagnosed cancer . . . and the second-leading cause of cancer death” among men in the United States; (2) POMx is a “time pill” because “stable levels of PSA,” which is defined for the reader as “prostate-specific antigens,” are “critical for men with prostate cancer,” “[p]atients with quick PSA doubling times are more likely to die from their cancer,” and “[a]ccording to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate”; and (3) “basic studies” indicate POMx may have the same effects as POM Juice with respect to “prostate health.” (CX1426 at 0041 (Compl. Ex. I)).

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335. The package insert expressly refers to “prostate cancer.” Moreover, the representations in F. 334, especially in the context of previous representations regarding the effect of POM antioxidants on cancer (F. 332), represent a connection between the consumption of POMx, a slowing of PSA doubling times, and a beneficial effect on the progress of prostate cancer, including avoiding death from prostate cancer. (CX1426 at 0041 (Compl. Ex. I)).
336. In addition, references on the final page of the advertisement to “backed by \$20 Million in medical research” and “clinically tested on adults” tend to bolster the nature and amount of clinical research or testing supporting the efficacy of the POM products for prostate cancer. (CX1426 at 0042 (Compl. Ex. I)).
337. In the context of this advertisement, use of the phrase “promote prostate health” is insufficient to alter the overall net impression that the advertisement is conveying a message about prostate cancer. (CX1426 at 0041 (Compl. Ex. I)).
338. Based on the overall, common-sense, net impression of CX1426 at 0038-42, including the statements and representations set forth below, a significant minority of consumers, acting reasonably under the circumstances, would interpret this package insert to contain a claim that drinking eight ounces of POM Juice or taking one POMx Pill daily treats, prevents or reduces the risk, of heart disease, by reducing arterial plaque or improving blood flow to the heart, and that these effects have been demonstrated by clinical testing. (CX1426 at 0038-42 (Compl. Ex. I); F. 339-342).
339. The final page of the package insert begins with a headline, which represents that POMx may have the same “cardiovascular health benefits” as POM Juice, which has been “proven” to “promote cardiovascular health.” This page further represents: (1) “groundbreaking” “preliminary studies” showed that “patients” who drank POM Juice “experienced impressive cardiovascular results”; including (2) a “pilot” study on 19 “patients”

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with “atherosclerosis,” which the text defines for the reader as “clogged arteries,” showed that “arterial plaque decreased 30%” for those that consumed 8 oz. of POM Juice daily”; (3) an “additional study” of 45 “patients” with “impaired blood flow to the heart” who drank POM Juice daily “experienced a 17% improvement in blood flow”; (4) POMx has “similar promise” for heart health; (5) POMx is high in antioxidants; and (6) “backed by \$20 Million in medical research” and “clinically tested on adults.” Depicted within these representations is an image captioned as “the heart.” (CX1426 at 0042 (Compl. Ex. I)).

340. The representations regarding “impressive cardiovascular results,” a decrease in “clogged arteries” and “improvement in blood flow to the heart” in “patients,” appear in the context of preceding representations regarding the effect of POM antioxidants on heart disease. Moreover, the representations of “proven” heart health benefits in the headline are juxtaposed to the descriptions of these study results. (CX1426 at 0042 (Compl. Ex. I); F. 339).
341. The package insert represents a link between consumption of POM-provided antioxidants, the referenced study results, and effectiveness for heart disease. (F. 339-340).
342. In the context of this advertisement, describing studies as “preliminary,” (particularly when described as “groundbreaking”), “initial” or “pilot” is insufficient to modify the overall net impression that the claimed efficacy is based upon clinical testing; however, such language does indicate that the nature of the referenced clinical testing is not fully conclusive. (CX1426 at 0038-42 (Compl. Ex. I); F. 338-341).

**ii. Newsletters**

343. The advertisements identified as CX1426 at 0046-48, which comprises Exhibit M to the Complaint in this matter, and CX1426 at 0049-51, which comprises Exhibit N to the Complaint, were disseminated by Respondents.

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(CX1426 at 0046-51; Complaint ¶ 10; Answer ¶ 10). These advertisements are reprinted in the Appendix to this Initial Decision. (Appendix at 34-39).

344. Exhibit M to the Complaint contains a notation, “POMx Heart Newsletter, Pills and Liquid, Monthly, 2nd Continuity Shipment, Summer ‘07-present (ongoing)” (hereafter, “Heart Newsletter”). Exhibit N to the Complaint contains the notation, “POMx Prostate Newsletter, Pills and Liquid, Monthly, 3rd Continuity Shipment, Fall ‘07-present (ongoing)” (hereafter, “Prostate Newsletter”) (collectively, the “Newsletters”). (CX1426 at 0046, 0049 (Compl. Exs. M, N)).
345. Each Newsletter consists of two pages, and is dense with text. (CX1426 at 0047-48, 0050-51(Compl. Exs. M, N)).

**(a) Heart Newsletter**

346. Based on the overall, common-sense, net impression of the Heart Newsletter, including the statements and representations in F. 347-349, a significant minority of consumers, acting reasonably in the circumstances, would interpret the Heart Newsletter as claiming that that drinking eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of heart disease, by decreasing arterial plaque, or by improving blood flow to the heart, and that these effects are based upon clinical testing. (CX1426 at 0047-48 (Compl. Ex. M); F. 347-350).
347. The Heart Newsletter begins with the heading “What’s New in the Lab by Dr. Mark Dreher” followed by a photograph of Dr. Dreher next to his title: Mark Dreher, PhD, Chief Science Officer, POM Wonderful, LLC. The introductory text, by Dr. Dreher, represents that the purpose of the Heart Newsletter is to advise readers of POM Wonderful’s “latest research.” This beginning to the Heart Newsletter implies a scientific or medical message. (CX1426 at 0047 (Compl. Ex. M)).

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348. The Heart Newsletter states or represents that (1) “58.8 million Americans suffer from some form of heart disease” and that reducing the risk of “cardiovascular disease” is a core part of lifelong wellness; (2) that diet and exercise are the best weapons against “heart disease”, but may not be enough, and that supplementation with antioxidants is “your ally” in fighting “heart disease”; (3) antioxidants fight free radicals and help prevent cell and tissue damage that lead to “disease”; (4) POM Juice and POMx have polyphenol antioxidants, which are unique and superior; and (5) POMx provides antioxidant supplementation without adding the calories of POM Juice. These representations draw a connection for the reader between POM antioxidants and prevention or reduction of the risk of heart disease. (CX1426 at 0047-48 (Compl. Ex. M)).
349. The Heart Newsletter further states that POM’s “scientists have found” that POM Juice “may help counteract factors leading to arterial plaque build up, as well as inhibit a number of factors associated with heart disease.” The text then proceeds to describe these findings, from “new research,” including (1) a “pilot” study involving 19 “patients” with “clogged arteries” which found a “30% decrease in arterial plaque,” among those drinking eight ounces of POM Juice daily; and (2) a study involving 45 “patients” with “impaired blood flow to the heart,” showing “17% improved blood flow” among those who consumed eight ounces of POM Juice daily. The Heart Newsletter further states that “the antioxidants in POMx are supported by \$20 million in initial scientific research.” (CX1426 at 0048 (Compl. Ex. M)).
350. The representations set forth in F. 349, in the context of the representations in F. 348, draw a connection between reducing arterial plaque and treating, preventing, or reducing the risk of heart disease. (CX1426 at 0048 (Compl. Ex. M)).

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**(b) Prostate Newsletter**

351. Based on the overall, common-sense, net impression of the Prostate Newsletter, including the statements and representations described in F. 352 and F. 353, below, a significant minority of consumers, acting reasonably in the circumstances, would interpret the Prostate Newsletter as claiming that drinking eight ounces of POM Juice or one POMx Pill taken daily, prevents, treats, or reduces the risk of prostate cancer, by prolonging PSA doubling time, and that these effects are clinically proven. (CX1426 at 0050-51 (Compl. Ex. N); F. 352-354).
352. The Prostate Newsletter draws a clear link for the reader between antioxidants and reduction of the risk of prostate cancer, including through the following statements or representations: The Prostate Newsletter states prominently “Prostate Cancer Affects 1 Out of Every 6 Men,” and that “Prostate cancer is the second leading cause of cancer related death in men in the United States . . . .” The associated text discusses “risk factors” for prostate cancer, including “diet,” and advises a diet that includes, among other things, “fruits rich in antioxidants.” (CX1426 at 0050-51 (Compl. Ex. N)).
353. The Prostate Newsletter draws a connection for the reader between research results showing prolonged PSA doubling time and effectiveness for prostate cancer, including through statements or representations that: early detection, including through a PSA test, increases prostate cancer survival rates; a “preliminary UCLA medical study” on 46 men treated for prostate cancer, showed that a majority of those consuming eight ounces of POM Juice daily “experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression – extended doubling time may indicate slower disease progression”; testing on “patient” blood serum showed a decrease in “cancer cell proliferation,” and “increase in cancer cell death”; in another study, “in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death” and that POMx has the

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same active ingredients in POM Juice. (CX1426 at 0050-51 (Compl. Ex. N)).

354. In the context of the Prostate Newsletter, reference to research as “preliminary” or “*in vitro*” is insufficient to modify the claim described in F. 351 that the claimed efficacy is based upon clinical testing, particularly in light of other statements and representations promoting the strength and credibility of the research, as part of \$25 million in “world-class research” including “clinical studies published in top peer-reviewed medical journals.” Such language does, however, indicate that the degree of proof provided by the referenced studies is not fully conclusive. (CX1426 at 0050-51 (Compl. Ex. N)).

**iii. Website advertising****(a) Website background facts**

355. POM’s websites include pomwonderful.com, pomegranatetruth.com, and pompills.com (collectively, the “websites”). (JX0003 ¶ B.11; Rushton, Tr. 1354-55; Leow, Tr. 433).
356. POM has maintained the pomwonderful.com website since approximately January 2003. (CX0013 at 0004). It has maintained the pomegranatetruth.com website since approximately January 2008. (CX0170 at 0002). POM launched pompills.com in early 2007. (CX1347 (Glovsky, Dep. at 135-36)).
357. Since at least September 2007, POM has had an online department. The online department is part of POM’s marketing department and handles anything related to the Internet, including marketing, engagement, interaction, and development. (Rushton, Tr. 1353-54).
358. Jeffrey Rushton was the Director of Marketing for Online for POM Wonderful, from September 2007 through March 2010. (Rushton, Tr. 1353).

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359. In approximately 2008, POM converted pomwonderful.com from a traditional static format to a blog format that sought engagement from external sources. (Rushton, Tr. 1354). POM launched this “Community” version of pomwonderful.com in approximately December 2009. (CX0473 (Dec. 2009, pomwonderful.com)).
360. In October 2009, one of the rotating frames on the pomwonderful.com homepage welcomed consumers to its “new community site.” (CX0473 (Oct. 2009, pomwonderful.com at 00:25)). The “community” design encouraged website visitors to “participate,” including by “Tell[ing] Us Your Health Story.” (CX0473 (Oct. 2009, pomwonderful.com at 00:25)).
361. Testimonials appeared on the POM Wonderful website briefly, for much less than a year. (L. Resnick, Tr. 134).
362. The “Community” section of the pomwonderful.com site also featured blog posts and videos by “POM Experts” like Dr. Aviram, Dr. Heber, and Susan Bowerman, Assistant Director at the UCLA Center for Human Nutrition. (CX0473 (Oct. 2009, pomwonderful.com at 06:52)). POM paid Susan Bowerman to, among other things, write blog posts for pomwonderful.com. (CX0203 at 0001; CX1346 (Rushton, Dep. at 145)).
363. To direct traffic to its website, POM used keyword advertising with search engines. With keyword advertising, marketers can pay for their advertisements to appear on the search results pages of search engines such as Google, Yahoo, Bing, among others, by purchasing keywords that consumers may search for. (Rushton, Tr. 1357-58).
364. Examples of keywords POM has used in its search engine advertising include: “prostate cancer prevention,” “prostate cancer info,” “prostate cancer research,” and “cancer prostate.” (CX0427 at 0004-05, 0007-08; Rushton, Tr. 1387-89).

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**(b) Website claims**

365. CX0473 consists of electronically recorded “captures” of Respondents’ websites on particular dates, as follows:

Pomwonderful.com – April, October, December, 2009 and January 2010;

Pompills.com – April 2009 and January 2010; and

Pomegranatetruth.com – April 2009

(CX0473).

366. Each website capture reflects an electronic recording of navigation through the pages of the subject website, “clicking” on various hyperlinks to other pages. The web captures total approximately 95 minutes of material, with each capture totaling approximately 15 minutes in length, except for CX0473 Ex. E-1 (pomegranatetruth.com), which is approximately 5 minutes in length. (CX0473).
367. Printouts of those pages referred to in the following findings are reprinted in the Appendix to this Initial Decision. (Appendix at 40-93).

**(i) Pomwonderful.com**

368. Based on the overall, common-sense, net impression of the pomwonderful.com website, including the “health benefits” or “health” pages and links therefrom, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pomwonderful.com website as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction, and that these effects are shown in clinical testing, as more fully explained below. (CX0473 (pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, January 2010); F. 369-381).

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369. In April 2009, the pomwonderful.com homepage included a link to a “health benefits” page. (CX0473 (Compl. Ex. E-2 at 00:04 and 00:15)).
370. In April 2009, the linked “health benefits” webpage displayed a large graphic depicting the POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in the manner of a hospital intravenous line, while the juxtaposed text refers to POM Juice being “backed by” \$25 million in “medical research” and “clinically tested.” The page then introduces the “medical results” in separate areas designated “cardiovascular health,” “prostate health,” and “erectile function” sections. Introductory text in each such section summarizes research, with the cardiovascular section providing a further link to “read more.” (CX0473 (Compl. Ex. E-2 at 00:17)).
371. In April 2009, the “Prostate Health” section of the health benefits webpage described “[a] preliminary UCLA medical study” on “46 men previously treated for prostate cancer,” published by “The American Association for Cancer Research,” showing that after drinking eight ounces of POM Juice daily for two years, “these men experienced significantly slower PSA doubling times.” The description clearly links the significance of this research finding to prostate cancer, stating “PSA is a biomarker for prostate cancer, and slower PSA doubling time may indicate slower disease progression.” (CX0473 (Compl. Ex. E-2 at 00:24)).
372. In April 2009, the “Erectile Function” section of the health benefits webpage reported a 2007 “pilot” study, published in the *International Journal of Impotence Research*, involving 61 male subjects with “mild to moderate erectile dysfunction,” showing that those men drinking eight ounces of POM Juice daily for four weeks “were 50% more likely to experience improved erections.” (CX0473 (Compl. Ex. E-2 at 00:24)).
373. In April 2009, the “Cardiovascular” section of the health benefits webpage described the results of studies as

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follows: (1) a 2005 study published in the *American Journal of Cardiology*, involving 45 “patients” with “coronary heart disease who had reduced blood flow to the heart,” showed that “patients” who drank eight ounces of POM Juice daily had “improved blood flow to the heart,” while those who did not drink POM Juice got worse; and (2) a “pilot” study on 19 “patients” with “atherosclerosis,” which the text defines for the reader as “clogged arteries,” showing that those “patients” who drank eight ounces of POM Juice daily for one year showed a decrease in arterial plaque, while those who did not drink POM Juice got worse. Each of these study descriptions offered a “read more” link. (CX0473 (Compl. Ex. E-2 at 00:24)).

374. In April 2009, the “read more” link from the “Cardiovascular” section of the health benefits webpage took the viewer to a page titled, “Heart Health-Emerging Science.” The text advises the reader that “heart disease” is a leading killer of men and women in the United States, that “atherosclerosis,” which is defined for the readers as too much “plaque,” is a leading factor in “heart attacks” and further describes the role of antioxidants in reducing LDL (defined as “bad” cholesterol) oxidation. The text then invites the reader who wants to learn more about consumption of POM Juice and cardiovascular health, to “click on” the links to a 2005 study on effect of pomegranate on myocardial perfusion published in the *American Journal of Cardiology*; a 2004 study on reduction of carotid intima-media thickness, blood pressure and LDL oxidation, published in the journal, *Clinical Nutrition*; and a 2001 study on reduction of systolic blood pressure, published in the journal, *Atherosclerosis*. This page draws a clear connection for the reader between “heart health” and “heart disease,” and between the effects referenced in the studies and effectiveness for heart disease. (CX0473 (Compl. Ex. E-2 at 00:30)).
375. While the link to the 2005 myocardial perfusion study (F. 374) took the viewer to a reprint of a copy of the actual published study, (CX0473 (Compl. Ex. E-2 at 00:45)), the link to the 2004 study on reduction of carotid intima-

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media thickness, blood pressure and LDL oxidation (F. 374)) took the viewer to a further description of the study with highlighted commentary by Dr. Aviram and graphs emphasizing the reduced plaque and “anti-atherosclerotic” effects of POM Juice. At the top of this page was a quote attributed to Dr. Aviram that “[t]he present study clearly demonstrates for the first time that pomegranate juice consumption by patients with carotid artery stenosis possesses anti-atherosclerotic properties.” (CX0473 (Compl. Ex. E-2 at 01:00, 01:06)).

376. The link to the 2001 study on reduction of systolic blood pressure (F. 374) took the viewer to a further description of the study. The description begins: “This pilot study demonstrates that pomegranate juice lowers blood pressure in patients with hypertension.” A quote attributed to Dr. Aviram states that the “potent inhibitory effect on lipid peroxidation” and the “inhibitory effect of pomegranate juice on serum ACE activity” “suggest[] that pomegranate juice consumption may offer wide protection against cardiovascular diseases.” The decreased ACE (angiotensin converting enzyme) activity is illustrated by a graph. (CX0473 (Compl. Ex. E-2 at 01:25)).
377. In April 2009, the “Health Benefits” section of pomwonderful.com also included links to other pages, including one titled, “Cancer.” (CX0473 (Compl. Ex. E-2 at 01:44)).
378. In April 2009, the linked “Cancer” page stated: “Emerging science has shown that diets rich in fruits and vegetables that contain antioxidants, along with regular exercise, might slow or help prevent the development of cancer. Two great sources of antioxidants are POM Wonderful Pomegranate Juice and POM Tea.” The page featured a link to the “Clinical Cancer Research.” (CX0473 (Compl. Ex. E-2 at 03:45)).
379. In April 2009, pomwonderful.com included a “Glossary,” which was linked to the “Health Benefits” page. A number of definitions reasserted and reinforced the study results referred to F. 374-376. For example, the

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definitions of “Atherosclerosis,” “ACE” (*i.e.*, angiotensin-converting enzyme), and “plaque” provided in the glossary explain for the reader the purported connection between the effects shown by the study results and effects for heart disease. (CX0473 (Compl. Ex. E-2 at 01:44, 04:15-07:08)).

380. Having fully reviewed later versions of the pomwonderful website, captured in October and December in 2009, and January 2010, they are not materially different with respect to linking viewers to text summarizing research results, under the categories of cardiovascular, prostate cancer, and erectile “function,” and drawing a connection for the reader between consumption of POM antioxidants, the research results summarized, and the prevention, treatment, or reduction of the risk of diseases associated with the conditions addressed in the research results. Thus, these later versions of the pomwonderful website also convey the claims described in F. 368 as to the April 2009 website. (CX0473; F. 381).
381. As an example that later versions of the pomwonderful website also convey the claims described in F. 368 as to the April 2009 website, in October 2009, links from the “health” page directed the viewer to a “research study synopses,” link, which page further stated *inter alia*: (1) under “cardiovascular,” the rate of “CIMT progression” slowed in nearly one-third of the “patients” having “cardiovascular risk factors,” (CX0473 (Oct. 2009, pomwonderful.com at 02:43)); (2) under “prostate cancer,” that “PSA doubling time increased” among the POM Juice drinkers, and that “PSA doubling time is an indicator of prostate cancer progression, (*Id.*); and (3) under “Erectile Function,” that POM Juice drinkers “reported 50% greater likelihood of experiencing improved erections.” (*Id.* at 02:52; *see also* CX0473 (January 2010, pomwonderful.com at 00:26; 00:50, “Featured Scientific Studies” page)); CX0473 (December 2009, pomwonderful.com, “Let’s Talk about Prostate Cancer” video, in which Dr. Heber states, *inter alia*, that “pomegranate inhibits inflammation in the prostate gland, that it also inhibits prostate cancer growth in animals, both

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in early prostate cancer and advanced prostate cancer. And in humans, we were able to reduce the rate of rise of PSA in men with prostate cancer”); CX0473 (Dec. 2009, pomwonderful.com at 08:06; CX0473 (Jan. 2010, pomwonderful.com at 00:54, and CX0473 (October 2009 pomwonderful.com at 7:25 (Dr. Aviram stating, regarding “The Unique Antioxidants of Pomegranates,” that pomegranates inhibit “atherosclerosis development, . . . as well as its consequent cardiovascular events”)).

382. The “POM Community” section of pomwonderful.com in December 2009 included consumer testimonials. (CX0336 at 0011-19).
383. Testimonials were in the “POM Community” section of pomwonderful.com for much less than a year. (L. Resnick, Tr. 134).
384. Attached to the expert report of Respondents’ linguistic expert, Dr. Butters, is a copy of what Dr. Butters identified as printouts from the pomwonderful.com website in 2011, taken on or before March 25, 2011, the date of Dr. Butters’ report. As of that date, the “health” page omits reference to “protective effects,” does not refer to any diseases, and does not summarize research results. The linked “glossary” omits the references described in F. 379. (PX0158 (Butters Expert Report at 0042); PX0160 at 0029-36, 0038-53, attachment 3) (“2011 website”)).
385. The health page of the 2011 website (F. 384) does provide a link to “view studies” on the POM products, which when activated brings up a disclaimer that the studies are not “intended to make express or implied health or disease claims, . . . do not constitute . . . advertising for any POM Wonderful product. . . . Instead they are intended solely for general educational and informational purposes.” The linked website is titled “wonderfulpomegranateresearch.com.” (PX0158 (Butters Expert Report); PX0160 at 0036-37, attachment 3)).

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**(ii) Pompills.com**

386. The pompills.com website is an e-commerce site that contains everything from learning about the product to ordering the product. (CX1347 (Glovsky, Dep. at 135)).
387. Based on the overall, common-sense, net impression of the pompills.com website, including the “health benefits” or “medical research” sections and the links to other information included therein, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pompills.com website to be claiming that taking one POMx Pill, or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease, prostate cancer, and/or erectile dysfunction, and that these effects are shown in clinical testing, as explained more fully below. (CX0473 (Pompills.com website: April 2009 (Compl. Ex. E-8)), January 2010 (Compl. Ex. E-9); F. 388-410).
388. In April 2009, the menu bar on the home page of pompills.com contained links, *inter alia*, to “POMx Pills,” “POMx Liquid,” “health benefits” and “Buy Now.” In January 2010, the menu bar was the same but the “health benefits” link is replaced by a link to “medical research.” (CX0473 (Compl. Ex. E-8 at 00:10); CX0473 (Compl. Ex. E-9 at 00:04)).
389. A review of the April 2009 and January 2010 web captures show that the pompills.com website made substantially the same representations as those contained in POMx Pill print advertising, described in F. 323 and F. 332, including that POMx Pills provide the same antioxidant “power” as POM Juice, without the calories (CX0473 (Compl. Ex. E-8 at 00:15-00:25); CX0473 (Compl. Ex. E-9 at 00:16)); that POMx Pills have the best available, polyphenol antioxidants (CX0473 (Compl. Ex. E-8 at 00:25); CX0473 (Compl. Ex. E-9 at 00:16, 00:30)); and that antioxidants “fight” free radicals which are linked to, among other things, “cancer and heart disease.” (CX0473 (Compl. Ex. E-8 at 04:37); CX0473 (Compl. Ex.

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E-9 at 01:01); *see also* CX0351; CX0355; CX1426 at 0040 (Compl. Ex. I) (POMx package insert)).

390. In April 2009, the POMx Liquid page on [pompills.com](http://pompills.com) stated that POMx Liquid is “the most concentrated source of pomegranate antioxidants available,” and that “POMx Liquid is a highly concentrated, incredibly powerful blend of all-natural polyphenol antioxidants made from the very same pomegranates in POM Wonderful 100% Pomegranate Juice.” The page also depicted the POMx Liquid bottle and teaspoon with the caption, “One teaspoon = the antioxidant power of 8oz. of POM Wonderful 100% Pomegranate Juice” and a link to “BUY NOW.” The menu bar on the POMx Liquid webpage also included a link to “health benefits.” (CX0473 (Compl. Ex. E-8 at 01:00 1:38)).
391. In April 2009, under the subheading “Science, Not Fiction,” the POMx Pills page represented, *inter alia*, that POMx is “backed by \$25 million in medical research,” and is “[c]linically tested.” (CX0473 (Compl. Ex. E-8 at 00:35); *see also* January 2010 [pompills.com](http://pompills.com) (CX0473 (Compl. Ex. E-9 at 00:16 (\$32 million); CX1426 at 0040 (Compl. Ex. I) (POMx package insert (\$20 Million in research))).
392. In April 2009 and January 2010, the POMx Liquid page on [pompills.com](http://pompills.com) contained the same language as set forth in F. 392 that appeared on the POMx Pills page. (*Compare* CX0473 (Compl. Ex. E-8 at 00:35) *with* CX0473 (Compl. Ex. E-8 at 01:15); *see also* January 2010 [pompills.com](http://pompills.com) (CX0473 (Compl. Ex. E-9 at 00:30)(\$32 million in research)).
393. In April 2009, and in January 2010, the “Health Benefits” section of [pompills.com](http://pompills.com) offered further links to web pages titled, “Research,” “Antioxidant Benefits,” “Heart Health,” and “Prostate Health.” (CX0473 (Compl. Ex. E-8 at 01:38); CX0473 (Compl. Ex. E-9 at 00:36)).
394. In April 2009, and in January 2010, the “Heart Health” section advised the reader that arterial plaque buildup is

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one of a number of factors “associated with heart disease” that POM Juice consumption may help “counteract.” In the context of this webpage, the term, “heart health” implies “heart disease.” (CX0473 (Compl. Ex. E-8 at 05:05); CX0473 (Compl. Ex. E-9 at 00:36).

395. In April 2009, the “Learn more” link on the “Heart Health” webpage took the consumer to a page titled “The Heart of The Matter.” This page, in April 2009 and in January 2010, noted that atherosclerosis, defined for the reader as “too much plaque in the arteries[is a leading cause of heart disease” and that “pomegranate antioxidants neutralize free radicals,” which “can oxidize LDL (also known as ‘bad’ cholesterol – turning it into plaque that clogs up arteries.” This page then summarizes results of the Aviram Carotid Intima-media Thickness/Blood Pressure (“CIIMT/BP”) Study and the Ornish Myocardial Perfusion (MP) Study in a manner that is substantially similar to the summaries on pomwonderful.com. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); CX0473 (Compl. Ex. E-9 at 01:22); *see* F. 373-374).
396. In April 2009, and in January 2010, the linked “Heart of The Matter” page on pompills.com displayed a large image of the caduceus symbol, juxtaposed to a subheading “Amaze your cardiologist. Take POMx.” This language and imagery convey a medical message. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); CX0473 (Compl. Ex. E-9 at 01:22)).
397. The language on the “Heart of The Matter” page of the pompills.com website that POMx is made from pomegranates “supported by \$25 million of initial scientific research” reinforces the message that the efficacy of POMx for heart disease is demonstrated by the results of clinical research. (CX0473 (Compl. Ex. E-8 at 05:09-05:10); *see also* CX0473 (Compl. Ex. E-9 at 01:22 (“supported by \$32 million”)).
398. In April 2009, the “Antioxidant Benefits” page of the pompills.com website advised the reader that “antioxidants neutralize free radicals,” which are “linked

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to [among other things] cancer and heart disease,” and that POMx is made from pomegranates having “\$25 million in medical research behind them.” This language, which also appears in the January 2010 version of pompills.com (“\$32 million”), draws a connection for the viewer between antioxidants and disease, and conveys the message of scientific support for the website’s claims. (CX0473 (Compl. Ex. E-8 at 04:37, 04:50); CX0473 (Compl. Ex. E-9 at 01:01)).

399. In April 2009, the “Research” link on the “Health Benefits” section of pompills.com took the viewer to a list of linked studies, including “Cardiovascular” studies and “Cancer” studies. The text of the links include: “Pomegranate juice improves myocardial perfusion in coronary heart patients,” “Pomegranate juice pilot research suggests anti-atherosclerosis benefits,” “Pomegranate juice helps promote normal systolic blood pressure.” The “Research” page of the January 2010 version of pompills.com contains the same text. (CX0473 (Compl. Ex. E-8 at 01:38); CX0473 (Compl. Ex. E-8 at 01:43-04:23); CX0473 (Compl. Ex. E-9 at 00:55))
400. Some of the linked study titles referred to in F. 399 appear to be paraphrases of the studies’ actual titles. (CX0473 (Compl. Ex. E-8 at 01:43-04:23); *see, e.g.*, CX0473 (Compl. Ex. E-8 at 02:10) (study listed as “Pomegranate juice improves myocardial perfusion in coronary heart patients,” was published with the title, “*Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*”); CX0473 (Compl. Ex. E-8 at 02:45) (study listed as “Pomegranate juice delays PSA doubling time in humans,” was published with the title “*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer*”)).
401. In April 2009, and in January 2010, the “Prostate Health” section of the “Health Benefits” page on pompills.com stated: “A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful

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results for men with prostate cancer who drank an 8oz. glass of pomegranate juice daily. And every POMx capsule provides the antioxidant power of an 8oz. glass of POM Wonderful 100% Pomegranate Juice. Learn more.” (CX0473 (Compl. Ex. E-8 at 05:50); CX0473 (Compl. Ex. E-9 at 00:36) (underlined hyperlink in original)). The “Learn more” link took the consumer to a page titled “Pomegranates and Prostate Health.” (CX0473 (Compl. Ex. E-8 at 05:55)).

402. Like “The Heart of the Matter” page (F. 397), in April 2009, the “Pomegranates and Prostate Health” page displayed the caduceus symbol. (CX0473 (Compl. Ex. E-8 at 05:55)).
403. In April 2009, on the “Pomegranates and Prostate Health” page of the [pompills.com](#) website, the explanatory text under the subheading “Prostate Health” states or represents: “Prostate cancer is the most commonly diagnosed cancer among men in the United States, and the second leading cause of cancer death in men, after lung cancer.” In the context of this webpage, the reference to “prostate health” clearly implies “prostate cancer.” The text then describes a study in which “A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time. . . . Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8oz. of juice daily, the average PSA doubling time increased to 54 months. That’s a 350% increase.” (CX0473 (Compl. Ex. E-8 at 05:55)).
404. The April 2009 the “Pomegranates and Prostate Health” page of the [pompills.com](#) website further linked the study results showing prolongation of PSA doubling time to the progress of prostate cancer, explaining “PSA (prostate-specific antigen) is a marker that is thought to be associated with the progression of prostate cancer; a slower PSA doubling time may reflect slower progression of the disease.” Placing the mouse over the hyperlinked word “doubling time” produced a pop-up text box that reiterated: “The amount of time it takes for the prostate-

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specific antigen[s] (also called PSA levels) to double in men with prostate cancer may reflect the progression of the disease. A longer doubling time may indicate a slower growing cancer.” (CX0473 (Compl. Ex. E-8 at 05:55-05:59, underlined hyperlink in original)).

405. The April 2009 the “Pomegranates and Prostate Health” page further represented that study results for POM Juice should apply to POMx by quoting Dr. Heber, identified as “Director of UCLA’s Center for Human Nutrition,” as stating: “The most abundant and most active ingredients in Pomegranate Juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and Pomegranate Juice have the same effect on prostate health.” The foregoing text was printed in bold font and was italicized. (CX0473 (Compl. Ex. E-8 at 05:59)).
406. In April 2009, the pomfills.com website also featured a “FAQs” page. (CX0473 (Compl. Ex. E-8 at 07:51)).
407. In April 2009, the response to the FAQ “Heart Disease: How does drinking pomegranate juice help the fight against cardiovascular disease?” stated: (1) “Improved Cardiac Blood flow,” juxtaposed to the representation that a “published human study . . . [on] 45 patients with impaired blood flow to the heart” showed that “[p]atients” who drank eight ounces of POM Juice “daily” experienced “improved blood flow” while the blood flow of the placebo group declined; and (2) “Decrease in Arterial Plaque” juxtaposed to the representation that “[a]nother published human study . . . [on] 19 patients with atherosclerosis (clogged arteries) showed that, for those who drank eight ounces of POM Juice “daily,” “artery plaque decreased 30%” while the placebo group experienced a worsening of arterial plaque buildup. This page further represented that results for POM Juice are applicable to POMx by quoting Dr. Aviram, identified as “one of the world’s preeminent cardiovascular researchers,” as commenting: “The results of our pre-clinical studies showed that POMx is as potent an antioxidant as pomegranate juice, and just like pomegranate juice may promote cardiovascular health.”

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The foregoing quotation was italicized. (CX0473 (Compl. Ex. E-8 at 09:05)).

408. In April 2009, the response to the FAQ “Erectile Dysfunction” stated: “Can pomegranate juice benefit men with erectile dysfunction?” stated: “Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8oz. of POM Juice daily experienced better erectile performance than the group who drank a placebo.” (CX0473 (Compl. Ex. E-8 at 9:05)).
409. In April 2009, the response to the FAQ “Prostate Cancer” stated: “There has been promising news on the benefits of pomegranate juice in the fight against prostate cancer. Is this really true?” summarized study results showing the effect of POM Juice on extending PSA doubling times (the Pantuck Phase II Prostate Cancer Study (2006)). (CX0473 (Compl. Ex. E-8 at 09:05)). The answer went on to state that “[a] new study is underway to more fully investigate the potential of POMx to extend PSA doubling time” and quoted Dr. Heber, identified as “Director of UCLA’s Center for Human Nutrition,” as commenting, “The most abundant and most active ingredients in pomegranate juice are also found in POMx. Basic studies in our laboratory so far indicate that POMx and pomegranate juice may have the same effects.” The foregoing quotation was italicized. (CX0473 (Compl. Ex. E-8 at 09:05)).
410. In April 2009, the response to the FAQ, “Dosage: How much POMx should I take?” stated: “Whether you choose pills or liquid, it is important to remember that to reap POMx’s full health benefits: you must take it every day.” (CX0473 (Compl. Ex. E-8 at 11:03)).

**(iii)Pomegranatetruth.com**

411. Based on the overall, common-sense, net impression of the pomegranatetruth.com website, including the “backed by science” and “heart health-emerging science” sections and

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links therefrom, a significant minority of consumers, acting reasonably in the circumstances, would interpret the pomegranatetruth.com website as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, and that these effects are clinically proven, as explained more fully below. (CX0473 pomegranatetruth.com (Compl. Ex. E-1); F. 412-414)).

412. In April 2009, the home page of pomegranatetruth.com stated or represented that POM is 100% authentic pomegranate juice, obtained through a unique process, and is the only pomegranate juice “backed by \$25 million in medical research” including “clinical studies” documenting its benefits, including heart benefits, prostate health, and “better erectile function.” Each subsection contained a “read more” link. This page displayed the caduceus symbol next to the “backed by science” reference. (CX0473 (Compl. Ex. E-1 at 00:10)).
413. The linked “Backed By Science” page on the pomegranatetruth.com website proceeded to introduce the “medical results” on POM Juice, dividing into subsections on “Heart Health,” “Prostate Health” and “Erectile Dysfunction.” The “Heart Health” section provided a “read more” link. (CX0473 (Compl. Ex. E-1 at 01:15)).
414. The linked “heart health” page on the pomegranatetruth.com website contained the headline “Heart Health – Emerging Science.” The text advises the reader that “heart disease” is a leading killer of men and women in the United States, that “atherosclerosis,” which is defined for the reader as too much “plaque,” is a leading factor in “heart attacks” and the role of antioxidants in reducing LDL (defined as “bad” cholesterol) oxidation. The text then invites the reader who wants to learn more about consumption of POM and cardiovascular health to review research studies on the effects of pomegranate on myocardial perfusion, reduction of carotid intima-media thickness, blood pressure, and LDL oxidation; and reducing systolic blood pressure. This page draws a clear connection for the reader between “heart health” and

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“heart disease,” and between the effects shown by the studies and the prevention, treatment or reduction of the risk of heart disease. (CX0473 (Compl. Ex. E-1 at 01:45)).

415. CX0473 Compl. Ex. E-1 does not show the content of the “prostate” page or the “erectile health” page, referred to in F. 413.

**iv. Press releases****(a) January 2003 Press Release (CX0013)**

416. POM issued a press release in January 2003 titled “Consumer Demand for POM Wonderful’s Refrigerated All-Natural Pomegranate Juice Grows as the Health Benefits of Pomegranate Juice Become Recognized.” (CX0013 at 0002-05). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 94-97).
417. Based on the overall, common-sense, net impression of CX0013, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by reducing arterial plaque, and that the effects have been clinically proven. (CX0013 at 0002-05; F. 418-420).
418. This press release had the subtitle, “Scientific support indicates that drinking pomegranate juice provides the body with an active source of antioxidants and shows promise against cardiovascular disease.” (CX0013 at 0002).
419. This press release further states or represents that “cardiovascular diseases rank as America’s No. 1 killer,” and that 61.8 million Americans have some form of “cardiovascular disease such as diseases of the heart, high blood pressure, and hardening of the arteries.” This release further states that “[m]edical research shows that daily consumption” of eight ounces of POM Juice

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“confers heart health benefits by lessening factors that contribute to atherosclerosis,” which is defined for the reader as “plaque in the arteries.” (CX0013 at 0002).

420. A paragraph titled “Effects on Heart Health” asserts that “[n]ew research is showing that antioxidants can play a highly beneficial role in reducing one of the major risk factors in heart disease: atherosclerosis (plaque in the arteries),” and explains the connection between “progression of atherosclerosis,” “oxidation of LDL cholesterol” and “adhesion of LDL molecules” to the blood vessel. The paragraph further explains that (1) “one human study” showed that drinking eight ounces of POM Juice for two weeks “lowered” LDC oxidation, “clumping and adhesion” and (2) an “additional human study showed that consuming pomegranate juice reduces . . . ACE (angiotensin converting enzyme)” which “lessens the progression of atherosclerosis.” “Pomegranate juice inhibited ACE by 36% after two weeks of juice consumption” and a “5% decrease in systolic blood pressure . . . a known risk factor for atherosclerosis.” (CX0013 at 0003).

**(b) September 2005 Press Release (CX0044)**

421. POM issued a press release in September 2005 titled, “Pomegranate Juice May Affect the Progression of Coronary Heart Disease,” which highlighted the results of the Ornish MP Study (2005). (CX0044 at 0001). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 98-99).
422. Based on the overall, common-sense, net impression of CX0044, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by improving blood flow to the heart, and that clinical studies prove these effects. (CX0044 at 0001; F. 423-427).
423. This press release stated that “Men and women with coronary heart disease who drink one glass of

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pomegranate juice daily may improve blood flow to their heart, according to a new study.” (CX0044 at 0001).

424. This press release described “the first randomized, double-blind, placebo-controlled trial showing that pomegranate juice may affect the progression of coronary heart disease, which is the #1 cause of death in the U.S. and in most of the world” and that “results . . . [would] be published in . . . the American Journal of Cardiology, one of the leading peer-reviewed cardiology journals.” (CX0044 at 0001).
425. This press release described the study as involving 45 “patients” with “coronary heart disease” having “reduced blood flow to the heart” and reported that the results showed “blood flow to the heart improved” in those drinking a daily glass of pomegranate juice, but showed worsening in the comparison group. (CX0044 at 0001).
426. The press release explained that “[p]omegranate juice from POM Wonderful was used in this study.” (CX0044 at 0002).
427. Dr. Ornish, identified as senior author of the referenced study (F. 424), founder of the Preventive Medicine Research Institute, and clinical professor of medicine at UCSF, is quoted as stating that although the study sample was “relatively small,” “the strength of the design and the significant improvements in blood flow to the heart observed after only three months suggest that pomegranate juice may have important clinical benefits in those with coronary heart disease” and that “[a]lso, it may help to prevent it.” In the context of Dr. Ornish’s entire statement, and in the context of the press release as a whole, the reference to a small sample, and use of words “suggest” and “may have” do not materially modify the overall net impression from the press release described in F. 422. (CX0044 at 0002).

**(c) July 2006 Press Release (CX0065)**

428. POM issued a press release in July 2006 titled, “POMx, a Highly Concentrated Form of Healthy Pomegranate

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Antioxidants, Becomes Available to Consumers for the First Time.” (CX0065 at 0001-02). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 100-101).

429. Based on the overall, common-sense, net impression of CX0065, a significant minority of reasonable consumers would interpret this press release as claiming that that drinking eight ounces of POM Juice or taking one POMx Pill daily, treats prostate cancer by prolonging PSADT and that these effects have been demonstrated by clinical studies. (CX0065 at 0001-02; F. 430-431).
430. This press release discussed research published by the American Association for Cancer Research “indicat[ing] that a daily pomegranate regimen has a positive effect for men with prostate cancer” and that “[s]pecifically, drinking 8 ounces of POM Wonderful pomegranate juice daily prolonged post-prostate surgery PSA doubling time from 15 to 54 months (*Clinical Cancer Research*, July 1, 2006). PSA is a protein marker for prostate cancer and the faster PSA levels increase in the blood of men after treatment, the greater their potential for dying of prostate cancer.” (CX0065 at 0002).
431. This press release represented that study results using POM Juice are applicable to POMx, by quoting Dr. Heber, identified as “Professor of Medicine and Director, UCLA Center for Human Nutrition,” as stating, “[b]asic studies indicate that the effects of POMx and POM Wonderful pomegranate juice on prostate cancer are the same. The most abundant and most active ingredients in pomegranate juice are also found in POMx.” (CX0065 at 0002).

**(d) June 2007 Press Release (CX0128)**

432. POM issued a press release in June 2007 titled, “POM Wonderful 100% Pomegranate Juice May Improve Mild to Moderate Cases of Erectile Dysfunction, Study Finds.” (CX0128 at 0002-04). A copy of this press release is reprinted in the Appendix to this Initial Decision. (Appendix at 102-104).

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433. Based on the overall, common-sense, net impression of CX0128, a significant minority of reasonable consumers would interpret this press release as claiming that drinking eight ounces of POM Juice treats erectile dysfunction, and that this effect has been demonstrated by clinical studies. (CX0128 at 0002-04; F. 434-439).
434. This press release stated, “[r]esearch shows 8 ounces a day of POM Wonderful 100% Pomegranate Juice may help the management of erectile dysfunction” and “[a]ccording to a pilot study released in the *International Journal of Impotence Research* (<http://www.nature.com/ijir>), POM Wonderful 100% Pomegranate Juice was found to have beneficial effects on erectile dysfunction (ED), a disorder that affects 1 in 10 men worldwide and 10 to 30 million men in the United States alone.” (CX0128 at 0002).
435. This press release describes the study as a “randomized, placebo-controlled, double-blind, crossover pilot study” on the “efficacy of pomegranate juice,” and notes that “to qualify” for the study, among other things, the “participants had to experience mild to moderate ED for at least 3 months.” The press release defined “mild” and “moderate” ED in relation to the extent of the “decreased ability to get and keep an erection.” (CX0128 at 0002).
436. This press release reported the results as showing that “[f]orty-seven percent of the subjects reported that their erections improved with POM Wonderful Pomegranate Juice.” (CX0128 at 0003).
437. The press release attributed the study results of improved erections to “enhance[d] blood flow,” which is an effect of “potent pomegranate antioxidants,” noting that in “previously published medical studies, pomegranate juice has been shown to enhance blood flow.” (CX0128 at 0003).
438. The press release disclosed that the “study did not achieve overall statistical significance”; however, in the context of the press release as a whole, this disclosure does not

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materially modify the overall net impression described in F. 433. (CX0128 at 0002-04).

439. Use of the phrase, “may help,” in the overall context of this press release, is insufficient to modify the net impression of the press release as a whole, described in F. 433. (CX0128 at 0002-04).

**b. Alleged efficacy claims**

**i. CX0031 (“Floss your arteries. Daily”)**

440. The advertisement identified as CX0031 (Floss your arteries. Daily) was disseminated on or about December 1, 2004. (CX0031 at 0001-02).
441. CX0031 is reprinted in the Appendix to this Initial Decision. (Appendix at 105).
442. POM first ran this advertisement in 2004 and stopped running it that same year. The “Floss your arteries” headline, image and body copy have not run as part of any advertisement since 2004. (Tupper, Tr. 2995-96).
443. Based on the overall, common-sense, net impression of the advertisement, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0031 to contain the message that drinking eight ounces of POM Juice daily treats, prevents or reduces the risk of heart disease, by reducing arterial plaque. (CX0031 at 0001; F. 444-445).
444. This advertisement draws a connection between the consumption of POM Juice and the prevention, treatment or reduction of the risk of heart disease, through statements and/or representations that (1) POM Juice has more antioxidants than other drinks; (2) antioxidants fight free radicals; (3) free radicals cause “artery clogging plaque”; (4) consumption of POM Juice “can reduce plaque by up to 30%!”; and (5) “Clogged arteries lead to heart trouble. It’s that simple. That’s where we come in.” (CX0031 at 0001).

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445. The headline, “Floss your arteries. Daily,” is clearly an exaggeration which would not be taken literally; however, in the context of this advertisement, the headline contributes to the overall net impression described in F. 433. (CX0031 at 0001).
446. An implied claim that consuming POM Juice is “clinically proven” to prevent, treat, or reduce the risk of heart disease is not reasonably clear or conspicuous on the face of the advertisement. A review of the advertisement alone, considering all its elements, does not lead to a confident conclusion that a significant minority of reasonable consumers would interpret CX0031 as claiming that POM Juice is “clinically proven” to prevent, treat or reduce the risk of “heart disease.” (CX0031 at 0001).
447. Among other things, in the context of this advertisement, the language that POM Juice “can” reduce plaque by “up to 30%” is qualified and non-definitive, and the citation to a study appears in a small print footnote, which states: “Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study.” (CX0031 at 0001).
448. Having fully examined CX0031 in its totality, and having further considered any extrinsic evidence in the record pertaining thereto (*see* Section II. E. 2, *infra*), the preponderance of the evidence fails to demonstrate that CX0031 conveys a claim that drinking eight ounces of POM Juice daily is “clinically proven” to prevent, treat, or reduce the risk of heart disease. (CX0031 at 0001; F. 446-447).

**ii. CX0033 (“Life Support”)**

449. CX0033 (“Life Support”) is an advertisement for POM Juice that was disseminated on or about December 30, 2004 in *Rolling Stone* magazine, and on or about February 1, 2005 in *Details* magazine. (CX0033 at 0001-02).
450. CX0033 is reprinted in the Appendix to this Initial Decision. (Appendix at 106).

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451. The advertisement's headline is "Life Support," next to a large image of a POM Juice bottle hanging upside down on a pole, with the juice running through a tube at the bottom of the bottle, in a manner reminiscent of an intravenous line. (CX0033 at 0001).
452. The body copy of this advertisement juxtaposes the statements and representations that (a) POM Juice possesses "more . . . antioxidants" than other drinks; (b) antioxidants "fight hard" against free radicals that "can cause heart disease"; and (c) if you drink POM Juice daily, "you'll be on life support – in a good way." (CX0033 at 0001).
453. Through the language and images described in F. 451 and F. 452, CX0033 draws a connection for the reader between consuming POM Juice and efficacy for heart disease. (CX0033 at 0001).
454. In the context of this advertisement, the reference to POM Juice as "refreshing" and "delicious" does not materially alter the overall message conveyed. (CX0033 at 0001; F. 453, 455).
455. Based on the overall, common-sense, net impression of CX0033, a significant minority of reasonable consumers, would interpret CX0033 to be claiming that drinking eight ounces of POM Juice daily prevents or reduces the risk of heart disease. (CX0033 at 0001; F. 451-454).

**iii. CX0034 ("Amaze your cardiologist")**

456. The POM Juice advertisement identified as CX0034 ("Amaze your cardiologist") was disseminated in *Prevention* magazine in February 2005. (CX0034 at 0001-02).
457. CX0034 is reprinted in the Appendix to this Initial Decision. (Appendix at 107).
458. This advertisement stopped running in 2005. (Tupper, Tr. 2996-97).

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459. The headline of the advertisement is “Amaze your cardiologist.” The headline is juxtaposed to an image of a POM Juice bottle with electrocardiogram (EKG) leads attached to it, in the manner of a patient having a heart exam. (CX0034 at 0001).
460. The body copy of CX0034 includes the statements or representations: (a) “Ace your EKG: just drink 8 ounces of delicious POM Wonderful Pomegranate Juice a day”; (b) POM Juice has more “antioxidants” than other drinks; (c) antioxidants fight free radicals that “can cause . . . artery clogging plaque”; (d) a glass of POM Juice a day “can reduce plaque by up to 30%!”; and (e) “your cardiologist will be amazed.” (CX0034 at 0001).
461. The advertisement draws a clear connection between consumption of POM Juice and reduction of arterial plaque. (CX0034 at 0001).
462. The advertisement draws a further connection between reduction of arterial plaque and effectiveness for heart disease through the juxtaposition of (1) the dressed bottle image undergoing an EKG (F. 459) and (2) the references to pleasing “your cardiologist” with positive EKG results. (CX0034 at 0001).
463. Based on the overall, common-sense, net impression of this advertisement, a significant minority of consumers, acting reasonably under the circumstances, would interpret CX0034 to contain the message that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of heart disease, by reducing arterial plaque. (CX0034 at 0001; F. 459-462).
464. The depiction of the POM Juice bottle with an EKG, even if itself humorous or not to be taken literally, does not materially alter the message conveyed by the advertisement. (CX0034 at 0001; F. 463).
465. An implied claim that consuming POM Juice is “clinically proven” to prevent, treat, or reduce the risk of heart disease is not reasonably clear or conspicuous on the face

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of the advertisement. A review of the advertisement alone, considering all its elements, does not lead to a confident conclusion that a significant minority of reasonable consumers, would interpret CX0034 as claiming that POM Juice is “clinically proven” to prevent, treat or reduce the risk of “heart disease.” (CX0034 at 0001).

466. Among other things, in the context of this advertisement, the language that POM Juice “can” reduce plaque by “up to 30%” is qualified and non-definitive, and the citation to a study is appears in a small print footnote, which states: “Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study.” (CX0034 at 0001).
467. In the context of this advertisement, the fact that the advertisement cites studies in connection with the arterial plaque representation is not enough to conclude, based on the face of the advertisement alone, that the advertisement claims POM Juice is clinically proven to prevent, treat, or reduce the risk of heart disease, including by reducing arterial plaque. (CX0034 at 0001).
468. Having fully examined CX0034 in its totality, and having further considered any extrinsic evidence in the record pertaining thereto (*see* Section II.E.2, *infra*), the preponderance of the evidence fails to demonstrate that CX0034 conveys a claim that POM Juice is “clinically proven” to prevent, treat, or reduce the risk of heart disease, including by reducing arterial plaque. (CX0034 at 0001; F. 465-467).

**iv. CX0036 (“Cheat Death”)**

469. In 2005 and 2006, POM disseminated a POM Juice advertisement with the headline, “Cheat Death.” The advertisement ran in *Rolling Stone* magazine in March, June, and July 2005; in *Prevention* magazine in May 2005; and in *Fitness* magazine in January 2006. (CX0036 at 0001-02).

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470. CX0036 is reprinted in the Appendix to this Initial Decision. (Appendix at 108).
471. The headline, “Cheat Death,” is juxtaposed to a large image of the POM Juice bottle with a noose around the bottle’s neck. (CX0036 at 0001).
472. The text of CX0036, which is brief, includes the statement that POM Juice “can help prevent” “heart disease.” (CX0036 at 0001).
473. This “Cheat death” advertisement, with the above-quoted body copy that POM “can help prevent” certain diseases stopped running in or around 2005. (Tupper, Tr. 2987-90).
474. Based upon the overall, common-sense, net impression of CX0036, particularly the statement that consumption of POM Juice “can help prevent . . . heart disease,” CX0036 would convey to a significant minority of reasonable consumers, a claim that that drinking eight ounces of POM Juice daily reduces the risk of heart disease. (CX0036 at 0001; F. 471-473).
475. In the context of this advertisement, use of the qualifying phrase “can help” does not alter the overall, common sense, net impression of CX0036 set forth in F. 474.
476. The headline and noose imagery, even if constituting humor or hyperbole, does not, in the context of the entirety of the advertisement, materially detract from the overall net impression of the advertisement, as described in F. 474.

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**2. Extrinsic evidence regarding advertisement interpretation****a. Summary of expert opinions****i. Respondents' expert Dr. Butters**

477. Dr. Butters offered his opinion as a linguistics expert on the meanings of Respondents' advertisements. (Butters, Tr. 2816-17).
478. Linguistics is the study of human language in all its forms and manifestations. (Butters, Tr. 2813). Linguistics encompasses a number of often intersecting scientific subfields, including semantics, the study of word and sentence meanings; pragmatics, the study of how such meaning is affected by nonlinguistic contexts; and semiotics, the study of extra-linguistic and paralinguistic meaning systems that individuals assign to nonlinguistic signs, such as pictures, colors, visual patterns, and icons. (PX0158 (Butters Expert Report at 0006-07)).
479. To draw his conclusions in this case, Dr. Butters applied all the subdivisions of linguistics, including semantics, pragmatics, and semiotics, and considered the nature of the product advertised, as part of the overall context for the advertisement. (Butters, Tr. 2814-15, 2817-18).
480. Dr. Butters reviewed an extensive number of POM advertisements, including the advertisements included as exhibits to the Complaint and representative samples of other advertisements admitted into evidence. (PX0158 (Butters Expert Report at 0008); Butters, Tr. 2817, 2847).
481. Dr. Butters offered opinions on Respondents' advertising in general, and also offered opinions on the meanings of many of the Challenged Advertisements in this case. (PX0158 (Butters Expert Report)).
482. In summary, Dr. Butters opined that the Challenged Advertisements do not expressly convey or convey by implication that the Challenged Products prevent, reduce

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the risk of, or treat heart disease, prostate cancer or erectile dysfunction, or that such alleged medical effects or benefits are scientifically established facts. (PX0158 (Butters Expert Report at 0003, 0042)).

483. In Dr. Butters' opinion, none of Respondents' advertisements that he reviewed stated or implied that POM products treated any disease. (Butters, Tr. 2822, 2825).
484. In linguistic terms, an advertisement "implies" a message if it is the meaning that a reasonable consumer "takes away," or infers, from the words and context of the advertisement. (Butters, Tr. 2826-2829).
485. Dr. Butters further opined, among other things, that the POM advertisements and POM communications he reviewed, make no definitive health claims, beyond the general accepted notion that consuming fruit products as part of an overall healthy diet is a healthy thing to do, including in order to reduce the risk of various diseases. (PX0158 (Butters Expert Report at 0042)).
486. Dr. Butters expressed his opinion that, at most, Respondents' advertising conveys that pomegranate juice is a healthy beverage; that POM products are high in antioxidants; that antioxidants are believed to fight free radicals and promote health; and that preliminary research performed on POM products indicates potential beneficial properties. (PX0158 (Butters Expert Report at 0003-04, 0043)).
487. In Dr. Butters' opinion, the POM advertisements he reviewed depend upon parody, exaggeration, and humor to bring their message to the potential purchaser. (PX0158 (Butters Expert Report at 0033)).
488. In Dr. Butters' opinion, the use of humor and parody in the advertisements work to "block" any inference that the advertisements are "intended to make definitive health claims" with respect to disease. (PX0158 (Butters Expert Report at 0004)).

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489. Dr. Butters opined that hyperbole and humor block literal interpretation of such headings as “I’m off to save prostates” because these are absurd terms which would not be viewed as making disease claims. (Butters, Tr. 2958; PX0158 (Butters Expert Report at 0004)).
490. In drawing his conclusions, Dr. Butters relied, in part, on the use of such words as “promising,” “pilot studies,” or “preliminary results” and that the advertisements generally encourage those reading and hearing the advertisements to investigate the research and draw their own conclusions. (PX0158 (Butters Expert Report at 0003-04, 0043)).
491. In Dr. Butters’ opinion, what people might infer with respect to a food product might be different than what they might infer with respect to a drug. (Butters, Tr. 2818).
492. In Dr. Butters’ opinion, an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim, than an advertisement promoting a drug. (Butters, Tr. 2825; *see also* Butters, Tr. 2818).
493. Dr. Butters analyzed the Challenged Advertisements from the perspective of the ordinary adult user of the English language in America. (Butters, Tr. 2816-17, 2831-32).
494. Dr. Butters did not take into account education or income level of the viewer of an advertisement, or whether the advertisement viewer was concerned about health issues. (Butters, Tr. 2832-34).
495. Dr. Butters stated that his conclusions about the Challenged Advertisements would be no different if analyzed from the perspective of more educated, affluent people, who are concerned about their health. (Butters, Tr. 2829-30).
496. In Dr. Butters’ opinion, the phrase, “I’m off to save prostates” could be interpreted by outliers (*i.e.*, viewers that are not ordinary or reasonable) to mean protect or

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rescue from disease but that interpretation is unlikely. (Butters, Tr. 2898; PX0350 (Butters, Dep. at 125)).

497. Dr. Butters stated that use of the term “may” would not cause a reasonable person to believe that the product will produce that result. (Butters, Tr. 2822-23).
498. In Dr. Butters’ opinion the representation that POM Juice will “fight for” “cardiovascular, prostate, erectile health” does not imply that the product will “treat cardiovascular, prostate, and erectile disease, or even give you cardiovascular, prostate, and erectile health.” Dr. Butters further opined that a closer possible inference is that pomegranate juice “improves your odds of maintaining” health in those areas, in a general way like any other food that is good for you, and to this extent, the language implies some kind of health benefit. (Butters, Tr. 2885-86, 2888; *see also* Butters, Tr. 2893 (phrase “fight for” “doesn’t necessarily mean that you are going to win it”).
499. Dr. Butters acknowledged that a reasonable viewer could take away from CX0016 (“Drink and be healthy”) that pomegranate juice, in general, and POM Wonderful, in particular, can help to reduce the risk of heart disease. (Butters, Tr. 2929-30).
500. According to Dr. Butters, a reasonable viewer could not take away from the entire advertisement comprising CX0016 “Drink and be healthy” that pomegranate juice, in general, and POM Wonderful in particular, will treat atherosclerosis. (Butters, Tr. 2930).
501. In Dr. Butters’ opinion, CX0274/1426 Ex. C (“I’m off to save PROSTATES”), could communicate to viewers, among other things, that POM Juice is protecting or defending prostates from disease. (Butters, Tr. 2899-2901).
502. Regarding CX0274/1426 Ex. C (“I’m off to save PROSTATES”), Dr. Butters opined that “the parodic method of presentation [use of parody] is so frivolous that no definite or clear claims will be understood, beyond the

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general notion that pomegranate juice is a good source of [anti]oxidants, and a healthy drink to include in one's diet." Dr. Butters has the same opinion with respect to CX0034 ("Amaze Your Cardiologist"); CX0031 ("Floss Your Arteries") and CX0351/CX0355 ("The Only Antioxidant supplement Rated X"). (PX0158 (Butters Expert Report at 0019-22)).

503. Regarding CX0034 Dr. Butters opined that the headline, "Amaze Your Cardiologist" is hyperbolic and cannot be taken literally. According to Dr. Butters, this language serves to "make explicit the theme of the importance of heart health using advertising-cliché language." (CX0034; PX0158 (Butters Expert Report at 0019-20)).
504. Dr. Butters opined that CX0351 and CX0355 (both having the title, "The Only Antioxidant Supplement Rated X"), convey the message that preliminary initial studies suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).
505. Regarding CX0351 and CX0355 ("The Only Antioxidant Supplement Rated X"), Dr. Butters opined that the advertisement only suggests that emerging science suggests that antioxidants are "critically important," and that "preliminary . . . initial studies" suggest that pomegranate extract, a strong source of antioxidants, could help alleviate erectile dysfunction. (Butters, Tr. 2943).
506. Regarding CX0260 ("Drink to Prostate Health"), Dr. Butters acknowledged that one inference that would be drawn is that POM Juice might be beneficial for people who have had prostate cancer, because this is what has been found in the preliminary medical study referenced in the advertisement.. (Butters, Tr. 2943-44; PX0158 (Butters Expert Report at 0024); PX0350 (Butters, Dep. at 121-22)).
507. Regarding CX0260 ("Drink to Prostate Health"), Dr. Butters expressed the opinion that ordinary consumers

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would not find that the advertisement communicates that POM Juice could treat, prevent, or reduce the risk of disease. Dr. Butters further testified that there may be some outliers who may interpret the advertisement to make such claims, but those outliers would, by definition, not be ordinary or normal. (PX0350 (Butters, Dep. at 121-25)).

508. Regarding CX0036 (“Cheat Death”), Dr. Butters opined that based on use of the words and phrases “can” and “help” with respect to heart disease, which words have intrinsic meaning in the English language, reasonable consumers would not interpret this advertisement to communicate that drinking eight ounces of POM Juice prevents or reduces the risk of heart disease. (PX0350 (Butters, Dep. at 102-05)).
509. Regarding CX0103 (“Decompress”), Dr. Butters testified that it would be a gross exaggeration for anybody to think that the image of a blood pressure cuff around the POM Juice bottle and the headline “Decompress” could literally mean drink a glass of pomegranate juice and your blood pressure will go down. (Butters, Tr. 2933).
510. According to Dr. Butters, the headline “Decompress,” juxtaposed to the “blood pressure cuff” dressed bottle image, and a sub-headline “the antioxidant power of pomegranate juice, would not likely communicate that drinking POM Juice lowers blood pressure, and it would be far-fetched to interpret this text and imagery as making a medical claim. (PX0350 (Butters, Dep. at 148-50)).
511. Regarding CX0348 and CX0350 (“24 Scientific Studies”), Dr. Butters testified that a viewer of the “24 Scientific Studies” advertisement would find it reasonable to believe that the headline is accurate and that there must be 24 scientific studies on POMx. (Butters, Tr. 2940).

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**ii. Complaint Counsel's rebuttal expert Dr. Stewart**

512. Complaint Counsel offered Professor David Stewart as a rebuttal witness to Dr. Butters. Dr. Stewart's area of expertise is advertising, marketing, consumer behavior, and survey methodology. Dr. Stewart is not an expert in linguistics, the subject of Dr. Butters' testimony. (Stewart, Tr. 3168-69).
513. Dr. Stewart was not asked by Complaint Counsel to conduct a facial analysis of the Challenged Advertisements to opine on what the advertisements meant. Dr. Stewart was asked to read and critique Dr. Butters' report, and to reach a conclusion as to whether or not he agreed with Dr. Butters' conclusions, and why. (Stewart, Tr. 3169, 3226).
514. Dr. Stewart opined that "[I]t is not possible to determine that an advertisement does or does not communicate certain implied messages simply from linguistic analysis." (CX1295 (Stewart Expert Report at 0006)).
515. According to Dr. Stewart, linguistic analysis fails to take into account the individual characteristics of the viewer and how that consumer processes information; it looks only at the advertisement stimulus. (Stewart, Tr. 3171-73).
516. According to Dr. Stewart, Dr. Butters' analysis ignores research related to how consumers use information, process advertising messages, and make decisions in the market place. (CX1295 (Stewart Expert Report at 0006); Stewart, Tr. 3170-71).
517. According to Dr. Stewart, well-educated, affluent, health-conscious consumers are more likely to be more attentive to health claims and more likely to draw pragmatic inferences about the benefits of POM products. (CX1295 (Stewart Expert Report at 0012-13)). However, Dr. Stewart defined a "pragmatic" inference as a meaning that is neither express, nor implied by the advertisement, and

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may or may not even follow, logically. (Stewart, Tr. 3227-28).

518. Dr. Stewart disagreed with Dr. Butters that a typical consumer would necessarily discern a difference between “can” and “will.” According to Dr. Stewart, when viewing an advertisement the typical consumer is looking at the totality of the advertisement including: the illustration, the headline, the text, and carrying away a net impression based on all of that information. The potential meaning of “can” versus “will” is defined by its context, according to Dr. Stewart. (Stewart, Tr. 3190-91).
519. Dr. Stewart disagreed with Dr. Butters over the effect of such words as “initial” or “pilot.” In Dr. Stewart’s opinion, the typical consumer would likely have little understanding of what “initial” or “pilot” means, particularly in the context of being referred to as having been published in a major journal. In such circumstances, according to Dr. Stewart, juxtaposing terms such as “initial” or “pilot” with mentions of a well-respected medical school (UCLA), “leading universities,” reference to professional journals in which support of the claims is found, reference to a Nobel laureate, and reference to the sum of money spent on research that is represented as supporting the advertising claims (*e.g.*, \$25 million), have the effect of establishing the credibility of claims for the POM products. (CX1295 (Stewart Expert Report at 0016-17); Stewart, Tr. 3191).
520. Dr. Stewart opined that the Bovitz Study (*see* subsection c, *infra*), which studied headlines from billboard advertisements, contradicts the notion that humorous headlines, such as “Amaze your cardiologist” and “Floss your arteries,” do not communicate any claims, as Dr. Butters concluded. (Stewart, Tr. 3202, 3204-06, 3230-31; *see* F. 497-489, 502-503).

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**b. Findings of fact regarding advertising interpretation, based upon testimony of Dr. Butters and Dr. Stewart**

521. More educated, affluent people, who are concerned about their health, are likely to be more discerning and careful readers of an advertisement. (Butters, Tr. 2829-30).
522. Better educated people are more likely to better understand an advertisement. (Stewart, Tr. 3240).
523. According to the New Oxford Dictionary (“NOAD”) the meaning of “defend” (*see* CX0274/1426 Ex. C), includes to “resist an attack made on (someone or something) and protect from harm or danger.” (Butters, Tr. 2899-2901).
524. In linguistic terms, “I’m off to save prostates” would not imply that a product will protect or rescue from disease. (Butters, Tr. 2898; PX0350 (Butters, Dep. at 125)).
525. In linguistics terms, the word “may” is a shortened way of saying “may or may not.” (Butters, Tr. 2822-23).
526. According to an ordinary desktop dictionary, “can” does not mean “will.” (Butters, Tr. 2915).
527. Whether a consumer will discern a difference between “can” and “will” depends on the context and the totality of the advertisement. (Stewart, Tr. 3190-91).
528. Some academic literature indicates that the use of qualifiers, such as “can,” “could,” “might,” or “up to” “encourage the audience of the advertisements to infer that a stronger claim is intended than the one that is actually entailed.” Dr. Butters disagrees with this assertion. (Butters, Tr. 2916-19; *see also* CX1295 (Stewart Expert Report at 0016-17) (discussing study finding use of the word “may” rather than the stronger term “will” created greater credence for the claim)).
529. In linguistic terms, to “prevent” a disease means to keep the disease from happening. (Butters, Tr. 2818).

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530. In linguistic terms, the word “treat” means medical treatment. (Butters, Tr. 2825).
531. In linguistic terms, the phrase, “backed by research” totaling a certain dollar amount, such as used in CX0475/1426 Ex. A, could be interpreted to mean there has been completed research with some results, or that there has been a certain dollar amount of research done so far and that research is ongoing. (Butters, Tr. 2876-78).
532. In the field of linguistics, hyperbole is a term used to refer to extreme exaggeration, and is not meant literally. (Butters, Tr. 2824).
533. Readers discount puffery and hyperbole because an advertisement using either, on its face, is an exaggeration; however, the fact that puffery and hyperbole are not to be taken literally does not mean that they cannot convey a claim that is serious. (Butters, Tr. 2824; Stewart, Tr. 3230).
534. Parody and humor have the effect of capturing the attention of the advertisement viewer, to help them connect with the message in the printed portion of the advertisement. (Butters, Tr. 2866).
535. Humor can induce further processing of an advertisement and a search for further information. (Stewart, Tr. 3229-30).
536. Contemporary speakers of American English would include “heart disease” within their understanding of the meaning of “heart trouble.” (Butters, Tr. 2850-51).
537. Contemporary speakers of American English could interpret the phrase “erectile function” to relate to the ability of men to achieve and maintain erections. Erectile function and the absence of erectile dysfunction are closely related. (Butters, Tr. 2851 (discussing CX0351 and CX0355)).

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538. Contemporary speakers of American English could interpret the phrase “prostate health” to include the condition of not being diseased. (Butters, Tr. 2851).
539. Contemporary speakers of American English could interpret the phrase “heart health” to include the condition of not being diseased. (Butters, Tr. 2851).
540. In the proper context, a visual of an intravenous drip bottle could be a symbol for drugs and medicine. (Butters, Tr. 2947).
541. The caduceus symbol, showing snakes curling around a staff, is a symbol that people associate with medicine. (Butters, Tr. 2944).<sup>3</sup>
542. Academic marketing and psychology literature indicate that the meaning of a particular communication really resides in the recipient, not in the actual stimulus. Consumers are not simply passive recipients of messages but are active processors. (Stewart, Tr. 3170).
543. To determine what a consumer would take away from the POM advertising, it is very important to know the characteristics of the viewer of the advertisements, including prior beliefs and prior knowledge, and how the consumer would process the information, and generally what the consumer brings to the viewing situation – all of which are really important in understanding the totality of what people will take away from an advertising message. (Stewart, Tr. 3171-73).

**c. Bovitz Billboard Survey**

544. In March 2009, at the request of Ms. Resnick, POM engaged the Bovitz Research Group (“Bovitz”) to design a consumer survey to evaluate the relative effectiveness of the then-running “Super Hero” advertising campaign compared to POM’s earlier “Dressed Bottle” advertising

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<sup>3</sup> The following is an image of a caduceus symbol:



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campaign. (CX0286; CX1378 at 0049 (Kuyoomjian, Ocean Spray Dep. at 191-92)).

545. The target POM consumer for purposes of the survey was identified for Bovitz as “Higher HH income \$75k+”, 25 to 64, concerned about their health and willing to buy premium, health products.” In recruiting participants, the survey eliminated individuals with incomes below \$75,000. Individuals who did not score high on a scale measuring certain attitudes and lifestyle choices related to health and diet were also disqualified from participation. (CX0286 at 0002-03; CX0369 at 0003).
546. The Bovitz Survey used a forced exposure methodology (*i.e.*, showing the advertisement for which one wants to ascertain the consumer takeaway, to the survey respondents) which, although not the typical, natural way that consumers are exposed to advertising, is a valid method for a survey measuring advertising communication. (CX0369 at 0004-07; Mazis, Tr. 2693-95; Reibstein, Tr. 2509-10).
547. The Bovitz Survey exposed survey respondents only to POM’s billboard advertising. (Reibstein, Tr. 2572-73, 2575; Stewart, Tr. 3207, 3209; PX0295a15 at 0005-06).
548. The Bovitz Survey compared consumers’ perceptions of the following ten billboard advertisements from POM’s Super Hero and Dressed Bottle advertising campaigns (hereinafter, “Bovitz Stimuli”), as follows:

Super Hero campaign advertisements:

Holy Health! \$25 million in medical research.

I’m off to save PROSTATES!

100% PURE pomegranate juice to the rescue!

BACK OFF ...impostor juices!

Risk your health in this economy? NEVER!

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Dressed Bottle campaign advertisements:

Cheat Death.

The Antioxidant Superpower.

Decompress.

Heart therapy.

Forever young.

(PX0295a15at0010-11).

549. The billboard advertisements from the Dressed Bottle campaign use humorous headlines and images. (Stewart, Tr. 3205).
550. Each of the Bovitz Stimuli also included a tagline related to antioxidants, such as “The Antioxidant Superpower” and the “The antioxidant power of pomegranate juice.” The Bovitz Stimuli contained no additional text. (PX0225 at 0005-06).
551. In the Bovitz Survey, a total of 150 target consumers and 100 existing POM users were exposed to the billboard advertisements from each campaign, identified in F. 544. (PX0225 at 0003-04).
552. Four of the billboard advertisements described in F. 548 (*i.e.*, “Heart therapy,” “Decompress,” “Cheat death” and “I’m off to save prostates”) share headlines and imagery that appear in certain of the Challenged Advertisements in this case. (*See* CX0109 at 0001 and CX0463 (“Heart therapy banner advertisement”), CX0103 at 0001 (“Decompress”), CX0036 at 0001 and CX0188 at 0001 (“Cheat death”), and CX0274 at 0001 and CX0466 (“I’m off to save PROSTATES!” banner advertisement)).
553. The headline of one test billboard included a reference to “\$25 million in . . . medical research,” (F. 548), which reference appears in some of the Challenged Advertisements. (*See, e.g.*, CX0274).

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554. The participants were shown various advertisements, in a variety of configurations, and asked a series of questions, including: “Other than trying to get you to buy the product, what do you think is the main idea” that the advertisement “is trying to get across to you?” (CX0369 at 0005-11).
555. Fourteen percent of the general target audience and seventeen percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline “Decompress” and a sub-headline “POM Wonderful Pomegranate Juice. The Antioxidant Superpower,” said the ad’s main idea was “helps/lowers blood pressure.” (PX0295a15 at 0011, 0018, 0046; Stewart, Tr. 3213-14).
556. Other “main ideas” identified in the Bovitz Survey by those shown the billboard advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline “Decompress” and a sub-headline “POM Wonderful Pomegranate Juice. The Antioxidant Superpower,” include: (1) 64% of the general population and 73% of the POM population stated that the “main idea” of the billboard was “healthy/health benefits/juice is good for you”; (2) 16% of the general population and 20% of the POM population responded “antioxidants”; and (3) 6% of the general population and 13% of the POM population said “calming/relieves stress/relaxing.” (PX0295a15 at 0018, 0046).
557. Forty-three percent of the general target audience and forty-eight percent of POM Juice users in the Bovitz Survey, when shown an advertisement picturing a POM Juice bottle saying, “I’m off to save PROSTATES!” and a sub-headline “The Antioxidant Superpower,” said the advertisement’s main idea was “good for prostates.” (PX0295a15 at 0010, 0017, 0045).
558. Other “main ideas” identified in the Bovitz Survey by those shown the billboard advertisement picturing a POM Juice bottle saying, “I’m off to save PROSTATES!” and a sub-headline “The Antioxidant Superpower,” include: (1)

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31% of the general population and 48% of the POM population said the “main idea” of the “I’m off to save PROSTATES!” billboard was “healthy/health benefits/juice is good for you” and (2) 12% of the general population and 28% of the POM population said “antioxidants.” (PX0295a15 at 0017, 0045).

559. Twenty-two percent of the general target audience and thirty-one percent of POM Juice users in the Bovitz Survey, who were shown an advertisement picturing a POM Juice bottle saying, “HOLY HEALTH! \$25 million in medical research” and a sub-headline “The Antioxidant Superpower,” said the advertisement’s main idea was “\$25 million spent on research/research based.” (PX0295a15 at 0010, 0017, 0045).
560. Other “main ideas” identified in the Bovitz Survey by those shown the “HOLY HEALTH!” billboard advertisements were: (1) 57% of the general population and 46% of the POM population said “healthy/health benefits/juice is good for you;” (2) 12% of the general population and 9% of the POM population responded “antioxidants.” (PX0295a15 at 0017, 0045).
561. According to Dr. Stewart, a test of headlines and images in the context of a billboard advertisement provides some insight into understanding what messages were communicated by the image and the headline. Other text that is added to a lengthier print advertisement might modify the messages communicated by the image and headline. (Stewart, Tr. 3205-06).
562. Bovitz Survey respondents were also exposed to all five tested advertisements from the “Super Hero” campaign or all five tested advertisements from the “Dressed Bottle” campaign and asked: “Based on the ads you just saw, what are the specific benefits, if any, of drinking POM Wonderful?” (CX0369 at 0008-09; Stewart, Tr. 3214-16).
563. Professor Reibstein testified that the question posed in F. 562 was a leading, biased question because it directed the survey participants to select a “specific benefit” which

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pressures them to identify a “specific benefit” even if they had not perceived a particular benefit. (Reibstein, Tr. 2515-16). Dr. Stewart testified that this question was open-ended and not leading. (Stewart, Tr. 3216).

564. Of the survey respondents exposed to the five “Dressed Bottle” advertisements, which included the images and headlines of the “Decompress” print advertisement (CX0103) and the “Heart Therapy” print and banner advertisements (CX0109; CX0463), 38% of the general target audience said that a benefit of drinking POM Juice was “good for your heart” and 21% said a benefit was “helps/lowers blood pressure.” (PX0225 at 0014; Stewart, Tr. 3216-17).
565. Bovitz Survey respondents who were exposed to the five “Super Hero” advertisements, which included an advertisement picturing a POM Juice bottle saying, “HOLY HEALTH! \$25 million in medical research,” were asked a close-ended question, “Based on the ads you just saw, which of the following do you think are true about POM Wonderful?” Survey respondents were provided a multiple-choice list and told to select as many or as few that applied. (CX0369 at 0010-11). Specifically, question 16 provided the following choices:
1. Backed by medical research
  2. Is good for cardiovascular health
  3. 100% pure pomegranate juice
  4. Contains all natural ingredients
  5. Is good for prostate health
  6. Like “health in a bottle”
  7. Contains naturally occurring antioxidants
  8. Is the original pomegranate juice
  9. Is good for you

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10. Will help you stay healthy
  11. Will help you live longer
  12. Is better than other pomegranate juices
  13. Has proven health benefits
  14. Tastes good
566. In response to Question 16, 63% of the general population and 78% of POM Juice users included the choice, “has proven health benefits.” (PX0295a15 at 0033, 0034).
567. Complaint Counsel’s expert, Dr. Stewart, acknowledged that because Question 16 was a closed-ended question, there is the possibility of yea-saying, *i.e.*, the tendency to give a yes or more socially desirable response in an effort to be agreeable. (Stewart, Tr. 3218-19).
568. According to Dr. Reibstein, by providing respondents with a list of choices in response to Question 16 of the Bovitz Survey, survey respondents were cued to select from attributes that they may not otherwise have thought of, and do not have the option of attributes that do not appear on the list. This tends to inflate results. (Reibstein, Tr. 2518-19).
569. According to Dr. Reibstein, the Bovitz Survey is methodologically flawed and unreliable because it had no control and, thus survey respondents might have had preconceived perceptions about pomegranate juice before being exposed to POM’s billboard advertisements. (Reibstein, Tr. at 2510-11).
570. Dr. Stewart testified he was “comfortable” with open-ended questions without a control, although he also testified that, without a control, you cannot draw a firm inference that an advertisement had a particular effect. (Stewart, Tr. 3241-42).
571. Dr. Reibstein opined that the Bovitz Survey is methodologically flawed and unreliable because the

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sample size of only 100 POM users and 150 target consumers exposed to each category of advertisements was too small to reach statistical significance at the 95% confidence level. (Reibstein, Tr. 2512-13).

572. None of the survey respondents in the Bovitz Survey answered that the main idea of the billboard advertisements was prevention, risk reduction, or treatment of any specific disease. The most common “main idea” communicated (at least 90%) was that POM Juice had general health benefits. (Reibstein, Tr. 2516-17; PX0225 at 0012-13).
573. Dr. Reibstein testified that the Bovitz Survey is methodologically flawed and unreliable because Question E (F. 574), which asked about health-related beliefs, resulted in accepting only recruits who were extremely health-focused, rather than merely health-oriented. According to Dr. Reibstein, such respondents would be more inclined to find health-oriented messages, particularly in light of the methodology of forced exposure and copy test questions cueing health. (Reibstein, Tr. 2511-12).
574. Question E of the Bovitz Survey stated as follows:

Listed below are some statements that may or may not describe you. Using the scale provided, please indicate the extent to which each of the following statements describes you.

(RANDOMIZE ROWS)	Describes me perfectly	Describes me well	Describes me somewhat	Describes me a little	Does not describe me at all
I use my diet to manage my health	5	4	3	2	1
High fiber foods are a regular part of my diet	5	4	3	2	1

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<b>(RANDOMIZE ROWS)</b>	<b>Describes me perfectly</b>	<b>Describes me well</b>	<b>Describes me somewhat</b>	<b>Describes me a little</b>	<b>Does not describe me at all</b>
I regularly work out to stay fit	5	4	3	2	1
I try to include plenty of fruits and vegetables in my diet	5	4	3	2	1
I believe that what I eat can directly affect my health	5	4	3	2	1
I am the first of my friends to try new gadgets and technology	5	4	3	2	1
I prefer to watch movies at home instead of a theater	5	4	3	2	1
I am adjusting my lifestyle to be conscious of the environment	5	4	3	2	1
I enjoy cooking and trying new recipes that I find online	5	4	3	2	1
I like to stay up on current events	5	4	3	2	1

To qualify for participation in the survey, respondents had to respond with a “5” or a “4” on the rating scale with respect to at least three of the five health-related statements (*i.e.*, Questions 1 through 5). (CX0369 at 0002).

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**3. Television interviews**

575. On November 20, 2008, Mrs. Resnick appeared on NBC's *The Martha Stewart Show*. Martha Stewart invited Mrs. Resnick to be interviewed on *The Martha Stewart Show*. (CX1426, Ex. E-6; L. Resnick, Tr. 137).
576. On February 19, 2009, Mrs. Resnick appeared on CBS' *The Early Show* in a segment on Cashing in on Ideas. (CX472 at 0003).
577. On March 20, 2009, *Newsweek* published on its website two pages of excerpts from an interview with Mrs. Resnick titled, "*Striking Out On Your Own. Is now a good time to start a company?*" (CX1426, Ex. F).
578. On June 17, 2008, Mr. Tupper provided a television interview on the Fox Network Business Channel. (CX1426, Ex. E-7; Tupper, Tr. 919).<sup>4</sup>

**4. Summary of findings on advertising claims**

579. In determining whether Respondents disseminated advertisements and promotional materials making the claims alleged in the Complaint, each of the Challenged Advertisements has been reviewed. Extrinsic evidence as to how the Challenged Advertisements would be interpreted by a reasonable consumer has also been considered.
580. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent, or

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4 As explained in Section III.C, *infra*, the four television interviews that Complaint Counsel challenges as "advertisements" (*see* Complaint ¶ 9, I-J; CCB Appendix A) are not actionable as "advertisements" under the FTC Act. *See* Section III.C.1. Thus, the interviews are hereinafter not included in the term, "Challenged Advertisements," and this Initial Decision does not include any findings regarding any claims allegedly made in those interviews.

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reduce the risk of heart disease, by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, as alleged in paragraph 12 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:

- CX0016 (print advertisement) (prevent/reduce the risk only) (F. 293);
- CX0029 (print advertisement) (F. 299);
- CX1426 (Compl. Ex. I) (package insert) (F. 338);
- CX1426 (Compl. Ex. M) (POMx Heart Newsletter)(F. 346);
- CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009 and January 2010 (F. 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387); pomegranatetruth.com website (Compl. Ex. E-1)(F. 411));
- CX0013 (press release) (F. 417); and
- CX0044 (press release) (F. 422).

581. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent or reduce the risk of prostate cancer by prolonging prostate-specific antigen (“PSA”) doubling time, as alleged in paragraph 14 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:

- CX0314 (magazine wrap) (F.310);

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- CX0372 (magazine wrap) (F. 310);
  - CX0379 (magazine wrap) (F. 310);
  - CX0380 (magazine wrap) (F. 310);
  - CX1426 (Compl. Ex. N) (POMx Prostate Newsletter) (F. 351);
  - CX1426 (Compl. Ex. I) (package insert) (F. 331);
  - CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, and January 2010 (F. 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387)); and
  - CX0065 (press release) (F. 429).
582. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, is clinically proven to treat, prevent or reduce the risk of erectile dysfunction, as alleged in paragraph 16 of the Complaint. The following advertisements and promotional materials contain one or more of the foregoing representations:
- CX0351 (print advertisement) (F. 325);
  - CX0355 (print advertisement) (F. 325);
  - CX0473 (Pomwonderful.com website: April 2009 (Compl. Ex. E-2); October 2009, December 2009, and January 2010 (F. 368, 380); Pompills.com website: April 2009 (Compl. Ex. E-8), January 2010 (Compl. Ex. E-9) (F. 387)); and

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- CX0128 (press release) (treatment only) (F. 433).
583. Respondents disseminated advertisements and promotional materials that impliedly represented either that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, treats, prevents or reduces the risk of heart disease, by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, without also representing clinical proof of these effects, as alleged in paragraph 19 of the Complaint. The following advertisements contain one or more of the foregoing representations:
- CX0031 (print advertisement) (F. 443);
  - CX0033 (print advertisement) (F. 455);
  - CX0034 (print advertisement) (F. 463); and
  - CX0036 (print advertisement) (F. 474).
584. The findings described in F. 580-583 are based upon the overall, common-sense, net impression of the advertisements themselves, and full consideration of any applicable extrinsic evidence. As to advertisements cited in F. 580-583, the weight of the applicable extrinsic evidence fails to sufficiently contradict the overall, common-sense, net impression gleaned from the advertisements themselves.
585. The following Challenged Advertisements were found to have made claims alleged in the Complaint, but the preponderance of the evidence fails to prove that these advertisements made all the claims asserted by Complaint Counsel. *See* Appendix A to Complaint Counsel's Post-hearing Brief. These advertisements and claims are: CX0031 ("clinically proven" claim not found); CX0034 ("clinically proven" claim not found); CX0065 (press release) (heart disease claim not found); CX0351 and CX0355 (prostate cancer and heart disease claims not

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found). It is not reasonably clear from the face of the advertisements alone that a significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as making the identified claims. A review of each of these advertisements, considering the interplay of all the elements of each such advertisement, failed to allow a confident conclusion that a significant minority of reasonable consumers would interpret the advertisements as making the identified claims. Among other reasons, the foregoing advertisements: do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a sufficiently clear connection for the reader, such as through associated explanatory text, between the health effects or study results referred to in the advertisements and the diseases alleged in the Complaint. Moreover, applicable extrinsic evidence fails to demonstrate that these advertisements make the identified claims.

586. Based on a thorough review of all the Challenged Advertisements, none expressly (*i.e.*, unequivocally and directly) states that “drinking eight ounces of POM Juice daily” or “taking one POMx Pill daily,” or “taking one teaspoon of POMx Liquid daily”(1) “treats,” “prevents,” or “reduces the risk” of “heart disease,” including by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, or that these effects are “clinically proven”; (2) “treats,” “prevents” or “reduces the risk” of “prostate cancer,” including by prolonging prostate-specific antigen doubling time, or that these effects are “clinically proven”; or (3) “treats,” “prevents,” or “reduces the risk” of erectile dysfunction, or that these effects are “clinically proven.”
587. As to the Challenged Advertisements not identified in F. 580-583 as making the representations alleged in the Complaint, after a thorough review it is not reasonably clear from the face of these advertisements that a

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significant minority of consumers, acting reasonably under the circumstances, would interpret these advertisements as making the claims alleged in the Complaint. A review of these advertisements, considering the interplay of all the elements of each such advertisement, failed to allow a confident conclusion that a significant minority of reasonable consumers would interpret these advertisements as making the claims alleged in the Complaint. These advertisements, which are all print advertisements except where noted, are: CX0103; CX0109; CX0188, CX0192; CX0260; CX0274; CX0475; CX0120; CX0122; CX0169; CX0180; CX0279; CX0280; CX0328; CX0331; CX0337; CX0342; CX0348; CX0350; CX0353; CX0463 (banner advertisement) and CX0466 (banner advertisement).

588. Among other reasons, the advertisements identified in F. 587: use language that is vague, non-specific, substantially qualified, and/or otherwise non-definitive; use language and/or imagery that in the context of the advertisements is inconsistent with the alleged claims; fail to mention specific diseases; and/or fail to draw a sufficiently clear connection for the reader, such as through associated explanatory text, between health effects or study results referred to in the advertisements and the diseases alleged in the Complaint.
589. As to the advertisements identified in F. 587, the weight of the applicable extrinsic evidence (*see* Section II.E.2, *infra*) fails to demonstrate that these advertisements make the claims alleged in the Complaint.
590. Having fully considered each of the advertisements identified in F. 587, as well as any extrinsic evidence pertaining thereto (*see* Section II.E.2, *infra*), the preponderance of the evidence fails to demonstrate that a significant minority of reasonable consumers would interpret these advertisements as making the claims alleged in the Complaint.
591. The evidence fails to show that CX0473 (pomegranatetruth.com website) made the prostate cancer

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and erectile dysfunction claims alleged in the Complaint because the web capture of this website did not include content pertaining to such claims. (F. 415).

**F. Level of Required Substantiation****1. Types of studies**

592. There are four study types for examining the relation between a food or nutrient and a disease outcome: (a) *in vitro* studies; (b) animal studies; (c) human observational studies; and (d) human clinical studies. (CX1293 (Stampfer Expert Report at 0008)).
593. “Basic science” refers to test-tube, animal studies, and preclinical research. (Dreher, Tr. 528).

**a. *In vitro* studies**

594. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. They are used to identify potential biologic mechanisms and generate hypotheses for studies in humans. (CX1293 (Stampfer Expert Report at 0008); CX1291 (Sacks Expert Report at 0015-16); *see* Melman, Tr. 1112). Human metabolism and disease processes are very complicated and cannot be replicated in a petri dish, and therefore, many *in vitro* studies produce results that cannot be replicated in humans. (CX1291 (Sacks Expert Report at 0015-16); Sacks, Tr. 1450; *see also* Stampfer, Tr. 725-26; deKernion, Tr. 3063-64).

**b. Animal studies**

595. Animal studies are tools for identifying potential treatments, mechanisms, and side effects. Animals are not the same as humans, either biologically or psychologically, and therefore, many findings of dietary or drug effects in animals are not confirmed in human testing. (CX1291 (Sacks Expert Report at 0016); Sacks,

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Tr. 1451; Melman, Tr. 1112-13; CX1289 (Melman Expert Report at 0011); *see* PX0355 (Ornish, Dep. at 66)).

596. Animal studies alone are not sufficient to show that a tested product will prevent or treat human disease. (Sacks, Tr. 1451-52; Melman, Tr. 1112-13; CX1289 (Melman Expert Report at 0011); Goldstein, Tr. 2644; PX0349 (Burnett, Dep. at 57, 112-13)).
597. Animal studies are very informative and provide for some clinical insights. (PX0349 (Burnett, Dep. at 111); PX0352 (Goldstein, Dep. at 122-24); Goldstein, Tr. 2644; Heber, Tr. 2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; PX0192 (Heber Expert Report at 0015, 0041-42, 0051-59). In an animal study, researchers can isolate mechanisms of action and accomplish toxicity or safety testing, as well as examine specific mechanisms by taking out their organs and cells, which cannot be done in humans. (PX0361 (Sacks, Dep. at 89-91). Results from such animal studies have potential for benefit of therapy at the human level. (PX0206 (Miller Expert Report at 10-11, 13); Miller Tr. 2194; PX0349 (Burnett, Dep. at 112); Burnett, Tr. 2262-63; Heber, Tr. 2086, 2149; CX1352 (Heber, Dep. at 243); Heber, Tr. 2086; 2149, 2182; PX0192 (Heber Expert Report at 0015, 0041-42, 0051-59).
598. Although there are limitations to extrapolating from animal studies to human studies, studies on animals have value in determining therapeutic efficacy. (PX0025 (Ornish Expert Report at 0007)).
599. Dr. Sacks, Complaint Counsel's cardiology expert, testified that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (PX0361 (Sacks Dep. at 71)). Similarly, Complaint Counsel's erectile dysfunction expert, Dr. Melman, testified that based on the results of his gene therapy erectile dysfunction product in an animal model, he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

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**c. Human observational studies**

600. Human observational studies are large human studies that compare intake of various levels of nutrients (for example, low vitamin C versus high vitamin C) with various endpoints, such as disease outcomes, over time. (CX1293 (Stampfer Expert Report at 0008); Stampfer, Tr. 719; *see* Heber, Tr. 2168).
601. Human observational studies can support a conclusion that there is an association between a nutrient and a disease of interest, but generally do not prove causation, due to the potential, even in well-designed studies, for unidentified biases or inadequately controlled confounding factors. (CX1293 (Stampfer Expert Report at 0008-09); Stampfer, Tr. 720-21; *see* Sacks, Tr. 1418-19).

**d. Human clinical studies**

602. Human clinical studies are those in which investigators assign the exposure level to participant – meaning that the investigators tell the subjects how much of a particular nutrient to consume, in contrast to observational studies, where the investigators study existing exposure levels within a particular population. (CX1293 (Stampfer Expert Report at 0009)).
603. There is a typical progression in human clinical studies, from exploratory research to randomized clinical trials. (PX0025 (Ornish Expert Report at 0010, 0024) (“Science usually progresses when someone publishes a study of a series of patients with a nonrandomized control group that shows an unprecedented finding which is then replicated by one or more subsequent randomized controlled trials[;]” “[t]here is a logical progression in science which often begins with a pilot study that has no control group”)).
604. Some researchers describe the progression of research in terms of “phases,” where: a Phase I trial tests treatments in a small number of patients to find a safe dose; a Phase II trial tests the intervention in a larger number of people to

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identify specific effects; a Phase III trial tests the treatment in a larger number of people, to compare it to “standard treatment”; and a Phase IV trial tests a treatment in several hundred to thousands of people to assess long-term safety and effectiveness. (CX1287 (Eastham Expert Report at 0009); CX1341 (Pantuck, Dep. at 28-29); *see also* Burnett, Tr. 2262).

605. Typically, researchers conduct pilot or exploratory studies. A pilot study is designed to investigate whether there is any evidence of a treatment effect. Such research can reveal potential changes from an intervention, allows the researchers to see if people can tolerate the intervention or if it causes unexpected side effects, and paves the way for more definitive research. (CX1338 (Padma-Nathan, Dep. at 87-88, 155); CX1193 at 0001; Melman, Tr. 1116; Stampfer, Tr. 747-48; CX1342 (Hill, Dep. at 45-48)).
606. Pilot studies are generally considered by scientists and clinicians in the scientific community to be valid, accurate, and reliable studies. (CX1336 (Davidson, Dep. at 232-33); CX1342 (Hill, Dep. at 48-49, 53); CX1339 (Ornish, Dep. at 23); CX1358 (Aviram, Dep. at 17)).
607. A “pilot” study does not mean that it is not as scientifically valid as a larger study. (CX1339 (Ornish, Dep. at 23, 119-20)). A small number of participants do not weaken the importance of the results, especially if they are in agreement with *in vitro*, mechanistical studies and in animal models. (CX1358 (Aviram, Dep. at 18)).
608. A reason a researcher conducts a “pilot” study is because he or she is not certain how many subjects it will take to adequately power the study. If there is no effect shown, then this allows the investigators to address any concerns regarding the study. (CX1342 (Hill, Dep. at 46-48)).

## 2. Randomized clinical trials

609. Well-designed, well-conducted, randomized, double-blinded, placebo-controlled human clinical studies are

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referred to by experts in the field of clinical testing as “RCTs.” (CX1291 (Sacks Expert Report at 10)).

610. It is standard practice, in human research, to begin with a *protocol*. (Stampfer, Tr. 760; Sacks, Tr. 1436-37; Heber, Tr. 2044-45). A protocol describes the key features of a study, such as objectives, methodology, statistical analysis plan, the definition of the *p* value (probability), and primary outcome variables (endpoints). (Sacks, Tr. 1436-37; Stampfer, Tr. 760; *see* Ornish, Tr. 2367). The purpose of identifying the primary outcomes in advance is to prevent a researcher from using positive results and ignoring negative ones, resulting in bias. (Sacks, Tr. 1475; CX1291 (Sacks Expert Report at 0021)).
611. A *controlled* study is one that includes a group of patients receiving the purported treatment (“treatment” or “active” group) and a control group (“placebo” or “control” group). (CX1291 (Sacks Expert Report at 0011)). A control group provides a standard by which results observed in the treatment group can be evaluated. (CX1287 (Eastham Expert Report at 0013)). A control group allows investigators to distinguish between real effects from the intervention, and other changes, including those due to the mere act of being treated (“placebo effect”), the passage of time, change in seasons, other environmental changes, and equipment changes (such as calibration changes). (CX1291 (Sacks Expert Report at 0011); Burnett, Tr. 2265; Eastham, Tr. 1268; *see* CX1293 (Stampfer Expert Report at 0009); Ornish, Tr. 2367). The control group should be approximately the same size and meet the same criteria as the treatment group. (Eastham, Tr. 1268-69; CX1287 (Eastham Expert Report at 0013); CX1291 (Sacks Expert Report at 0011); Melman, Tr. 1095; CX1289 (Melman Expert Report at 0009)). It also should receive the same measurements and attention from the researchers as the treatment group. (CX1291 (Sacks Expert Report at 0011)).
612. *Randomization* means assigning subjects to the active product group or the control group in a random fashion, whether using a computer program, random number table,

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or coin toss. It is another way to control for bias. (Burnett, Tr. 2264-65; CX1291 (Sacks Expert Report at 0011); CX1339 (Ornish, Dep. at 20); Eastham, Tr. 1266; Melman, Tr. 1096). It increases the likelihood that the treatment and control groups are similar in relevant characteristics, so that any difference in the outcome between the two groups can be attributed to the treatment. (CX1291 (Sacks Expert Report at 0011-12); CX1293 (Stampfer Expert Report at 0009); CX1287 (Eastham Expert Report at 0012-13); CX1339 (Ornish, Dep. at 20) (“[B]y randomizing people, if there were some unknown factor that was biasing your outcomes, it would be likely to be distributed across both groups”). It also prevents the investigator from deciding who gets which treatment, which can introduce bias into the study. (CX1345 (deGroof, Dep. at 62); Melman, Tr. 1096).

613. A *placebo* is an inactive product or treatment given to the control group, in lieu of the intervention being tested. (Stampfer, Tr. 708; Eastham, Tr. 1267-68; Melman, Tr. 1094-95). For example, in a study of a pill, the placebo would be a pill that looks like the intervention, but does not contain the active ingredient. (Stampfer, Tr. 708). A placebo should be identical, in all ways possible, to the active treatment. (CX1291 (Sacks Expert Report at 0011); Melman, Tr. 1095). A double blind study, *see* F. 614, blinds participants and investigators as to whether study participants are in the active or placebo group. (CX1293 (Stampfer Expert Report at 0009); Melman, Tr. 1095-96).
614. *Blinding* refers to steps taken to ensure that neither the study participants nor the researchers conducting the outcome measurements are aware of whether a patient is in the active group or the control group. (CX1291 (Sacks Expert Report at 0012); Melman, Tr. 1097).
615. *Double-blinding*, that is, blinding of both the patients and investigators, is optimal to prevent bias arising from actions of the patients or investigators. (CX1293 (Stampfer Expert Report at 0009); Stampfer Tr. 708-09; Eastham, Tr. 1267; Melman, Tr. 1098; CX1287 (Eastham Expert Report at 0013); *see also* Heber, Tr. 2044). In

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some instances, the blinding of patients is not possible. A study that is unblinded can still have value. (Sacks, Tr. 1435-36; PX0361 (Sacks, Dep. at 104-05); Ornish, Tr. 2345; Eastham, Tr. 1327, 1339).

616. Once a randomized controlled trial is completed and all the data is collected, data for the control and active treatment groups is compared through use of appropriate *statistical analyses*. (Eastham, Tr. 1272; CX1287 (Eastham Expert Report at 0014); CX1291 (Sacks Expert Report at 0012-13)). If the results of the treatment group are *statistically significant* from those of the control group at the end of the trial, it can be concluded that the tested product is effective. This analysis is called a *between-group analysis*. (CX1291 (Sacks Expert Report at 0012-13); Burnett, Tr. 2269).
617. A *within-group* analysis, where a researcher compares the treatment group participants' "before" data to their "after" data, has much less scientific value, because it relies on the assumption that without the intervention there would have been no change in the study participants' condition. (Stampfer, Tr. 714).
618. Evaluating data from a clinical trial for *statistical significance* is the standard practice to demonstrate that a study's hypothesis has been proven. (Burnett, Tr. 2269; CX1287 (Eastham Expert Report at 0014)). *Statistical significance* is recognized as being attained if the statistical test for probability, referred to as the "*p*" value, is less than or equal to 0.05 ( $p \leq 0.05$ ), which means that there is only a 5 percent or less chance that the difference between the treatment and placebo groups is due to chance. (CX1291 (Sacks Expert Report at 0012); Eastham, Tr. 1273; Ornish, Tr. 2368; Melman, Tr. 1102-03; CX1289 (Melman Expert Report at 0010)). It means that the results demonstrated would occur no more than one time out of 20, and therefore, other causes of the result, such as chance, are less likely as an explanation. (Stampfer, Tr. 710-11).

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619. Statistical significance is an arbitrary convention in the context of studying a whole food. (Ornish, Tr. 2340, 2368; Goldstein, Tr. 2598-99 (choosing a significance level is technically an arbitrary task, and “in specific situations a different value could be utilized”)).
620. Results that do not have a *p*-value of less than 0.05 can still evidence a clinically meaningful benefit that is scientifically supportable. (PX0352 (Goldstein, Dep. at 108-09); Goldstein, Tr. 2599; PX0189 (Goldstein Expert Report at 0013); PX0349 (Burnett, Dep. at 67, 138-39); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-91); PX0361 (Sacks, Dep. at 109); Sacks, Tr. 1608-09).
621. *Validated* endpoints or surrogate markers are those outcomes that, while not direct endpoints, have been shown to be so closely linked to a direct endpoint that a change in the surrogate marker is confidently predictive of a change in the disease. (*See* CX1291 (Sacks Expert Report at 0013); *see* CX1287 (Eastham Expert Report at 0010) (“Changes in a surrogate are expected to reflect changes in a clinically meaningful endpoint”). *Validated* measures or assessment tools are those that have been established as reliable through rigorous assessments involving a large number of individuals. (Burnett Tr. 2266-67; Melman, Tr. 1100).
622. Certain validated measures, like the International Index of Erectile Function (“IIEF”), were originally intended for pharmaceutical products and “not necessarily designed for a nutraceutical [a food product that provides medical or health benefits].” (PX0352 (Goldstein, Dep. at 67-69); Goldstein, Tr. 2603-04, 2633).
623. Certain non-validated measures are very “informative and . . . valuable to use in clinical studies.” (Burnett, Tr. 2294).
624. *Clinical significance* means that the treatment makes a real difference in a patient’s life. (Melman, Tr. 1103; Eastham, Tr. 1274; PX0361 (Sacks, Dep. at 109)). A result may also be clinically significant even if it did not

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reach statistical significance. (PX0352 (Goldstein, Dep. 108-09); Goldstein, Tr. 2599; PX0189 (Goldstein Expert Report at 0013); PX0349 (Burnett, Dep. at 67, 138-39); Burnett, Tr. 2270-71; CX1350 (Liker, Dep. at 190-91). A result may be statistically significant, but not clinically significant. (Melman, Tr. 1104; Eastham, Tr. 1274).

625. *Replication* is intended to ensure that the results obtained in one study are not due to chance. Even with the safeguards contained in an RCT, the results contained in any one study may be due to chance or may not be generalizable due to uniqueness of the study sample. (Sacks, Tr. 1446; CX1291 (Sacks Expert Report at 0014-15)).

### **3. Testimony from Complaint Counsel's experts on whether RCTs are required**

#### **a. Dr. Meir Stampfer**

626. Dr. Stampfer provided the following opinion regarding the appropriate level of evidence of substantiation: randomized, double blind, placebo-controlled trials are needed for nutrient supplements when they are used as medical interventions to prevent or treat diseases. (CX1293 (Stampfer Expert Report at 0029)).
627. Dr. Stampfer testified that if there is a claim that a cause and effect relationship (causal link) between a nutrient or food and a disease has been established, then one has to have evidence to back it up. (Stampfer, Tr. 830-31).
628. Dr. Stampfer testified that the level of scientific evidence required to support a claim depends on the claim being made. (Stampfer, Tr. 830-31).
629. Dr. Stampfer explained that it is an efficacy claim to say that a product reduces the risk of a disease, but it is not an efficacy claim to say that users of a product have a lower incidence of a particular disease. To state that users of a product have a lower incidence does not mean that use of

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the product caused them to have a lower incidence. (Stampfer, Tr. 798).

630. Dr. Stampfer further testified that a statement that studies indicate that a product lowers the risk of heart disease and diabetes does not imply that a causal link is established. (Stampfer, Tr. 817).
631. Dr. Stampfer testified that if the claim does not imply a causal link, for example, if the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. (Stampfer, Tr. 830-31; CX1293 (Stampfer Expert Report at 0029-30) (it may be appropriate to use evidence short of randomized clinical trials for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available. This advice should distinguish between recommendations based on good evidence of a causal relation from those that are based on evidence that is suggestive but falls short of a firm casual conclusion.)).
632. Dr. Stampfer further testified that in a nutritional context, a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 831-32; PX0362 (Stampfer, Dep. at 73, 99); CX1293 (Stampfer Expert Report at 0030) (long term trials of diet and disease outcomes are often unfeasible due to the financial and participant burden required to perform such studies, but it is indisputable the randomized clinical trial is the best study design that permits strong causal inference concerning the relationship between an administered agent (whether drug or nutrient) and any specific outcome)).
633. Dr. Stampfer also testified, that the failure to act, in the absence of conclusive RCT evidence, increases the risk of forgoing benefits to the public that might have been achieved with little risk and little cost and that one should

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“definitely” make that potential benefit available to the public rather than withhold it. (Stampfer, Tr. 837-38).

634. In a recently published article titled “*Evidence-based criteria in the nutritional context*,” Dr. Stampfer opined that the general principles of evidence-based nutrition “can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group.” (Stampfer, Tr. 831; RX5007 at 483). Dr. Stampfer also opined that because RCT study designs may not be “available” (economically or scientifically) for nutrients, “nutrient related decisions could be made at a level of certainty somewhat below that required for drugs.” (RX5007 at 481).
635. Dr. Stampfer also stated in the article “*Evidence-based criteria in the nutritional context*” that some of the intellectual fathers of evidence based medicine “stressed” that evidence based medicine was “not restricted to randomized trials and meta-analyses.” (RX5007 at 483). Dr. Stampfer further stated that “certain features of [evidence-based medicine] seem ill-suited to the nutrition context.” (RX5007 at 479). He also opined that “to fail to act in the absence of conclusive RCT evidence increases the risk of forgoing benefits that might have been achieved with little risk and at low cost.” (RX5007 at 481).
636. In the article “*Evidence-based criteria in the nutritional context*,” Dr. Stampfer noted that some of the differences between the evaluation of drugs and nutrients are: “(i) medical interventions are designed to cure a disease *not* produced by their absence, while nutrients prevent dysfunction that would result from their inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large and with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the “noise” range of biological variability; (iv) drug effects tend to be monotonic, with response varying in proportion to dose,

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while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake range; (v) drug effects can be tested against a nonexposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate – a difference with significant implications for the feasibility of conducting pertinent RCTs.” (RX5007 at 479; PX0362 (Stampfer, Dep. at 78)).

637. Dr. Stampfer admitted that he has made public health recommendations about foods that were not supported by RCTs. (Stampfer, Tr. 810, 813-14; PX0362 (Stampfer, Dep. at 173)).

**b. Dr. Frank Sacks**

638. Dr. Sacks provided the following opinion regarding the appropriate level of evidence of substantiation: appropriately analyzed results of well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies, demonstrating significant changes in valid surrogate markers of cardiovascular health would be necessary (a) to substantiate that a product, including a conventional food or dietary supplement, can treat, prevent or reduce the risk of heart disease and/or (b) to support a claim that clinical studies, research, or trials prove that a product treats, prevents or reduces the risk of heart disease. In addition, Dr. Sacks opined that at least two well-designed studies, conducted by different researchers, and each showing strong results, are needed to constitute reliable evidence. (CX1291 (Sacks Expert Report at 0010-11, 0014-15)).
639. Dr. Sacks testified that most scientists in the fields of nutrition, epidemiology and the prevention of disease believe that at least two well-designed RCTs, conducted by independent researchers, and each showing strong results, are needed to constitute reliable evidence that an

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intervention causes a result. (Sacks, Tr. 1446; CX1291 (Sacks Expert Report at 0014-15)).

640. Dr. Sacks testified that pomegranate juice has not been proven for safety and that double-blinded, placebo-controlled tests would be necessary to prove pomegranate juice to be safe. (Sack, Tr. 1534).
641. Dr. Sacks acknowledges that in some instances, such as studies on foods, the blinding of patients is not possible, and that if a study becomes unblinded or does not have a placebo, it can still have value. (Sacks, Tr. 1435; PX0361 (Sacks, Dep. at 104-105, 111, 137)).
642. In an article titled "*The Importance of Population-Wide Sodium Reduction as a Means to Prevent Cardiovascular Disease and Stroke: A Call to Action From the American Heart Association*" published in their journal (*Circulation*, 2011 Mar 15;123(10):1138-43), Dr. Sacks, as one of the authors, wrote: "Some scientists still question the evidence supporting population-wide sodium reduction. Common arguments include the absence of a major trial with hard clinical outcomes. It is well-known, however, that such trials are not feasible because of logistic, financial, and often ethical considerations." (Sacks, Tr. 1561; PX0361a03). In writing about "financial considerations" in this article, Dr. Sacks conceded that he meant the cost of conducting a major trial. (Sacks, Tr. 1561).
643. Dr. Sacks has never researched whether a single fruit, such as the pomegranate, has health benefits, but instead has only studied "fruits and vegetables as a category." (PX0361 (Sacks, Dep. at 54, 56)).
644. Dr. Sacks served as the Chairman of the Design and Analysis Committee for the DASH ("Dietary Approaches to Stop Hypertension") diet sponsored by the National Heart, Lung and Blood Institute, part of the National Institute of Health. The DASH study was a multi-center study to look at the effect of fruits and vegetables in lowering blood pressure and the effect of a total dietary approach in lowering blood pressure, including the

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reduction of sodium intake. The DASH diet showed that diets high in fruits and vegetables, among other things, substantially lowered blood pressure in subjects compared to the control group. (PX0361a03 at 002; PX0361 (Sacks, Dep. at 48-49); Sacks, Tr. 1417-18).

645. Dr. Sacks testified that you do not need RCTs to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. However, Dr. Sacks also opined that you do need two RCTs to test pomegranate juice. (Sacks, Tr. 1546-47).
646. Dr. Sacks also testified that *in vitro* studies can be competent and reliable evidence of an agent's effect on a particular mechanism. (Sacks, Tr. 1578; PX0361 (Sacks, Dep. at 123-24)).
647. Dr. Sacks further testified that there are common clinical recommendations today that have not been proven by RCTs and that major trials with hard clinical outcomes are often not feasible because of the costs of conducting them. (Sacks, Tr. 1559-61).

**c. Dr. James Eastham**

648. Dr. Eastham provided the following opinion regarding the appropriate level of evidence of substantiation: qualified experts in the field of urology, including the prevention and treatment of prostate cancer, and in the field of clinical testing relating to the prevention and treatment of prostate cancer, would require claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or are clinically proven to do so, to be supported by at least one well-conducted, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and with an appropriate endpoint. (CX1287 (Eastham Expert Report at 006, 012)).
649. Dr. Eastham testified that even if a product is safe and might create a benefit, like a fruit juice, he would still

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require an RCT to justify claims that Respondents are charged with making. (Eastham, Tr. 1325-31).

650. Dr. Eastham testified that studies of disease prevention should involve 10,000 to 30,000 men and that such studies are “incredibly expensive” and in the range of \$600 million. (Eastham, Tr. 1328).
651. Dr. Eastham testified additionally that animal or *in vitro* studies alone do not provide sufficient scientific evidence to support a claim that a product prevents or treats prostate cancer, even where the agent being tested is nontoxic. (Eastham, Tr. 1284-85).
652. Dr. Eastham has performed over 200 radical prostatectomies per year for a number of years before there were any RCTs showing that they worked. (Eastham Tr. 1331-32; PX0358 (Eastham, Dep. at 154-55)). Dr. Eastham performed these radical operations without RCTs despite the fact that the side-effects of this operation are significant and include impotence, incontinence, bleeding, embolisms, and infection, plus risks of general anesthetic. (Eastham, Tr. 1331-32).
653. Dr. Eastham testified that he has removed hundreds of prostates despite all the above stated risks and without RCT substantiation, yet he would not consider the use of pomegranate juice to treat, prevent or reduce the risk of prostate cancer unless supported by RCTs. (Eastham, Tr. 1332).

**d. Dr. Arnold Melman**

654. Dr. Melman provided the following opinion regarding the appropriate level of evidence of substantiation: to constitute competent and reliable scientific evidence demonstrating efficacy in preventing, reducing the risk of, or treating erectile dysfunction, experts in the field of erectile dysfunction would require at least one clinical trial, involving several investigatory sites, which is well-designed, randomized, placebo-controlled, and double-blinded. (CX1289 (Melman Expert Report at 0004-05)).

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655. Dr. Melman testified that the only kind of science to support claims that a product helps with erectile dysfunction are two double-blind placebo based randomized trials, conducted in two separate institutions, with a group large enough to produce a statistically significant ( $p < 0.05$ ) result. Dr. Melman testified that you cannot properly make public claims that a product helps with erectile dysfunction in absence of such trials. (Melman, Tr. 1135, 1138-39; CX1289 (Melman Expert Report at 0008-11)).
656. Dr. Melman also testified that the men's sexual partners must also confirm the result; that for a study to claim any improvement in participants, the men must have reached orgasm; and that the sexual partner must achieve sexual satisfaction. (Melman, Tr. 1139-43).
657. Dr. Melman testified that "pomegranate juice is a drug," and therefore the FDA standard for pharmaceutical drugs should apply. (PX0360 (Melman, Dep. at 17-19); Melman, Tr. 1141).
658. Dr. Melman conceded that he has never conducted any clinical work on a food product, including pomegranates. (Melman, Tr. 1164-65).
659. Dr. Melman is developing a gene-transfer therapy for erectile dysfunction called hMaxi-K which is injected into the penis. (Melman, Tr. 1148, 1192). Dr. Melman announced to the public, in an interview with the *New York Observer*, that his hMaxi-K produced spontaneous normal erections in men suffering from erectile dysfunction. (Melman, Tr. 1154). Dr. Melman acknowledged that people have died or gotten very sick from gene-transfer therapy. (Melman, Tr. 1158).
660. While Dr. Melman testified that Respondents must have at least one clinical trial, involving several investigatory sites, which is well-designed, randomized, placebo-controlled, and double-blinded before they can publicize the positive effects of pomegranate juice on men with erectile dysfunction, Dr. Melman publicized preliminary

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results of studies on his gene-transfer therapy based only on the results of an animal study. (Melman, Tr. 1149-55).

**4. Testimony from Respondents' experts on whether RCTs are required****a. Dr. Denis Miller**

661. Dr. Miller provided the following opinion regarding the appropriate level of evidence of substantiation: because pomegranates are a food, an appropriate level of scientific substantiation regarding the health benefit claims of pomegranates should be flexible, and consider several factors (including the risk of harm) with the desirability of getting information to the public, the validity of the science, costs of the science, and the nature of the claim. (PX0206 (Miller Expert Report at 15)).
662. Dr. Miller opined that the standard for substantiating claims for pure foods which are clearly safe need not be as rigorous as that for a new drug or anticancer agent, but should be based on reliable and competent scientific data that confirm its safety, and support a relevant and beneficial effect; and that valid, scientifically conducted basic science could be enough to support a claim, depending on the claim, so long as the product is not claimed to be a substitute for conventional drug therapies or medical care. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194).
663. Dr. Miller opined that if the product is a whole food or a derivative of a whole food and it is obviously safe, there should be a cost benefit analysis to determine whether it makes sense to report possible, or probable benefits of consumption, and to err on the side of giving more information to the public and medical community, so long as the claim does not suggest (by use of absolutes or in other ways) that an individual forgo conventional medical care or treatment based on the consumption of the product and/or suggest that the underlying science is valid. (PX0206 (Miller Expert Report at 7-8)).

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664. Dr. Miller opined that retrospective or prospective observational cohort or case-control studies are not feasible to study the benefits of a food and that a double-blind, placebo controlled trial evaluating POM Products as prostate cancer protective agents would take decades and thousands of patients and would have to control for other naturally occurring, dietary antioxidants, anti-inflammatory, and anticancer agents as well as life-style activities (*e.g.*, exercise, smoking, alcohol use), genetic predisposition, racial and ethnic factors, benign prostatic hypertrophy, and other factors that might have an effect on carcinogenesis of prostate cancer. (PX0206 (Miller Expert Report at 0014)).
665. Dr. Miller opined that the claim being made about a product is relevant to the level of substantiation required. (Miller, Tr. 2195, 2210).
666. Dr. Miller opined that even if a food were marketed for the treatment or prevention of a disease, the level needed to substantiate claims about a food is more relaxed or less rigorous than it would be for a drug because with a drug, one would have to consider the safety of the agent, the efficacy of the agent, and the risk-benefit ratio. (Miller, Tr. 2210-11).
667. Dr. Miller testified that if one were claiming a fruit juice prevents prostate cancer, and there was reliable scientific data to support that claim, one could make that claim without an RCT. (Miller, Tr. 2201).
668. Dr. Miller testified that you do not need to go through the process of clinical testing and randomized clinical trials to establish the safety and efficacy of a food when there is already reliable scientific evidence supporting that. (Miller, Tr. 2205-06).
669. Dr. Miller opined that if a dietary supplement is derived from a pure food it should require the same level of substantiation as a food. In the alternative, if a dietary supplement is “a mixture of fifty different minerals and elements and vitamins,” then it is different than a food and

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would require a different level of substantiation. (Miller, Tr. 2213).

670. Dr. Miller testified that because a food is not patentable, it is not reasonable to require the maker of a potentially beneficial foodstuff to conduct a prohibitively expensive RCT to claim that it is beneficial to health. (PX0206 (Miller Expert Report at 16)).

**b. Dr. David Heber**

671. Dr. Heber provided the following opinions regarding the appropriate level of evidence of substantiation: (1) double-blind placebo-controlled trials have limited usefulness for nutritional research; (2) the nutritional complexity of pomegranate juice and extract makes controlled studies less suitable for researching the health benefits of pomegranate juice and extract; (3) prospective randomized controlled trials demand that a nutrient act like a drug and that is an unreasonable requirement for nutritional studies because nutrients occur in a food matrix; and (4) the prospective randomized trial cannot practically be imposed as a requirement for nutritional science. (PX0192 (Heber Expert Report at 0013-16)).
672. Dr. Heber testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (Heber, Tr. 2166, 2182).
673. Dr. Heber testified that in dealing with nutrients, RCTs are often infeasible and too expensive; that the drug standard should not be applied to nutrients; and that most experts in the field of nutrition believe that RCTs have some significant drawbacks when it comes to the study of nutrient substances like pomegranates. (Heber, Tr. 1948-50).

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**c. Dr. Dean Ornish**

674. Dr. Ornish provided the following opinion regarding the appropriate level of evidence of substantiation: it is important to carefully examine the totality of scientific evidence in determining whether or not pomegranate juice in its various forms is beneficial and that in a nutritional context, *in vitro* and animal studies may be more effective in testing the efficacy of a nutrient. (PX0025 (Ornish Expert Report at 0005); Ornish, Tr. 2327-31).
675. Dr. Ornish testified that new drugs, which always have toxicities and side effects, need to be held to a higher standard than a juice that is derived from a fruit that has been around for thousands of years. (Ornish, Tr. 2324-25, 2340, 2381).
676. Dr. Ornish testified that if a fruit or beverage is held to the standard required of drugs, no one would be able to meet that standard. No manufacturer would spend billions of dollars to test a fruit unless it is a drug like Lipitor, where one could make billions of dollars a year and it would be worthwhile to make such an investment. (Ornish, Tr. 2324-25).
677. Dr. Ornish opined that there is a world of difference between offering juice as a healthy lifestyle choice or as an *adjunct* to conventional treatments versus offering it as a replacement for conventional medical care. (PX0025 (Ornish Expert Report at 0008)).
678. Dr. Ornish also opined that “it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug.” Dr. Ornish further opined that the study of pomegranates or pomegranate juice is different than studying a new drug, in which harmful side-effects, both short-term and long-term, are the rule rather than the exception. (PX0025 (Ornish Expert Report at 0008)).

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679. Dr. Ornish opined that RCTs, even when conducted perfectly, do not control for all sources of bias and may inject new ones unique to RCTs. For example, in studying a fruit or food, it is hard to do double-blind, randomized, placebo-controlled trials. Once a participant is assigned to the control group, and they know what the intervention is, they can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. (PX0025 (Ornish Expert Report at 0008); Ornish, Tr. 2328-29, 2356).
680. Dr. Ornish also testified that RCTs have shown that angioplasties and stents do not prevent heart attacks or prolong life, yet the number of these procedures performed is greater than ever. (PX0025 (Ornish Expert Report at 0007); Ornish, Tr. 2380-81).
681. Dr. Ornish opined that while there are limitations to extrapolating from *in vitro* and animal studies to human studies, it is false to say this research has no value in determining therapeutic efficacy. (PX0025 (Ornish Expert Report at 0007)).

**d. Dr. Jean deKernion**

682. Dr. deKernion provided the following opinion regarding the appropriate level of evidence of substantiation: if you have a drug with toxicities, it is extremely important to have a test with a placebo group, because it gives one a valid measure of the toxicity of the drug. But in the case of something like fruit juice, that has low or no toxicity at all, is it not necessary to use an RCT or placebo-controlled kind of test. (deKernion, Tr. 3060).

**e. Dr. Arthur Burnett**

683. Dr. Burnett provided the following opinion regarding the appropriate level of evidence of substantiation: (1) because pomegranate juice is a harmless fruit product that creates no material risk of harm and assuming that drinking pomegranate juice is not advocated as an alternative to following medical advice, information of

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pomegranate juice's likely benefit may be communicated to consumers; and (2) studies such as double blinded, placebo-based tests are not required before permitting this information to be given to the public. (Burnett, Tr. 2272-74; PX0149 (Burnett Expert Report at 0006-07)).

684. Dr. Burnett testified that the standard of substantiation is different for a product that is directly associated as a treatment for erectile dysfunction and for a product that claims to have helpful benefits for or improves one's erectile function. (Burnett, Tr. 2260-62, 2303).

**f. Dr. Irwin Goldstein**

685. Dr. Goldstein provided the following opinion regarding the appropriate level of evidence of substantiation: health care practitioners who treat patients concerned with erectile health would not hold pomegranate juice to the standards of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (including performance of large, double-blind, placebo-controlled pivotal clinical trials) before recommending pomegranate juice to their patients. (PX0189 (Goldstein Expert Report at 0003, 0014)).
686. Dr. Goldstein testified that when studying pomegranate juice and its effect on erectile function, RCT studies are not necessary because the safety of natural fruit juice is not questionable. Furthermore, Dr. Goldstein questioned whether one could make a placebo pomegranate juice. By contrast, Dr. Goldstein testified that RCTs are needed for pharmaceutical drugs, which are unnatural and developed in laboratories, to assess safety and efficacy. (Goldstein, Tr. 2599-01, 2619).
687. Dr. Goldstein testified that an article he co-authored stated that RCTs are considered the criterion standard for determining causality, but that that article was written in the context of the pharmaceutical industry and pharmaceutical drugs like Viagra, Levitra and Cialis that have been studied with randomized clinical trials for determination of their safety and efficacy. Dr. Goldstein

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further testified that it would be ideal if there could be randomized clinical control data for nutraceuticals, but that in reality, that is not going to happen or it is not possible. (Goldstein, Tr. 2613-14).

**5. Determinations on the required level of substantiation****a. Type of claims**

688. The level of scientific evidence required to support a claim depends on the claim being made. (Stampfer, Tr. 830-31; Miller, Tr. 2195, 2210).
689. Claims of efficacy can be made only when a causal relation with human disease is established. (CX1293 (Stampfer Expert Report at 0030)).
690. A claim that users of a product have a lower incidence of disease is not the same thing as a claim that use of the product caused them to have a lower incidence of disease. (Stampfer, Tr. 798).
691. A claim that studies indicate that a product lowers the risk of heart disease and diabetes does not imply that a causal link is established, *i.e.*, that the product caused users to have lower risk of heart disease and diabetes. (Stampfer, Tr. 817).
692. If the claim does not imply a causal link, for example, if the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. (Stampfer, Tr. 830-31; CX1293 (Stampfer Expert Report at 0029-30)).
693. If the claim does not suggest (by use of absolutes or in other ways) that an individual should forgo conventional medical care or treatment based on the consumption of a safe product, one can relax the requirement for an RCT. (Miller, Tr. 2201-02; PX0206 (Miller Expert Report 7-8)).

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**b. Type of product**

694. The level of scientific evidence required to support a claim depends on the product being promoted. (Miller, Tr. 2196, 2198; PX0206 (Miller Expert Report at 8)).
695. The potential risk of the product must be weighed against the potential benefit and harm of keeping information from the public. (Sacks, Tr. 1559; PX0361 (Sacks, Dep. at 137)). In recommending a food or drug, you have to take into account the risk of harm from the product. (Stampfer, Tr. 829).
696. RCTs are needed for pharmaceutical drugs to assess safety and efficacy because pharmaceutical drugs are unnatural, developed in laboratories, and have toxicities. (Goldstein, Tr. 2600-01, 2620; deKernion, Tr. 3060).
697. Pharmaceutical drugs, which are not known to be safe and always have toxicities and side effects, are held to a higher standard than a juice that is derived from a fruit that has been around for thousands of years. (Ornish, Tr. 2324-25, 2340, 2381; PX0025 (Ornish Expert Report at 0008); Goldstein, Tr. 2600-01, 2620; deKernion, Tr. 3060).
698. The standard applied to new drugs should not be applied to nutrients as long as the product is not claimed to be a substitute for conventional drug therapies or medical care. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194; Heber, Tr. 1948-50; PX0025 (Ornish Expert Report at 0008)).
699. Pomegranate juice is a natural fruit product with health promoting characteristics. The safety of pomegranate juice is not in doubt. (Miller, Tr. 2194, 2201; PX0206 (Miller Expert Report at 10); Heber, Tr. 1948-50; PX0025 (Ornish Expert Report at 0007)).

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**c. Feasibility of RCTs**

700. RCTs can be beneficial, but they are not perfect and, when dealing with nutrition, they have their own set of limitations as well. (Ornish, Tr. 2329).
701. In a nutritional context, a hypothesis about disease causation can rarely, if ever, be directly tested in humans using the RCT design. (Stampfer, Tr. 832-33; PX0362 (Stampfer, Dep. at 73, 98); CX1293 (Stampfer Expert Report at 0029-30); PX0361 (Sacks, Dep. at 111, 137); PX0192 (Heber Expert Report at 0009-12)).
702. In studying a drug, RCTs are possible because placebos can be used and subjects, therefore, do not know if they are getting a drug or not. (Ornish, Tr. 2328).
703. In studying a fruit or food, it is difficult to do double-blind, randomized, placebo-controlled trials because the subjects know what they are consuming. Once a participant is assigned to the control group, and they know what the intervention is, the participant can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. (PX0025 (Ornish Expert Report at 0008); Ornish, Tr. 2328-29, 2356; Goldstein, Tr. 2600-01, 2620).
704. In a nutritional context, RCTs are extremely expensive and often not feasible because of the costs of conducting them. (Sacks, Tr. 1559-61; Stampfer, Tr. 810, 813-14; Heber, Tr. 1948-50; PX0192 (Heber Expert Report at 0013-16); Goldstein, Tr. 2613-14; (Eastham, Tr. 1328) (the standard studies for chemoprevention should involve 10,000 to 30,000 and are “incredibly expensive,” costing in the range of \$600 million)).
705. Because a food, unlike a pharmaceutical drug, is not patentable, it is not reasonable to require the maker of a potentially beneficial foodstuff to conduct an RCT to claim that it is beneficial to health. (PX0206 (Miller Expert Report at 16)). No manufacturer would spend billions of dollars to test a fruit unless it is a drug where

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one could make billions of dollars a year and was worthwhile to make such an investment. (Ornish, Tr. 2324-25).

**d. Conditions where RCTs are necessary**

706. RCTs are needed for a nutrient supplement if one makes a claim that the product causes the effect of treating, preventing, or reducing the risk of a disease and offers the nutrient supplement as a replacement to medical care to prevent, treat or reduce the risk of disease. (PX0206 (Miller Expert Report at 15); Miller, Tr. 2194; PX0025 (Ornish Expert Report at 0008); *see also* CX1293 (Stampfer Expert Report at 0029); Stampfer, Tr. 830-31).
707. RCTs are not required to convey information about a food or nutrient supplement where: the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice. (PX0149 (Burnett Expert Report at 0006-07); deKernion, Tr. 3060; Goldstein, Tr. 2600-01, 2620; PX0025 (Ornish Expert Report at 0008)).

**e. Necessary substantiation**

708. If a dietary supplement is derived from a pure food, it should require the same level of substantiation as a food. By contrast, if a dietary supplement is “a mixture of fifty different minerals and elements and vitamins,” then it is different than a food and requires a different level of substantiation. (Miller, Tr. 2213).
709. Because pomegranate juice is a food, the appropriate level of scientific substantiation regarding health benefit claims of pomegranate juice in its various forms should be flexible, and consider several factors, including the risk of harm, the validity of the science, costs of the science, and the nature of the claim, including whether it is offered as a substitute or replacement for a conventional therapy. (Miller, Tr. at 2201; PX0206 (Miller Expert Report at 11, 15). *See also* PX0025 (Ornish Expert Report at 0005); Ornish, Tr. 2329-31).

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**G. Substantiation for Respondents' Heart Disease Claims****1. Substantiation standard for heart disease claims**

710. Experts in the field of cardiovascular health would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (Ornish, Tr. 2327-30; *see also* Miller, Tr. 2194, 2201; *but see* Sacks, Tr. 1545-48) (testifying that RCT trials are not necessary to test the benefit of food categories that are included in a diet that has already been tested, like the DASH diet; that pomegranates are in the fruit category and, thus, do not need to be tested with RCTs; but that pomegranate juice is different from pomegranates and thus held to a higher standard).
711. Experts in the field of cardiovascular health would require that a product be scientifically evaluated through rigorous scientific and clinical studies, which does not necessarily include RCTs, to make claims that the product can treat, prevent or reduce the risk of heart disease. (Heber, Tr. 1948-49, 2058, 2085, 2166, 2182 (food products must be evaluated on the totality of the scientific evidence that is competently performed, which includes *in vitro* animal studies and human studies, along with basic science about nutritional uptake on metabolism). *But see* Sacks CX1291 (Sacks Expert Report at 0010) (requiring “well-designed, well-conducted, randomized, double-blinded, controlled human clinical studies” with strong “*p*” values)).
712. To substantiate a claim that a food or a diet supplement can treat heart disease, one needs appropriately analyzed data showing significant changes in valid surrogate markers of cardiovascular health and the study subjects must have established cardiovascular disease (“CVD”) or coronary heart disease (“CHD”). To substantiate a claim that a food or a diet supplement can prevent or reduce the risk of heart disease, the study subjects may be persons with *or* without CVD or CHD. (*See* CX1291 (Sacks Expert Report at 0010-11 (also stating requirement of RCTs)).

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713. The same level of evidence stated in F. 711-712 is needed to show that clinical studies, research, or trials prove that a product treats heart disease. (See CX1291 (Sacks Expert Report at 0011)).
714. There must be a sufficient number and diversity of subjects tested in a study to conclude that the measured effect of a product on heart disease can be generalized to a larger population. The study also must be of sufficient duration to show that the effect will last. (CX1291 (Sacks Expert Report at 0014)).

**2. Overview of cardiovascular disease**

715. A heart attack occurs when there is a sudden rupture of inflamed plaque which covers about 50 percent of the inner surface (lumen) of a coronary vessel. (Heber, Tr. 1959).
716. Plaque is the end result of decades of damage to the blood vessel, which begins with oxidation. The process of plaque formation begins when a protein called low-density lipoprotein (“LDL”) or so-called “bad cholesterol,” which circulates through the blood, becomes oxidized. (Heber, Tr. 1959).
717. When the LDL cholesterol gets oxidized, the chemical nature of the protein changes, causing the protein to reside and deposit in the wall of the blood vessel, where it accumulates. (Heber, Tr. 1959; CX1358 (Aviram, Dep. at 5)).
718. Regular cholesterol passes in and out of the arteries, but the oxidized cholesterol remains there. (Heber, Tr. 1959-60).
719. Macrophages (white blood cells that respond to inflammation by digesting cellular debris) come in and they eat up this oxidized cholesterol. (Heber, Tr. 1960).
720. Macrophages have ravenous appetites which do not stop, and they continue to accumulate until they become what

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are called foam cells, which are full of cholesterol and actually burst into the area, bringing in more cells and more inflammation. (Heber, Tr. 1960).

721. Oxidation is followed by inflammation, which is followed by damage to the interior of the blood vessel. This damage is detected as yellow streaks in the coronary arteries. As this process progresses, plaque forms and begins to fill those lumen. (Heber, Tr. 1960).
722. Plaque can have different characteristics; it can be stable or unstable. Unstable plaque is full of oxidized cholesterol and macrophages, reft with inflammation. (Heber, Tr. 1960).
723. By blocking inflammation and oxidation, it is possible to stabilize plaque. (Heber, Tr. 1960; PX0192 (Heber Expert Report at 0033)).
724. Inhibitors of the oxidation process are called antioxidants. (CX1358 (Aviram, Dep. at 5)). Punicalagin, an ellagitannin, is the most abundant polyphenol that accounts for more than 50% of the antioxidant activity. (PX0025 (Ornish Expert Report at 0008)).
725. Several studies have indicated that pomegranate juice has antioxidant and anti-atherosclerotic properties due to the presence of multiple polyphenols such as tannins, flavonols, anthocyanins and ellagic acid. (PX0025 (Ornish Expert Report at 0008)).
726. Antioxidants are well known to enhance the biological actions of nitric oxide (“NO”) by virtue of their capacity to improve endothelial NO synthase (“eNOS”). (PX0055 at 0002; PX0056).
727. Antioxidants are well known to increase and prolong cellular concentrations of NO by protecting it from oxidation. Antioxidants accomplish this task by neutralizing free radicals. (PX0055 at 0002; PX0056 at 0002; PX0057; PX0059 at 0001, 0004; PX0190 at 0006).

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728. The negative effects on NO caused by shear stress (the force of friction caused by perturbed blood flow around atherosclerosis) and on the expression of oxidation-sensitive genes can be mitigated by antioxidants. (PX0055 at 0002; PX0056).
729. Dr. Louis Ignarro demonstrated that POM Juice and POMx were able to attenuate the effects of perturbed shear stress and atherogenesis. However, POMx was significantly more effective at enhancing the expression of endothelial nitric oxide synthase (eNOS – an enzyme necessary for cellular NO production), decreasing oxygen-sensitive gene expression, and reducing lesion size. (PX0056).
730. Antioxidants enhance the bioavailability of NO. (Heber, Tr. 1816; CX0908 at 0001, 0002; PX0058).
731. NO helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body, including the heart. (Heber, Tr. 1816, 1969).

**3. Respondents' basic science studies**

732. Respondents have sponsored many published studies in cellular and animal models evaluating the effects of pomegranate juice and/or its extracts on cardiovascular function. (PX0007; PX0008; PX0010; PX0015; CX0543; PX0017; PX0022; PX0055; PX0056, PX0057; PX0058; PX0059; CX0053).

**a. Dr. Aviram's *in vitro* and *in vivo* studies**

733. The earliest heart studies on pomegranate juice were carried out by Dr. Aviram at the Technion Institute in Israel. (Heber, Tr. 1957).
734. Dr. Aviram is a professor and head of the Lipid Research Laboratory at the Technion Faculty of Medicine, Rappaport Institute for Research in the Medical Sciences and Rambam Medical Center, in Haifa, Israel. (CX1116 at 0001).

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735. Dr. Aviram is considered an internationally renowned researcher, pioneer, and one of the leading experts in the world on cholesterol, lipid oxidation and the protective role of dietary antioxidants related to cardiovascular disease. (Heber, Tr. 1957-58).
736. Dr. Frank Sacks, Complaint Counsel's expert on cardiovascular health, acknowledges that Dr. Aviram's basic science is good and that Technion is a good research institution. (Sacks, Tr. 1571).
737. For the last 30 years, Dr. Aviram's major research focus has been on dietary antioxidants and antioxidants in general, especially their role in cardiovascular disease. (CX1358 (Aviram, Dep. at 5)).
738. Before studying pomegranates, Dr. Aviram examined a number of antioxidants from plants, including lycopene from tomatoes, green tea, citrus fruits, and red wine. (Heber, Tr. 1958).
739. Dr. Aviram published a red-wine study, which explained partially the "French paradox," that people in France, even though they eat fatty foods like people in Finland, they do not get heart attacks in France compared to Finland. It was shown epidemiologically that it has to do with drinking red wine, because red wine contains antioxidants from the skin of the grape. (CX1358 (Aviram, Dep. at 5)).
740. Dr. Aviram was approached by POM and asked to do the same type of study that he did for red wine, and other fruits and vegetables, but now for pomegranates. (CX1358 (Aviram, Dep. at 6)).
741. After a year of studying in 1998 or 1999, Dr. Aviram concluded that pomegranate juice had greater antioxidant potencies than red wine. (CX1358 (Aviram, Dep. at 6)).
742. High-density lipoprotein cholesterol ("HDL" or so-called "good cholesterol") contains an antioxidant enzyme, called "paraonase" or "PON1" which acts to protect the body against oxygen radicals. (Heber, Tr. 1961).

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743. Dr. Aviram found that pomegranate juice benefits the activity of paraoxonase or PON1 by increasing its binding to HDL cholesterol. (Heber, Tr. 1961).
744. Beginning in 2000 and continuing until as recently as 2010, Dr. Aviram's *in vitro* and *in vivo* research on pomegranate juice and/or POMx pills showed reduction in oxidation of LDL cholesterol; lessening the uptake of oxidized and native LDL cholesterol by macrophage foam cells; diminishing the size of atherosclerotic lesions and foam cells; inhibition of macrophage cholesterol biosynthesis; decrease in macrophage oxidative stress; protection against cellular lipid peroxidation; reduction of serum lipids and glucose levels; improvement of PON1; and lessening of platelet aggregation. (PX0007; PX0008; PX0010; PX0015; CX0543; PX0017; PX0022; CX0053).
745. Dr. Sacks acknowledges that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on the mechanisms involved in cardiovascular disease and that *in vitro* studies, like Dr. Aviram's, can be competent and reliable evidence of an agent's effect on a particular mechanism. (Sacks, Tr. 1578).
746. Dr. Sacks agrees that Dr. Aviram's *in vitro* studies showed that pomegranate juice inhibits macrophage uptake of oxidized LDL, which is one component of atherosclerosis, and a significant reduction in atherosclerotic vessels, but that changes in macrophage levels are not a reliable surrogate marker of heart health. (Sacks, Tr. 1572, 1579, 1622).

**b. *In vitro* and *in vivo* studies on nitric oxide**

747. Respondents have also sponsored research in the area of nitric oxide and understanding its role in cardiovascular health. (PX0055; PX0056; PX0057; PX0058; PX0059).
748. Respondents have sponsored *in vitro* and *in vivo* research by Dr. deNigris, Dr. Napoli, and, Dr. Ignarro to conduct basic research on the effects of pomegranate juice on nitric

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oxide in the human body. (PX0055; PX0056; PX0057; PX0058; PX0059).

749. Nitric oxide is produced by the cells lining the heart blood vessels and by the cells lining the blood vessels of many organs around the body. Nitric oxide opens up tiny blood vessels and helps, among other things, preserve blood flow to the heart. (Heber, Tr. 1966-68).
750. Nitric oxide is beneficial in that it improves blood flow to almost every organ in the body that is dependent upon blood flow. (Heber, Tr. 1969-70).
751. In their *in vitro* and *in vivo* studies, Dr. deNigris, Dr. Napoli, Dr. Ignarro, and others found that pomegranate juice and/or POMx pills demonstrated: increasing and preserving levels of nitric oxide and decreasing expression of genes associated with stress and progression of atherosclerosis; reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells; reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels; decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and improving biological activity of nitric oxide. (PX0055; PX0056; PX0057; PX0058; PX0059).

**c. Experts' analysis on Respondents' basic research**

752. Complaint Counsel's expert witness, Dr. Sacks, opined the following regarding Respondents' basic research:
- *in vitro* studies do not provide reliable scientific evidence of what effects a treatment will have inside the human body;
  - animal studies cannot be generalized to describe what effects a treatment has on human subjects and, thus, do not provide reliable scientific evidence on whether an agent can

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treat, prevent or reduce the risk of cardiovascular disease in humans;

- *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease; and
- there is value in conducting *in vitro* and animal studies because it is possible to isolate mechanisms of action and accomplish toxicity or safety testing.

(CX1291 (Sacks Expert Report at 0015-16); PX0361 (Sacks, Dep. at 91)).

753. Respondents' expert witness, Dr. Ornish, opined the following regarding Respondents' basic research:

- *in vitro* and animal studies are important in considering the totality of evidence in determining whether or not pomegranate juice in its various forms is beneficial; and
- *in vitro* and animal studies have value in determining therapeutic value, but there are limitations to extrapolating from *in vitro* and animal studies to humans.

(PX0025 (Ornish Expert Report at 005, 007)).

**d. Determinations on Respondents' basic research**

754. Respondents' basic and animal science shows that pomegranate juice and/or its extract may be beneficial toward cardiovascular health by, among other things, reducing the oxidation of LDL cholesterol and its uptake, diminishing the size and scope of atherosclerotic lesions, macrophages, and foam cells, lessening platelet aggregation, and enhancing the presence of nitric oxide. (PX0007, PX0008, PX0010, PX0015, CX0543, PX0017, PX0022, CX0053, PX0055, PX0056, PX0057, PX0058, PX0059).

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755. The basic research relied upon by Respondents is part of the totality of evidence that must be examined in evaluating the effects of the POM Products, but *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease. F. 752-753.

**4. Overview of Respondents' clinical trials and surrogate markers in clinical studies on heart disease**

756. Respondents have sponsored approximately ten published studies on humans evaluating the effect of pomegranate juice and/or its extracts on cardiovascular health. (PX0004; PX0005; CX0611; PX0014; PX0020; PX0021; PX0023; PX0038; PX0127; PX0139). Two of these published human studies, the Davidson CIMT Study and the Ornish MP Study (discussed below), were designed as RCTs. In addition, Respondents conducted several unpublished human studies on POM Juice and POMx Pills related to cardiovascular health, also discussed below.
757. Respondents worked with Dr. Aviram and two other pre-eminent research scientists in the field of cardiovascular health to evaluate the potential benefits of pomegranate juice and/or its derivatives in humans: Dr. Dean Ornish and Dr. Michael Davidson. (PX0014; PX0023).
758. The qualifications of Dr. Ornish, who also testified as an expert for Respondents, are set forth in F. 227-230.
759. Dr. Davidson is the Clinical Professor of Medicine and Director of Preventive Cardiology at the University of Chicago Medical Center, Medical Director of Radiant Research, Chicago, and a practicing physician who typically treats patients with cholesterol abnormalities, coronary artery disease, or clinical atherosclerosis. Dr. Davidson has been involved, in some manner, in over 700 clinical studies over the past 25 years. (JX0003 at 0004; CX1134 at 0001; CX1336 (Davidson, Dep. at 218-21)).

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760. Dr. Sacks regards Dr. Davidson as one of the foremost clinical researchers in the cardiovascular field with a superb reputation for top-quality clinical trial research in cardiovascular disease. (Sacks, Tr. 1490).
761. In considering whether a study shows a benefit to cardiovascular disease, it is important to look at what endpoints have been measured. There are two kinds of endpoints: direct endpoints and surrogate markers. (CX1291 (Sacks Expert Report at 0013)).
762. In the case of heart disease, direct endpoints are heart attack, unstable angina, or the need for coronary artery bypass or angioplasty. Surrogate markers are measurements that are closely linked to the disease process such that a change in a surrogate marker can confidently be predictive of a change in the disease. (CX1291 (Sacks Expert Report at 0013)).
763. Blood pressure and LDL cholesterol are recognized as valid surrogate markers of cardiovascular health in clinical guidelines and by the FDA. (Ornish, Tr. 2334; Sacks, Tr. 1441; CX1291 (Sacks Expert Report at 0013)).
764. LDL cholesterol is a risk factor for heart disease, but is not actually heart disease. For that reason, Dr. Ornish testified, LDL cholesterol cannot be a valid surrogate. (Ornish, Tr. 2334). Dr. Heber further explained, when a person has a biomarker such as high LDL cholesterol which increases his or her risk, it is very distal or far away from the actual event of a heart attack which may be affected by many other factors, such as inflammation and oxidation. (Heber, Tr. 1974). There are a number of people who have low cholesterol levels, but get heart disease. (Ornish, Tr. 2334-35). About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. (Heber, Tr. 1974). There are people who have high cholesterol levels who do not have heart disease, and the same is true with high blood pressure. (Ornish, Tr. 2334-35).

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765. While the FDA, for the purposes of drug registration and testing, only accepts a limited number of surrogate markers, the number of indicators that physicians and scientists use is much greater and indicators can be at many points along the pathway of heart disease. (Heber, Tr. 1973).
766. Most experts (but not all) also recognize C-reactive protein, HDL cholesterol, and triglycerides as valid surrogate markers. (Sacks, Tr. 1441; CX1291 (Sacks Expert Report at 0013)).
767. Carotid intima media thickness, or “CIMT,” testing measures the combination of the vessel muscle and atherosclerosis (arterial plaque). There is a moderate connection between a reduction in the intima-media thickness and a reduction in atherosclerosis. (CX1291 (Sacks Expert Report at 0013); Sacks, Tr. 1442-43)).
768. Dr. Sacks acknowledged that the CIMT test is “a worthy test” and is relevant to cardiovascular health, but noted there is disagreement among experts on the prognostic value of CIMT. (Sacks, Tr. 1589-90; CX1291 (Sacks Expert Report at 0013)).
769. Dr. Sacks opined that if CIMT measures show consistent improvement, this would be an indicator that a treatment may be beneficial, but that he would be reluctant to rely on CIMT improvements alone, if these were the only evidence that an intervention treated heart disease. Dr. Sacks referenced a recent article in a leading cardiology journal that analyzed CIMT in relation to cardiovascular events and found that among a meta-analysis of 41 randomized trials, “there was no significant relationship between IMT regression and CHD [coronary heart disease] . . . events . . . CBV [cerebrovascular] events. . . and for all-cause death.” From this, Dr. Sacks opined, there is broad consensus that at least two types of imaging studies must be obtained to make inferences on benefit to cardiovascular disease. (CX1291 (Sacks Expert Report at 0014)).

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770. Myocardial perfusion (MP) is a measure of blood flow to the heart. Dr. Sacks opined that change in MP is not recognized as a surrogate marker of therapeutic effects on CHD. Even where blood flow is shown to be improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks Expert Report at 0020-21)).
771. Dr. Ornish opined that when researchers measure myocardial perfusion, researchers are actually measuring what matters most. How much blood flow the heart receives is really the “bottom line” in coronary heart disease. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2334-35).

**5. Cardiovascular studies sponsored by Respondents****a. Aviram 2000 Study**

772. In 2000, in a study titled, “*Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice*” by Aviram M, Dornfeld L, Rosenblat M, Volkova N, Kaplan M, Coleman R, Hayek T, Presser D, and Fuhrman B (Am. J. Clin. Nutr. 2000: 71;1062-76), (“Aviram 2000 Study “), Dr. Aviram and his colleagues examined the effect of pomegranate juice consumption on the atherogenesis process (the development of fatty plaques in the walls of arteries) in humans, animal models, and cells.
773. The Aviram 2000 Study consisted of two human studies: one involving 13 subjects who consumed pomegranate juice daily for two weeks; and one involving 3 subjects who consumed increasing doses for 10 weeks. The authors concluded that the study “showed the antiatherogenic capabilities of PJ [pomegranate juice] in 3 related components of atherosclerosis, plasma lipoproteins, arterial macrophages, and blood platelets. The potent antioxidative capacity of PJ against lipid peroxidation may be the central link for the

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antiatherogenic effects of PJ on lipoproteins, macrophages, and platelets.” (PX0004 at 0001-02, 0004-05, 0014).

**b. Aviram ACE/BP Study****i. About the Aviram ACE/BP Study**

774. In 2001, in a study titled, “*Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure*” by Aviram M and Dornfeld L, (*Atherosclerosis* 158 (2001) 195-198) (“Aviram ACE/BP Study”), Dr. Aviram and his co-workers conducted a study with ten elderly, hypertensive patients who drank 50 ml. of pomegranate concentrate daily, for two weeks. (CX0542 at 0002; CX1358 (Aviram, Dep. at 21)).
775. The Aviram ACE/BP Study measured angiotensin converting enzyme (“ACE”) activity and blood pressure. (CX0542 at 0001). ACE is an enzyme that alters the function of angiotensin, which relates to blood pressure for each patient. (Stampfer, Tr. 742).
776. The Aviram ACE/BP Study was unblinded and had no control group; instead, each patient’s “before” measures were compared to his or her “after” measures. (CX1358 (Aviram, Dep. at 22-24); CX0025 at 0012).
777. According to the Aviram ACE/BP Study, seven of the ten patients experienced a statistically significant 36% reduction in serum ACE activity from their baseline measure. (CX0542 at 0001). The article does not reveal what happened to the ACE levels of the other three patients or analyze the overall results in all ten patients. (CX1291 (Sacks Expert Report at 0016-17); CX0542 at 0002-03; *see also* Stampfer, Tr. 741-42; CX1293 (Stampfer Expert Report at 0017-18)). Dr. Aviram testified that there was “no effect” from pomegranate juice on the other three patients’ ACE levels. (CX1358 (Aviram, Dep. at 23)).

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778. The Aviram ACE/BP Study reports that all ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. (CX0542 at 0002-03; CX1291 (Sacks Expert Report at 0016-17)).
779. The Aviram ACE/BP Study concludes that, “pomegranate juice consumption can offer a wide protection against cardiovascular disease.” (CX0542 at 0003).

**ii. Experts’ analysis on the Aviram ACE/BP Study**

780. Complaint Counsel’s experts criticized the Aviram ACE/BP Study on the following grounds:
- the sample size of ten patients is too small to provide reliable evidence that the observed effects would be generally applicable to a larger population
  - the two-week period of the study was too short to provide reliable evidence that the reported improvement in ACE activity and blood pressure would be enduring; and
  - ACE (one of the study endpoints) is not a recognized surrogate marker of cardiovascular disease.

(CX1291 (Sacks Expert Report at 0017); *see also* Stampfer, Tr. 748).

781. Complaint Counsel’s experts also testified that although blood pressure reduction is a validated surrogate for heart disease, the Aviram ACE/BP Study does not provide competent and reliable evidence to support a claim of effectiveness for heart disease because it was not a blinded, placebo-controlled study. According to these experts, given the lack of a control group, it is not possible to conclude what caused the reported improvements in the subjects’ blood pressure levels; and without a control

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group, this study was simply an observational study on patients given pomegranate juice concentrate. (CX1291 (Sacks Expert Report at 0017); Sacks, Tr. at 1452-54; *see also* Stampfer, Tr. 748, 771; CX1293 (Stampfer Expert Report at 0019)).

782. Dr. Ornish's response to Complaint Counsels' experts' criticism (F. 780-781) is that the Aviram ACE/BP Study should be viewed in the larger context of other studies in this area, as its findings are congruent with, and supportive of, other research. (PX0025 (Ornish Expert Report at 0009)).
783. Dr. Ornish testified that there is a common misconception that a larger study is a better study, but the opposite can be argued. When a study has a smaller number of patients, the treatment has to be that much more powerful and that much more consistent for it to be statistically significant. (Ornish, Tr. 2362-63; CX1339 (Ornish, Dep. at 22-23)).
784. Dr. Aviram explains that comparing the statistics from each patient after treatment to his or her own statistics before treatment is a valid method to conduct a study. (CX1348 (Aviram, Dep. at 12-13)).
785. A study with a small number of subjects or conducted without a placebo does not weaken the importance of the result, especially if the results are in agreement with previously published findings conducted through *in vitro*, mechanistic, and animal models. (CX1348 (Aviram, Dep. at 18)).

**iii. Determination on the Aviram ACE/BP Study**

786. The Aviram ACE/BP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 774-785).

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**c. Aviram CIMT/BP Study****i. About the Aviram CIMT/BP Study**

787. The carotid arteries are located on each side of the neck and provide the main blood supply to the brain. Carotid artery stenosis (“CAS”) is a narrowing or constriction of the inner surface (lumen) of the carotid artery, usually caused by atherosclerosis. (JX0003 at 0001).
788. Stenosis occurs when a person has more than a 50 percent blockage in one of the carotid arteries. To remove a blockage in the carotid artery, a person undergoes an operation called an endarterectomy, where the buildup is removed and a graft is placed in the artery. CAS is a risk factor for heart disease. (Heber, Tr. 1963).
789. In 2004, Dr. Aviram and his co-workers investigated, among other things, the effects of pomegranate juice consumption by patients with CAS in a study titled, “*Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation*” by Aviram M, Rosenblat M, Gaitini D, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, (Clin Nutr. 2004; 23:423-33), (“Aviram CIMT/BP Study”). (CX0611).
790. In the Aviram CIMT/BP Study, a group of ten patients with severe CAS consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. A second group of nine patients who did not consume pomegranate juice acted as a control. (CX0611 at 0001-02).
791. In the Aviram CIMT/BP Study, in the control group that did not consume pomegranate juice, the patients’ carotid intima-media thickness increased by 9% during one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. (CX0611).

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792. In the Aviram CIMT/BP Study, in two out of the ten patients on pomegranate juice (after 3 and 12 months) due to clinical deterioration, carotid endarterectomy surgery was performed. Their carotid lesions were analyzed and compared to lesions obtained from seven patients that did not consume pomegranate juice (not the patients of the placebo group). The cholesterol content in carotid lesions from the two patients that consumed pomegranate juice was lower by 58% and 20%, respectively, in comparison to lesions obtained from CAS patients that did not consume pomegranate juice. The lipid peroxides content in lesions obtained from the patients after pomegranate juice consumption for 3 or 12 months was significantly reduced by 61% or 44%, respectively, as compared to lesions from patients that did not consume pomegranate juice. (PX0025 (Ornish Expert Report at 0011)).
793. Dr. Ornish testified that the findings in the Aviram CIMT/BP Study suggest that oxidative stress, including oxidation of LDL to a form that makes it more likely to cause arterial blockages and cause foam cell production in macrophages (macrophage-derived foam cells play integral roles in all stages of atherosclerosis) may have been reduced by pomegranate juice consumption in these patients. (PX0025 (Ornish Expert Report at 0011)).
794. The Aviram CIMT/BP Study reports that the pomegranate juice group members' systolic blood pressure was significantly ( $p < 0.05$ ) reduced by 12% after one year of pomegranate juice consumption compared to their baseline values. In the group that did not consume pomegranate juice, blood pressure was unchanged. (CX0611 at 0005).
795. The CIMT and blood pressure changes described in the Aviram CIMT/BP Study are *within-group* analyses. The Study did not provide any *between-group* statistical analysis, that is, analysis of changes in CIMT and blood pressure between the active and control groups at the end of the study. (Sacks, Tr. 1456-57; CX0163 at 0017 (stating that between group analysis was not performed for any of the outcomes)). Dr. Aviram explained that each

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subject in the study served as his or her own control. (CX1358 (Aviram, Dep. at 27-28, 32)).

796. The Aviram CIMT/BP Study concluded: “pomegranate juice consumption (by patients with carotid artery stenosis) possess anti-atherosclerotic properties, as it substantially decreased serum oxidative stress and, in parallel, reduced common carotid intima-media thickness.” (CX0611 at 0009).
797. The Aviram CIMT/BP Study also concluded that the “results of the present study thus suggest that PJ [pomegranate juice] consumption by patients with CAS decreases carotid IMT and systolic blood pressure and these effects could be related to the potent antioxidant characteristics of PJ polyphenols.” (CX0611 at 0002).

**ii. Experts’ analysis on the Aviram CIMT/BP Study**

798. Dr. Sacks testified that a qualified scientist would not be able to conclude with any credibility that the Aviram CIMT/BP Study’s reported improvements in the treatment group were caused by their consumption of pomegranate juice and not some other factor because of: the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size, and the lack of any between-group statistical analysis. (Sacks, Tr. at 1459, 1585; CX1291 (Sacks Expert Report at 0019)).
799. Dr. Sacks concedes that he has no basis to disagree with Dr. Aviram’s numbers. (Sacks, Tr. 1589-90).
800. Dr. Stampfer concluded the Aviram CIMT/BP Study does not support Respondents’ heart disease prevention and treatment claims or their lower blood pressure claims. (CX1293 (Stampfer Expert Report at 0018)).
801. Dr. Ornish responds to Complaint Counsels’ experts’ criticism (F. 798-800) that the Aviram CIMT/BP Study should be viewed in the larger context of other studies in

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this area, as its findings are congruent with and supportive of other research. (PX0025 (Ornish Expert Report at 0010-11)).

802. Dr. Ornish agreed that the Aviram CIMT/BP Study was limited in scope and opined: “Thus, while not at all conclusive, the study suggests a benefit.” He further testified that the Aviram CIMT/BP Study (2004) was “very provocative and interesting and laid the groundwork for even more conclusive studies.” (PX0025 (Ornish Expert Report at 0010-11); PX0355 (Ornish, Dep. at 107)).
803. Dr. Heber also testified that small studies can be more informative than large studies. (Heber, Tr. 1963).

**iii. Determination on the Aviram CIMT/BP Study**

804. The Aviram CIMT/BP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 789-803).

**d. Ornish MP Study**

805. Dr. Dean Ornish and the Preventative Medicine Research Institute (“PMRI”) conducted two studies for Respondents: (1) Sumner M, et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005) (“Ornish MP Study”) (CX1198; *see* JX0003 ¶ B.16); and (2) the Ornish CIMT Study (unpublished, 2005). (CX0754; *see* JX0003 ¶ B.16).
806. These studies (F. 805) were the only studies ever conducted by Dr. Ornish to consider whether a single food product has health benefits. (Ornish, Tr. 2464).
807. The contract setting forth the terms of the two studies conducted by Dr. Ornish (F. 805) was a September 19,

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2003, letter agreement between the Resnicks, as Trustees of the Stewart and Linda Resnick Revocable Trust, and Dr. Ornish's organization, PMRI. (CX0613 at 0001). Attached to the letter agreement were protocols for the two studies. Although the Ornish MP Study budget was \$708,436, and the CIMT Study budget was \$496,390, the funding of these studies was cut short. (Ornish, Tr. 2431-35, 2436, 2441, 2454).

**i. About the Ornish MP Study**

808. In the Ornish MP Study, Dr. Ornish and his colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion (or blood flow) in 45 patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study. (PX0023 at 0001; Ornish, Tr. 2336).
809. In the Ornish MP Study, patients were randomly assigned into one or two groups: a pomegranate juice group (240 ml./day, approximately 8 ounces) or a placebo group that drank a beverage of similar caloric content, amount, flavor, and color. (PX0023 at 0001-02).
810. The Ornish MP Study provides data on three imaging measures at baseline and three months for myocardial perfusion: the summed rest score, or "SRS" (imaging results before the pharmacologic or exercise challenge), the summed stress score, or "SSS" (imaging results after the pharmacologic or exercise challenge) and the summed difference score, "SDS" (calculated by subtracting the SRS from the SSS). (CX1198 at 0003 (Table 2); CX1291 (Sacks Expert Report at 0020)).
811. The Ornish MP Study indicated that after three months there was a significant ( $p = 0.05$ ) improvement of 17% in the SDS score in the POM Juice group, as compared to an average worsening of 18% in the control group. The comparative benefit of the pomegranate juice group to the placebo group in the Ornish MP Study was about 35

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percent. (PX0023 at 0001; Ornish, Tr. 2337-38; Heber, Tr. 1972).

812. Those differences (F. 811) were statistically significant and the results were published in the *American Journal of Cardiology*. (PX0023; Ornish, Tr. 2337-39; Heber, Tr. 1971-72).
813. The Ornish MP Study also indicated that there were no statistically significant differences between the two groups in SSS and SRS, and no significant changes in blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX1198 at 0003-04, Table 3 (notation below table); CX1291 (Sacks Expert Report at 0024)).
814. A conclusion of the Ornish MP Study was that “[t]he results of this study demonstrate, for the first time, that daily consumption of pomegranate juice for 3 months may decrease myocardial ischemia and improve myocardial perfusion in patients who have ischemic CHD [coronary heart disease] as measured by the SOS.” (PX0023 at 0004).
815. Another conclusion of the Ornish MP Study was that “[a]lthough the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period suggest that daily consumption of pomegranate juice may have important clinical benefits in this population. (PX0023 at 0004).
816. The American Heart Association (“AHA”) rejected the Ornish MP Study abstract in August 2004. Dr. Ornish asked the AHA’s chairman of scientific sessions to reconsider, but the chairman responded that “[m]ultiple qualified, blinded graders scored this abstract below acceptable range.” (CX0672, CX0680).
817. In November 2004, the *Journal of the American Medical Association* (“JAMA”) rejected the Ornish MP Study manuscript. In response to Dr. Ornish’s request for

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feedback, the Deputy Editor of JAMA responded that “the study appears very preliminary, with small sample size, apparent baseline imbalances between groups, use of an intermediate endpoint as main outcome measure, and modest differences with large variability.” (CX0699 at 0001-02).

818. Dr. Ornish then submitted the Ornish MP Study manuscript to the *American Journal of Cardiology*. The editor accepted it without external peer-reviews. (CX1339 (Ornish, Dep. at 200); CX0715).

**ii. Experts’ analysis on the Ornish MP Study**

819. In trial testimony and in his expert report, Dr. Ornish acknowledged that “some problems” occurred during the Ornish MP Study that were not “optimal.” (Ornish, Tr. 2394; PX0025 (Ornish Expert Report at 0016)).
820. In the Ornish MP Study, although 41 patients completed the study, the published report provided data on only 39 patients. Complaint Counsel’s experts opined that alterations in the original sample size may be critical when there is a borderline “*p*” value. (CX1291 (Sacks Expert Report at 0022); Sacks Tr. 1478-79; Ornish, Tr. 2394; *see* CX1198 at 0003 (Table 2); CX0664 at 0001).
821. Dr. Ornish agrees that a mistake was made in the Ornish MP Study in not reporting data on 41 patients, but opined that when data on all 41 patients was analyzed, the difference in SDS remained statistically significant and, therefore, the conclusions of the study remain valid. If anything, according to Dr. Ornish, the results were more statistically significant and even stronger because the sample size was slightly larger. (PX0025 (Ornish Expert Report at 0015); Ornish, Tr. 2347-48; 2394).
822. Dr. Sacks criticized the Ornish MP Study because two subjects in the placebo group did not receive a placebo treatment. They were tested at baseline and three months, with no intervention, and their data was included in the

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final study results. (Sacks, Tr. 1475-77; CX1339 (Ornish, Dep. at 168-70); CX0580 (patients' names *in camera*)).

823. Dr. Ornish explained that, initially, the two patients had been randomized to the control group in the Ornish MP Study and their measurements taken at baseline. As a result of funding issues, however, the study was put on hold. Three months later, the myocardial perfusion study resumed. Because these patients were already in the control group and their measurements taken at baseline, the decision was made to include them in the control group. Dr. Ornish explained his rationale for doing so as follows: “effectively, having nothing is the same as having a placebo beverage. I think it is probably worth putting in context that in any study there are things that are not optimal because you are dealing with human beings and all the vagaries of that and particularly in a study where the funding was changed midstream . . . . But the question is whether those things are considered likely to have impacted the validity of the study, including in this case the answer is no.” (CX1339 (Ornish, Dep. at 169-71); PX0025 (Ornish Expert Report at 0016)).
824. Complaint Counsel’s experts criticize the Ornish MP Study on the additional ground that that six patients were unblinded before their three-month test dates – meaning the study patients discovered which beverage they were consuming. Dr. Ornish testified that the unblinding of the patients did not undermine the validity of the study or its conclusions. Dr. Ornish further testified that the expectation that an intervention is beneficial has the potential for confounding the outcome of a study, but such an outcome was unlikely to have occurred in this study because at the time that the study was conducted, there was not an awareness in the general population that pomegranate juice was beneficial or even that the subjects were drinking pomegranate juice (the study was titled a “beverage study”). (Ornish, Tr. 2345-46, 2403-09; (CX1339 (Ornish, Dep. at 146-49); PX0025 (Ornish Expert Report at 0016)).

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825. Drs. Sacks and Stampfer testified that the Ornish MP Study did not use a recognized surrogate marker of heart disease. (CX1291 (Sacks Expert Report at 0020-21); Sacks, Tr. 1464 (myocardial perfusion, a measure of blood flow, is not used as the primary outcome in studies of treatment efficacy for coronary heart disease); Stampfer, Tr. 771-72 (blood flow is a research tool but not a recognized surrogate marker)). Even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. (CX1291 (Sacks Expert Report at 0020-21)).
826. Dr. Sacks also testified that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. (Sacks, Tr. 1593).
827. Dr. Ornish opined that blood flow is essential to life, an important measure of heart disease, and the “bottom line” in coronary heart disease (along with how well the heart is pumping blood) and, thus, when researchers measure myocardial perfusion, researchers are actually measuring what matters most. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2331-35).
828. Dr. Ornish further explained: Blood carries oxygen and nutrients that feed the heart. If the blood flow the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. If the reduction in blood flow is temporary, then the person often experiences angina, or chest pain. If this reduction in blood to the heart lasts more than a few hours, then that portion of the heart that is underperfused may die and turn in to scar tissue – this is commonly referred to as a “heart attack.” (PX0025-0012; Ornish, Tr. 2331-35).
829. Respondents’ experts testified that in comparing myocardial perfusion and LDL cholesterol, myocardial

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perfusion is more closely connected as a surrogate marker for cardiovascular disease. When a person has a biomarker like high LDL cholesterol which increases his or her risk, that is far away from the actual event of a heart attack, which may be affected by many other factors, such as inflammation and oxidation. There are a number of people who have low cholesterol levels, but get heart disease. About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. There are people who have high cholesterol levels who do not have heart disease, and the same is true for blood pressure. When measuring myocardial perfusion, researchers are actually measuring what matters most, which is how much blood flow the heart is receiving. (Ornish, Tr. 2334-35; Heber, Tr. 1974).

830. Dr. Ornish also opined that the degree of blockage is only one of several mechanisms that affect perfusion, or blood flow to the heart. Other mechanisms include changes in vasomotor tone (how dilated or constricted the coronary arteries are), platelet aggregation (how sticky the platelets are that can form blood clots that may partially or completely occlude the flow of blood to the heart), and collateral blood flow (the heart can grow new blood vessels that provide additional blood flow around partial or even completely blocked arteries if the blockage occurs slowly overtime). (PX0025 (Ornish Expert Report at 0012)).
831. Dr. Sacks testified that another problem with the Ornish MP Study was that the primary endpoint measurement indicated in the published study as the main proof of benefit (SDS) was not identified as the primary endpoint in the protocol. The protocol for the Ornish MP Study provided for measurement of perfusion, but did not identify whether the primary endpoint would be SSS, SRS, SDS or some other imaging measurement. (CX1291 (Sacks Expert Report at 0021); *see also* CX0613 at 0009-10). Dr. Ornish conceded that he did not specify that changes in SDS would be the primary endpoint measure. (PX0025 (Ornish Expert Report at 0014); *see also* Sacks, Tr. 1475).

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832. Dr. Ornish explained in response to Dr. Sacks' criticism (F. 831) that although the Ornish MP Study did not specify that changes in SDS would be the primary endpoint measure, it was not necessary to do so since SDS is a measure of how much of the heart was not receiving enough blood flow. Because SDS is derived by subtracting SRS from SSS, it is a way of factoring out the amount of infarcted or hibernating myocardium, so Dr. Ornish could focus on what he was most interested in: SDS. PX0025 (Ornish Expert Report at 0014)).
833. The 35 percent improvement in myocardial perfusion indicated in the Ornish MP Study pertained only to the SDS scores, and not to the SRS and SSS data. (Sacks, Tr. 1622-24). Dr. Sacks and Dr. Stampfer both stated that the .05 "*p*" value of the reported SDS improvement is not very persuasive where, as here, there were three possible outcome measures (SSS, SRS, and SDS) and only one just met significance. (CX1198 at 0003; Sacks, Tr. 1467 ("when there are . . . multiple outcomes . . . then a *p*-value of .05 . . . doesn't convey the same level of confidence than in a situation where there is one primary outcome"); CX1291 (Sacks Expert Report at 0021-22); Stampfer, Tr. 751 ("[T]he second reason I don't put a lot of weight on this is that the results were only slightly significant just for one of the three endpoints that was not specified as the primary outcome in advance.")).
834. Dr. Ornish testified that while the Ornish MP Study did indicate a statistically significant change in the SDS, Dr. Ornish did not ignore the SSS and SRS measures that were shown in Table 2 of the study. The Ornish MP Study examined all three measurements in an effort to divine the SDS, as the primary hypothesis was that pomegranate juice would result in an improvement in SDS, a measure of the heart not receiving enough blood. (PX0023 at 0003; PX0025 (Ornish Expert Report at 0001); PX0355 (Ornish, Dep. at 128-29; 139)).
835. Complaint Counsel's experts also criticized the Ornish MP Study based on the large discrepancy in the blood flow values between the placebo and active groups at baseline.

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The baseline SSS for the placebo group was  $9.6 \pm 6.5$ , and the baseline SSS of the juice group was  $6.4 \pm 3.5$ , meaning that the placebo group was sicker than the juice group when the study started. (CX1198 at 0003 (Table 2); CX1291 (Sacks Expert Report at 0022-23); Sacks, Tr. 1469-72, 77; Stampfer, Tr. 750-52). Study documents from Dr. Ornish's clinic files show that the difference between the baseline SSS values of the placebo and juice groups was so large as to be statistically significant. (CX0701 at 0001 (email from M. Sumner to M. Eller, forwarded to D. Ornish, stating, "[t]here was a baseline difference in SSS between the experimental and the control groups ( $p < .04$ ). We don't have to mention this, but we should keep this in mind."))).

836. Complaint Counsel's experts further opined that the imbalance in baseline values in the Ornish MP Study shows that randomization did not produce an active group and a placebo group that were similar on relevant characteristics. (Stampfer, Tr. 751-52; CX1293 (Stampfer Expert Report at 0019); CX1291 (Sacks Expert Report at 0023)). It could be predicted that the control group, having worse coronary perfusion than the POM Juice group at baseline, would have a more accelerated form of the disease and show worsening on follow-up. (CX1291 (Sacks Expert Report at 0022-23); Sacks, Tr. 1469-72, 77; *see also* Stampfer, Tr. 751 ("[H]ere, the placebo group was worse off at the start, and it's easy to imagine that if you're worse off at the start, you are going to get worse faster over time. So, the evidence isn't persuasive.")). Dr. Sacks stated that the baseline difference should have been reported in the publication. (Sacks, Tr. 1477; CX1291 (Sacks Expert Report at 0023)).
837. Dr. Ornish testified that although there was a difference in SSS at baseline, the Ornish MP Study employed an "analysis of variance," which took into account any baseline differences. The Ornish MP Study stated: "To test for the effects of experimental condition and time (and their interaction) on medical characteristics, 2 (experimental vs. placebo) X 2 (baseline vs. 3 months) analyses of variance for repeated measurements were run,"

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which built into the analysis controlling for baseline differences. Further, when researchers recruit randomly and look at a number of different measures, it is not uncommon that one difference may be statistically significant in the group. Even if there had been a difference in SSS at baseline, this would not have undermined the validity of the study, particularly since it was not Dr. Ornish's primary endpoint measure. (Ornish, Tr. 2343-44, 2394; PX0025 (Ornish Expert Report at 0015)).

838. Dr. Sacks criticized the Ornish MP Study on the additional basis that blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. (CX1291 (Sacks Expert Report at 0024)).
839. Dr. Ornish himself concluded that "blood pressure . . . did not improve" in the Ornish MP Study. (PX0025 (Ornish Expert Report at 17)).
840. Dr. Ornish also explained, the fact that other factors such as blood pressure and cholesterol did not improve in the Ornish MP Study does not in any way provide evidence that pomegranate juice was not beneficial, as its effects may have been mediated via other pathways. (PX0025 (Ornish Expert Report at 0017-18)).
841. Dr. Heber testified that in the Ornish MP Study, even though there was no change in blood pressure, one could not conclude that there was no effect of pomegranate juice on blood pressure, because the primary endpoint was blood flow, not blood pressure. (Heber, Tr. 2101-02).
842. In any clinical study, it is routine to take a blood pressure, pulse, body temperature, among others, to make sure patients are healthy. Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. (Heber, Tr. 2101, 2040).
843. Dr. Sacks notes that Dr. Ornish's study originally was designed to last for 12 months, with measurements at

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baseline, three months, and 12 months, but was halted after three months. Dr. Sacks opined that the study was terminated under unusual circumstances because, according to correspondence, at the time, the *p*-value was considered significant rather than at the time the trial was originally set to end. Dr. Sacks further opined that the shortened study period and failure to report the planned duration is inconsistent with widely-accepted standards for conduct of clinical trials and undermines any confidence in the findings. (CX1291 (Sacks Expert Report at 0023-24); Sacks, Tr. 1474-75).

844. Dr. Ornish testified that the Ornish MP Study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the *p*-value was statistically significant at three months. Dr. Ornish further opined that while he did not have 12 months of follow-up data, this does not undermine the confidence in the three-month findings of the Ornish MP Study. (PX0025 (Ornish Expert Report at 0017)).
845. Complaint Counsel's experts concluded: The interpretation of the Ornish MP Study that is most consistent with principles of clinical study design and conduct is that the pomegranate juice treatment had no effect on any measure of cardiac health. (CX1291 (Sacks Expert Report at 0024)). Experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit, either in terms of prevention or treatment. (Sacks, Tr. 1472, 1526-28). In light of the problems in the design and conduct of the study, and the discrepant results of the SSS, SDS, and SRS measures, the study does not even support the conclusion that pomegranate juice had a favorable effect on coronary perfusion (blood flow to the heart). CX1291 (Sacks Expert Report at 0024); CX1293 (Stampfer Expert Report at 0018-19)).
846. Respondents' experts concluded the following about the Ornish MP Study:

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- Myocardial perfusion (or blood flow to the heart) is a good predictor or surrogate for cardiac events and a better scientific test than coronary angiography. (PX0025 (Ornish Expert Report at 0012); Ornish, Tr. 2331-34; Heber, Tr. 1973-74).
  - SDS is considered a valid surrogate for coronary heart disease and the Ornish MP Study showed SDS, but not SRS or SSS, because SDS measures the primary endpoint, how much blood flow the heart is getting when compared to rest and stress. (Ornish, Tr. 2341-42).
  - Differences at baseline for SRS and SSS did not affect the outcome of the Ornish MP Study. (Ornish, Tr. 2343-44, 2394; PX0025 (Ornish Expert Report at 0015)).
  - Omissions of patient data did not alter the results of the Ornish MP Study. (PX0025 (Ornish Expert Report at 0015); Ornish, Tr. 2347-48; 2394).
  - The unblinding of patients or lack of a placebo does not diminish the validity of the Ornish MP Study. (Ornish, Tr. 2345-46; PX0025 (Ornish Expert Report at 0016); CX1339 (Ornish, Dep. at 148-49)).
  - The results of the Ornish MP Study are valid even though they were tested over only a three-month period. (PX0025 (Ornish Expert Report at 0017)).
847. Dr. Ornish concluded that the Ornish MP Study constitutes credible and reliable science showing that pomegranate juice lessens the risk of cardiovascular problems, that in people who have already had heart disease, it improves the blood flow and reverses the progression of heart disease; and if you can begin to

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reverse a disease, it would only make sense that pomegranate juice would work even better to help prevent heart disease in the first place. (Ornish, Tr. 2354-55).

**iii. Determination on the Ornish MP Study**

848. The Ornish MP Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 808-846).

**e. Ornish CIMT Study****i. About the Ornish CIMT Study**

849. The second study Dr. Ornish conducted for Respondents, the Ornish CIMT Study, was completed in 2005 and is unpublished. (JX0003 ¶ B.16).
850. The Ornish CIMT Study was a randomized, double-blind, placebo-controlled 73-person study that measured CIMT, blood pressure, and other related mechanisms for 12 months. The primary endpoint of the Ornish CIMT Study was to investigate the effects of pomegranate juice on CIMT and indices of arterial stiffness for the common carotid arteries (CCA) in patients with at least one cardiovascular risk factor. The treatment group drank one cup (eight ounces) of pomegranate juice concentrate daily, and the control group drank one cup of placebo beverage, daily, for one year. (CX0754 at 0002; CX0613 at 0020).
851. The Ornish CIMT Study was designed to include 200 patients, not 73 patients. Dr. Ornish estimated that he would need at least 200 patients to show a statistically significant difference in CIMT however, because recruitment took longer than anticipated (since most patients with heart disease ended up having angioplasty, stents, and/or bypass surgery at a much higher rate than anticipated), the funding was cut, so Dr. Ornish was only able to recruit 73 patients, from which 56 patients' pre and post data was collected. (Ornish, Tr. 2352; PX0355a007 at 0002).

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852. The primary purpose of the Ornish CIMT Study was to determine if pomegranate juice will affect the progression of early/subclinical carotid atherosclerosis. (PX355a0006 at 0004; PX0355a007 at 0010).
853. On or about October 21, 2004, PMRI finished its data collection. (CX0697). Commenting on the study data, Dr. Sumner of PMRI stated, “very few significant interactions . . . a mixed, but relatively disappointing bag so far.” (CX0717 at 0001; CX1344 (Sumner, Dep. at 151-52)).
854. On March 24, 2005, Dr. Sumner stated, “I am looking into additional ways to analyze the data” and suggested sending “the IMT results to [another researcher] to check before [sending] them to Harley [Liker]/the Resnicks.” (CX0717 at 0001; *see also* CX0718 at 0001). The next day, another PMRI employee suggested having a biostatistician analyze the data “before concluding the juice had a null effect.” (CX0719 at 0001).
855. Dr. Ornish testified that it would be wrong to classify the Ornish CIMT Study as a “null” study. Instead, Dr. Ornish explained that the study was underpowered because PMRI knew from the beginning that they needed 200 patients. Thus, the study ended with an indeterminate finding, not a clearly nonsignificant finding. (Ornish, Tr. 2456-61).
856. The final analysis for the Ornish CIMT Study results was conducted in approximately June 2005 and the results of the study were provided to Dr. Ornish. (CX1344 (Sumner, Dep. at 168-69); CX0752).
857. In the Ornish CIMT Study, Dr. Ornish observed an improvement in the carotid artery significant to the 0.13 level as opposed to the 0.15 level. Dr. Ornish testified that if that degree of change had occurred in the larger number of patients he had projected (*i.e.*, 200 instead of 73), it would have been at the 0.05 level or less and, thus, would have reached statistical significance. (Ornish, Tr. 2352-54).

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858. According to the Ornish CIMT Study unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. (CX0754 (transmitting “Bev 2 Summary 6-16-05.doc”)).
859. In the Ornish CIMT Study unpublished final report, there also were no significant differences in the treatment group relative to the placebo group over time for any of the other heart-related measurements, including systolic and diastolic blood pressure, cholesterol, LDL, HDL, or triglycerides. (CX0754 at 0003, 0005; CX1291 (Sacks Expert Report at 0024-25); Stampfer, Tr. 754-55; CX1293 (Stampfer Expert Report at 0019-20)).

**ii. Experts’ analysis of the Ornish CIMT Study**

860. Complaint Counsel’s expert opined that the Ornish CIMT Study appears to have been well-designed and well-conducted. (Sacks, Tr. 1485-88, 1603; CX1291 (Sacks Expert Report at 0026)).
861. Dr. Sacks described the results of this study as “convincingly null, showing that pomegranate juice treatment did not improve CIMT or the other tested parameters” including elasticity of the arteries, blood pressure, or cholesterol. (Sacks, Tr. 1484-86; CX1291 (Sacks Expert Report at 0026); *see also* CX1293 (Stampfer Expert Report at 0019-20); Stampfer, Tr. 755).
862. Dr. Sacks opined that the null results of the Ornish CIMT Study confirm that the purportedly positive results of Dr. Aviram’s unrandomized, uncontrolled 19-patient CIMT/BP Study lack credibility. (Sacks, Tr. 1486-88; CX1291 (Sacks Expert Report at 0026)).
863. Dr. Ornish opined that it would be more accurate to see the Ornish CIMT Study as a validation of the studies by Dr. Aviram and Dr. Davidson, since the differences in CIMT would have been statistically significant if the findings measured in 73 patients were found in the 200

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patients that Dr. Ornish originally planned to enroll. (PX0025 (Ornish Expert Report at 0019)).

864. Dr. Ornish testified that the Ornish CIMT Study was an indeterminate study that cannot be relied upon: “It neither proves or disproves. It would be, again, as wrong to say that it proves as it would be for Dr. Sacks to assert that it disproves it.” (PX0355 (Ornish, Dep. at 192-93)).
865. Dr. Heber did not consider the results of the Ornish CIMT Study in reaching his conclusions on the adequacy of Respondents’ substantiation, because it was “incomplete.” Dr. Heber observed that the Ornish CIMT Study “had inadequate power at that number of subjects,” so no conclusions could be drawn from the study. (PX353 (Heber, Dep. at 180-81); Heber, Tr. 2133-34).
866. Dr. Heber opined: “The failure of any clinical trial to show a difference cannot be interpreted as a negative finding, however. Only a probability that any difference has been excluded can be calculated, using the so-called beta type II error calculation, which was not done by Dr. Stampfer.” (PX0192 (Heber Expert Report at 0053)).
867. Dr. Sacks admits that the lack of statistical significance for a positive result in the Ornish CIMT Study is not proof of a negative and does not mean pomegranate juice is not beneficial. (Sacks, Tr. 1608-09).

**iii. Determination on the Ornish CIMT Study**

868. The Ornish CIMT Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 849-867).

**f. Davidson CIMT Study**

869. In 2003, Dr. Liker approached Dr. Davidson about conducting a CIMT study and a brachial artery reactivity testing study for Respondents. From the beginning, Dr. Liker indicated that the he wanted the study to be

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randomized, double-blind, and placebo-controlled. (CX1336 (Davidson, Dep. at 92-93); CX0586).

870. In a summary of cardiovascular studies sent to a scientific consultant for POM, Dr. Liker described the Aviram ACE/BP Study, the Aviram CIMT/BP Study, the Ornish MP Study (2005), and the unpublished Ornish CIMT Study, and stated that POM was still exploring its research options “in its efforts to understand whether or not the consumption of pomegranate juice offers cardiovascular benefits.” (CX0579 at 0003-04).
871. Dr. Davidson conducted two studies for Respondents: (1) Davidson MH., et al., *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009) (“Davidson CIMT Study”) (CX1065; see JX0003 ¶ B.17); and (2) Davidson MH, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation* (unpublished, 2004) (“Davidson BART/FMD Study”) (CX0684; see JX0003 ¶ B.17). The cost for the two studies, sponsored by the Stewart and Lynda Resnick Revocable Trust, was \$2,940,494. (CX1134 at 0001).

**i. About the Davidson CIMT Study**

872. The Davidson CIMT Study was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial conducted at two clinical research sites in accordance with good clinical practice guidelines and under a protocol approved by an institutional review board. (PX0014 at 0001-02).
873. The Davidson CIMT Study was designed to test the effect of pomegranate juice on CIMT progression rates in subjects at moderate coronary heart disease risk. (PX0014 at 0001-02).
874. The Davidson CIMT Study analyzed the results of 289 persons, but actually screened and enrolled 876 and 383

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subjects, respectively. (PX0014 at 0002; CX1065 at 0001; CX1291 (Sacks Expert Report at 0027)).

875. Participants in the Davidson CIMT Study were middle-aged men and women with one or more coronary heart disease risk factors (high LDL, low HDL, hypertension or use of hypertension medication, or cigarette smoking) and were required to have a baseline posterior wall common CIMT measurement of  $> 0.7$  and  $< 2.0$  mm on  $\geq 1$  side (right or left). The study excluded persons with actual coronary heart disease or diabetes. (PX0014 at 0002; CX1065 at 0001-02; CX1291 (Sacks Expert Report at 0027)).
876. Participants in the Davidson CIMT Study drank eight ounces of pomegranate juice or placebo juice daily. Adherence to study product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. (CX1065 at 0002).
877. The protocol for the Davidson CIMT Study called for ultrasound testing of the carotid artery at baseline, at 12 months, and at 18 months. (CX0716 at 0018-19). The primary outcome variable identified in the protocol was the difference between placebo and pomegranate juice in posterior wall common CIMT progression rate in mm/year, using non-contrast images, and a secondary outcome measurement was the difference between placebo and pomegranate juice in the anterior wall common CIMT progression rate in mm/year, using contrast images. (CX0716 at 0028). Exploratory endpoints included changes in blood pressure, lipids, and various measures of inflammation and oxidative stress. (CX0716 at 0011; CX1291 (Sacks Expert Report at 0027)).
878. The Davidson CIMT Study indicated the following:
  - With the exception of apolipoprotein-B100, which decreased more with pomegranate juice than with control . . . , there were no differences between treatment groups for changes from baseline in traditional

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cardiovascular risk markers, including fasting lipoprotein lipids, blood pressures, or smoking status (data not shown).

- Of the 152 subjects (52%) agreeing to the optional administration of intravenous contrast agent for anterior wall imaging, as expected, baseline values for the anterior wall of the common carotid artery were larger than for the posterior wall.
- Anterior and posterior wall CIMT values and progression rates did not differ significantly between treatment groups at any time point.
- The composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group . . . However, this difference was no longer significant at the end of the treatment period.
- Exploratory analyses of several subgroups indicated significantly lower values for pomegranate juice versus control after treatment for anterior wall and/or composite CIMT values: subjects in the top tertiles for baseline triglycerides (TG), . . . total cholesterol/HDL cholesterol ratio .; composite. . . , TG/HDL cholesterol ratio . . . and apolipoprotein-B100 and the lowest tertile for HDL cholesterol. There were no significant differences between treatments in any of these subgroups at baseline for any CIMT measurements or after treatment in posterior wall CIMT values.
- Results of the present study showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. However, results from *post hoc* exploratory

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analyses, which should be interpreted with caution, suggest that the rate of CIMT progression may have been slowed in subgroups characterized by more rapid CIMT progression, including those with increased levels of TG-rich lipoproteins, low levels of HDL cholesterol, and greater oxidative stress.

- Whether possible benefits of pomegranate juice consumption on CIMT progression in some subgroups relate to antioxidant activity is uncertain. A lack of significant improvements in most markers of oxidative stress argues against an important role for antioxidant activity. However, specific reactive oxygen/nitrogen species may be scavenged by pomegranate unique polyphenolic hydrolysable tannins. Indeed, a subgroup for whom there was an apparent benefit was the top tertile for baseline PD – AAPH, suggesting that antioxidant effects may have played a role in the protection against CIMT progression by pomegranate juice consumption.
- Pomegranate juice and/or polyphenol consumption might favorably influence CIMT progression through effects on platelet activity, endothelial function, or shifts in the production of prostacyclin production. However, because none of these variables were measured in the present trial, their potential roles here are unknown.

(PX0014 at 0005-06).

879. The Davidson CIMT Study included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations and stated that there were significantly lower anterior and/or composite CIMT progression rates with higher CVD risk factors. (CX1065 at 0001, 0006; CX1336 (Davidson, Dep. at 57-69)).

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880. Dr. Davidson initially submitted a manuscript of the study to the journal, *Arteriosclerosis, Thrombosis, and Vascular Biology*, in late 2008. That journal rejected the manuscript, concluding that it was a negative study. (CX1336 (Davidson, Dep. at 202-03) (discussing CX1016)).
881. In May 2009, Dr. Davidson submitted the manuscript (F. 880) to the *American Journal of Cardiology*. Two expert reviewers provided recommendations and comments. (CX1336 (Davidson, Dep. at 77-78); see CX1057 at 0024-27).
882. One reviewer of the manuscript (F. 880) stated that, given the large number of *post hoc* analyses performed, it would be appropriate to conduct a statistical correction for multiple comparisons. (CX1057 at 0025; CX1336 (Davidson, Dep. at 80-81)). Dr. Davidson did not do the statistical correction, but committed to revise the discussion section to emphasize “[t]he possibility of type I errors, the exploratory nature of these findings, and caution regarding interpretation of post-hoc subgroup analyses.” (CX1336 (Davidson, Dep. at 73); CX1057 at 0025).
883. Another reviewer of the manuscript (F. 880) advised that “The study needs to be reported as a negative study as it is.” (CX1057 at 0027). In response, Dr. Davidson “affirm[ed] that it was a negative study,” and committed to revise the manuscript to emphasize that “caution is warranted” with regard to the subgroup findings, and that those findings “should be considered hypotheses that will need to be replicated in future trials designed to assess the efficacy of pomegranate juice consumption” in those subgroups. (CX1336 (Davidson, Dep. at 78-85); CX1057 at 0027).

**ii. Experts’ analysis of the Davidson CIMT Study**

884. Dr. Sacks testified that the Davidson CIMT Study is the largest of the heart studies conducted on pomegranate

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juice; was carefully designed, in that the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted; and that there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). Dr. Sacks concluded that the Davidson CIMT Study is “competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors.” (CX1291 (Sacks Expert Report at 0029)).

885. Dr. Ornish and Dr. Heber testified that the Davidson CIMT Study constitutes competent and reliable evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. (PX0025 (Ornish Expert Report at 0019-22); PX0192 (Heber Expert Report at 0039, 0053); Heber Tr. 1979-86; PX0014).
886. In his expert report, Dr. Sacks expressly stated the following regarding the Davidson CIMT Study:
- According to the Davidson [C]IMT report, at the end of the study, there were no significant differences in CIMT progression rates between the subjects in the pomegranate juice and control groups.
  - The “composite rate” for all measured carotid artery walls had shown a significantly smaller value at 12 months in the pomegranate juice group, but this difference was no longer significant at the end of the study.
  - Further, the anterior wall values and rates, and the posterior wall values and progression rates did not differ significantly at any point in the trial.
  - There were also no statistically significant changes in the measured indicators of

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inflammation and oxidative stress, or in fasting lipoprotein lipids or blood pressure.

(CX1291 (Sacks Expert Report at 0028)).

887. Dr. Ornish agreed with Dr. Sacks' conclusion that the Davidson CIMT Study showed no significant differences in the overall CIMT progression rates between the active and placebo groups at 18 months. (PX0025 (Ornish Expert Report at 0019-20)).
888. In his expert report, Dr. Ornish expressly stated the following regarding the Davidson CIMT Study:
- the fact that these differences in CIMT measurements were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months;
  - the bottom line is that pomegranate juice *did* show a statistically significant improvement in CIMT after 12 months in the measure that was most clinically relevant; and
  - the Davidson CIMT Study does provide supporting evidence that there was statistically significant lower CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors.
- (PX0025 (Ornish Expert Report at 0020-22)).

889. Dr. Heber acknowledged that the results at 18 months suggest that in subjects at risk with moderate coronary heart disease, pomegranate juice consumption had no significant effect on overall CIMT progression rate, opining as follows:
- No significant difference in overall CIMT progression rate was observed between pomegranate juice and control treatments.

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- In exploratory analyses, in subjects in the most adverse tertiles for baseline serum lipid peroxides, triglycerides (TGs), high-density lipoprotein (HDL) cholesterol, TGs/HDL cholesterol, total cholesterol/HDL cholesterol, and apolipoprotein-B100, those in the pomegranate juice group had significantly less anterior wall and/or composite CIMT progression versus control subjects.
- In conclusion, these results suggest that in subjects at moderate coronary heart disease risk, pomegranate juice consumption had no significant effect on overall CIMT progression rate, but may have slowed CIMT progression in subjects with increased oxidative stress and disturbances in the TG-rich lipoprotein/HDL axis.

(PX0192 (Heber Expert Report at 0039)).

890. Dr. Ornish opined that a potential reason for lack of a change in the CIMT progression rate at 18 months was that participants in the Davidson CIMT Study may have stopped drinking the juice after 12 months. In his 34 years of directing RCTs, Dr. Ornish notes that it is very challenging to motivate patients to continue following any intervention for more than one year. Dr. Ornish further observes that it is not unusual for patients to be less than honest in describing their compliance as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. (PX0025 (Ornish Expert Report at 0020-21); PX0355 (Ornish, Dep. at 202-03)).
891. Dr. Davidson evaluated the compliance with product consumption guidelines during the Davidson CIMT Study. He testified that his review of compliance diaries showed high levels of compliance with product consumption. (CX1336 (Davidson, Dep. at 151-52); CX0788).

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892. Dr. Stampfer provided the opinion that that the main result from the Davidson CIMT Study (2009) provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. (CX1293 (Stampfer Expert Report at 0020-21); Stampfer, Tr. 758-59 (“So it seems clear that this is a null study, and that’s what the authors concluded”)).
893. Dr. Heber expressly disagrees with Dr. Stampfer’s conclusion in (F.892) above: Dr. Stampfer contends that the CIMT benefit demonstrated in the subgroup of individuals at increased oxidant stress with increased triglycerides and low HDL does not override his conclusion that “the main result from this large trial provides substantial evidence against the hypothesis that pomegranate juice can reduce progression of CIMT.” I disagree. The subgroup data is particularly important because the CIMT benefit was associated with the specific subgroup that had increased risk factors. (PX0192 (Heber Expert Report at 0053)).
894. The Davidson CIMT Study included a *post hoc* analysis of changes in the CIMT measurements for some of the study subpopulations. The Davidson CIMT Study described the subgroup analyses as “post hoc exploratory analyses, which should be interpreted with caution[.]” It stated that, “[b]ecause the decrease in CIMT progression in these subgroups was based on analyses that were not preplanned and had no correction for multiple comparisons . . . , these findings will need to be confirmed in future investigations.” (CX1065 at 0001, 0006; CX1336 (Davidson, Dep. at 57-69)).
895. A *post hoc* analysis is one that is conceived after the researchers have seen the data and, thus, is generally a less valid approach than one planned for in the protocol, because it is more subject to bias. (Sacks, Tr. 1500-01).
896. Respondents’ experts opined that in scientific research, *post hoc* analysis is routine. (Heber, Tr. 1984). Although the exploratory analysis was not called for by the protocol,

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such analyses, including those on subgroups, are commonly done. (CX1336 (Davidson, Dep. at 57, 221)).

897. With respect to the Davidson CIMT Study, Dr. Ornish opined: “While this is post hoc analysis, and thus not as rigorous as one stated a priori, it does provide supporting evidence that there was statistically significant lower CIMT progression rates for pomegranate versus control subjects in those with higher cardiovascular disease risk factors.” (PX0025 (Ornish Expert Report at 0021)).
898. Dr. Sacks also noted that the subgroup analysis had not been corrected for multiple comparisons, as stated in the Davidson CIMT Study. (CX1291 (Sacks Expert Report at 0030)). When multiple endpoints are being measured, the *p*-value needs to be adjusted downward to correct for multiple comparisons. Without the correction, with each additional subgroup analyzed, the chances increase that one or more will turn out to have a *p*-value of less than .05, by chance alone. (Sacks, Tr. 1505-06; Stampfer, Tr. 760-61). Dr. Davidson never did a correction for multiple comparisons on the subgroup analysis. (CX1336 (Davidson, Dep. at 73)).
899. Dr. Sacks further opined: because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the *post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduce the risk of, or treat heart disease in the subpopulations identified in Figure 3 of the Davis CIMT Study. (CX1291 (Sacks Expert Report at 0029-30)).

**iii. Determination on the Davidson CIMT Study**

900. The Davidson CIMT Study does not provide competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 872-899).

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**g. Davidson BART/FMD Study****i. About the Davidson BART/FMD Study**

901. The brachial artery is a major blood vessel of the arm. Brachial artery reactivity testing (“BART”) is a measurement of how much the brachial artery dilates (enlarges) after a blood pressure cuff is inflated, and then released. This is also called flow mediated dilation (“FMD”) testing. (JX0003 ¶ A.1-2; CX1336 (Davidson, Dep. at 34-35)).
902. Flow mediated dilation is the amount by which the brachial artery dilates (gets larger) after the blood pressure cuff is deflated. (JX0003 ¶ A.8).
903. Dr. Davidson conducted the Davidson BART/FMD Study on a subset of 45 Davidson CIMT Study participants. It was a 13-week, randomized, double-blind, placebo-controlled trial to evaluate the effect of consuming POM Juice or placebo on BART, also referred to as FMD testing. (JX0003 ¶ A.1; CX0684; CX0716 at 0010-11, 0074-81; CX1336 (Davidson, Dep. at 37, 102-03); Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).
904. At the conclusion of the Davidson BART/FMD Study, there were no significant differences between the treatment and placebo groups and no written report was prepared. (PX0019; CX0684 at 0001; CX1336 (Davidson, Dep. at 87-89); Sacks, Tr. 1510-13; CX1291 (Sacks Expert Report at 0030-31); CX1293 (Stampfer Expert Report at 0021); CX0695 at 0001; CX1336 (Davidson, Dep. at 125)).
905. The Davidson BART/FMD Study also took measurements of blood pressure and other vital signs. However, blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, paraoxonase (PON), and thiobarbituric acid reactive substances (TBARS) were not primary or secondary endpoints of the Davidson BART/FMD Study. (CX0684; CX0716 at 0010-11, 0074-81; Sacks, Tr. 1508-10; Stampfer, Tr. 764-66).

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906. At the end of the Davidson BART/FMD Study, there were no significant differences between treatment and placebo groups in blood pressure, cholesterol, HDL cholesterol, non-HDL cholesterol, triglycerides, ACE, PON, and two TBARS measurements. (CX1336 (Davidson, Dep. at 86-88; CX0684 at 0005-13, 0019; CX1291 (Sacks Expert Report at 0031)).

**ii. Experts' analysis of the Davidson BART/FMD Study**

907. Complaint Counsel's expert, Dr. Sacks, opined that the Davidson BART/FMD Study appears to have been properly designed and conducted. The protocol identifies the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted. There is no indication of critical problems in the conduct of the study. (CX1291 (Sacks Expert Report at 0032)).
908. Dr. Sacks opined that although BART/FMD is not a valid or generally recognized surrogate marker of coronary heart disease, it does provide relevant information because FMD is a measure of nitric oxide. Dr. Sacks further opined that if pomegranate juice meaningfully affected nitric oxide metabolism, one would have expected to see a positive result in the FMD testing. (CX1291 (Sacks Expert Report at 0032); Sacks, Tr. 1510-12).
909. Dr. Sacks further opined that the Davidson BART/FMD Study finding of no statistically significant difference in blood pressure or ACE due to POM Juice consumption is inconsistent with Dr. Aviram's ACE/BP Study findings. (F. 774-779; Sacks, Tr. 1512-13; CX1291 (Sacks Expert Report at 0032)).
910. Dr. Heber testified that in the Davidson BART/FMD Study, the primary endpoint was flow-mediated dilation, not blood pressure, and, therefore, any results for blood pressure cannot be relied upon as negative evidence. (Heber, Tr. 2106-07).

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911. Dr. Sacks concedes that just because the Davidson BART/FMD Study does not show statistically significant changes with respect to blood pressure and ACE, among other measurements, the absence of such evidence is not proof there is no effect. (PX0361 (Sacks, Dep. at 230)).
912. Respondents' experts explain that the absence of evidence is not evidence of absence, so the fact that a statistically significant change in ACE or blood pressure was not found does not mean that the result does not exist. (Heber, Tr. 1981; *see also* Sacks, Tr. 1608).
913. Respondents' experts opined that no conclusion can be drawn from the absence of statistically significant changes in the Davidson BART/FMD Study. (Heber, Tr. 1981; Sacks, Tr. 1608-09).

**iii. Determination on the Davidson BART/FMD Study**

914. The Davidson BART/FMD Study does not constitute competent and reliable scientific evidence supporting a claim that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 903-913)

**6. Additional biomarker studies sponsored by Respondents****a. The Overweight Studies**

915. In 2006, POM sponsored Dr. James Hill, University of Colorado, Denver, to examine the safety and antioxidant activity of POMx on overweight individuals with increased waist size ("Denver Study"). Also in 2006, POM sponsored Dr. Heber and Accelovance to study the safety of POMx and the effect of POMx on biomarkers and inflammation in overweight people ("San Diego Study") (collectively, the "Overweight Studies") (CX0934; CX0819 at 0021-22; CX0859 at 0001).

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**i. About the Denver Study**

916. In 2006, Dr. Hill and his colleagues conducted an unblinded, uncontrolled study of POMx capsules in Denver, Colorado, known as the Denver Study. (CX1291 (Sacks Expert Report at 0032-35); *see* Sacks, Tr. 1513-14).
917. The Denver Study enrolled 24 adults (19 females, 5 males) ages 40 to 70 with abdominal adiposity. Subjects received two POMx capsules per day for 28 days. (CX0877 at 0002-10; CX0934 at 0003-04).
918. The Denver Study measured a “wide range of biomarkers for oxidative stress and inflammation” at baseline and at four weeks, including TBARS (thiobarbituric acid reactive substances) and PON1 activity. TBARS is an important biomarker of oxidative stress in humans and strongly predictive of cardiovascular events in people with stable coronary artery disease, independent of traditional risk factors and inflammatory markers. High-density lipoprotein cholesterol (“HDL” or so called “good cholesterol”) contains an antioxidant enzyme, called “paraoxonase” or “PON1” which acts to protect the body against oxygen radicals. Additional measurements included blood pressure, triglycerides, cholesterol, and C-reactive protein. Although the subjects’ triglycerides, cholesterol, and C-reactive protein were measured, the study was not designed to assess those factors. (CX0877 at 0002-10; CX1342 (Hill, Dep. at 42-44); Heber, Tr. 1961; CX0934 at 0003-04).
919. Twenty-two subjects completed the Denver Study. According to the Preliminary Data Analysis, dated February 15, 2007, the participants gained an average of 1.3 pounds during the study, which Dr. Hill attributed to its being conducted during the holiday season. (CX0877 at 0002-03; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 99-103)).
920. TBARS was the primary endpoint chosen to assess the antioxidant activity of the POMx capsules in the Denver

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Study. (CX1342 (Hill, Dep. at 41-42)). The authors of the study concluded that POMx is safe and that there was evidence of antioxidant activity through a significant reduction in TBARS linked with cardiovascular disease risks. (CX0934 at 0004).

921. After adjusting the statistical analysis for the weight change, during the Denver Study TBARS decreased and free fatty acids increased. The study statistician stated that the change in TBARS was “of borderline significance [and had] not been adjusted for the number of comparisons made.” (CX0877 at 0002-03, 0008 (TBARS); CX1291 (Sacks Expert Report at 0032-33)).
922. In the Denver Study, there was no change in PON1 and there were no statistically significant changes in blood pressure. The subjects’ blood pressure was taken as a safety measure to protect the subjects, as the study was not designed to assess whether or not POMx capsules had an effect on blood pressure. (CX0877 at 0002-03, 0008, 0010; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 71-72, 97-103, 111-13, 118-19)).
923. Although inflammation was not explored as the primary endpoint, the Denver Study concluded, “[w]e did not detect any effect of POMx on inflammation but identification of better biomarker assays for inflammation is needed . . . . [T]his pilot project suggests that a larger trial is warranted in abdominally obese subjects who may be at risk for development of metabolic diseases.” (CX0877 at 0002-03; CX1291 (Sacks Expert Report at 0032-33); CX1342 (Hill, Dep. at 41-42); CX0934 at 0001).

**ii. About the San Diego Study**

924. The protocol for the San Diego Study was titled, *A Placebo-Controlled, Randomized, Double-Blind Study to Compare Antioxidant Levels in Normal Subjects with Elevated Waist Circumference When Administered 1 or 2 Pomegranate Dietary Supplement Capsules for 4 Weeks.*

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(CX0819 at 0014 (Protocol, July 14, 2006); CX1291 (Sacks Expert Report 0033-34)).

925. The San Diego Study was designed as a safety assessment. (CX0934 at 0001).
926. The San Diego Study recruited 64 generally healthy male and female subjects who took either two POMx capsules, two placebo capsules, or one placebo and one POMx capsule, per day, for four weeks. (CX0859 at 0010 (Clinical Study Report); CX1291 (Sacks Expert Report at 0033-34)).
927. Measurements in the San Diego Study included blood pressure, oxidized phospholipids, oxidized LDL/HDL, serum nitric oxide, and PON, but these were not primary endpoints. (CX0934 at 0001; CX0859 at 0003; CX1291 (Sacks Expert Report at 0033-34)).
928. A portion of the San Diego Study data was presented in a January 11, 2007 Clinical Study Report. (*See* CX0859). This document described the conduct of the study, adverse events, vital signs, and blood pressure data. It stated that “[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature.” The San Diego Study report also stated that the efficacy results of antioxidant and anti-inflammatory levels were shown separately. (CX0859 at 0018, 0020).
929. Dr. Heber prepared a slide presentation about the results of the San Diego Study in which he stated: “there were no changes in . . . markers of oxidative stress or inflammation that were studied,” including in C-reactive protein, oxidized phospholipids, lipoprotein (a), and nitric oxide and that “[t]he variation among subjects suggests that a more focused study would be more likely to demonstrate significant changes.” (CX1254 at 0026; CX1254 at 0001, 0006-26; Heber, Tr. 2119-21).
930. Dr. Heber sent this presentation (F. 929) to POM employees on January 9, 2007 with an accompanying

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email stating, “we have not proved or disproved efficacy at this point.” By efficacy, Dr. Heber meant changes in biomarkers of oxidant stress or inflammation. (CX0858 at 0001). (CX1352 (Heber, Dep. at 107-11) (discussing CX1254)).

931. Dr. Heber’s article on the San Diego Study results was published in late 2007 as Heber D. et al., *Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). (See CX0934).
932. Dr. Hebers’s article (F. 931) on the Overweight Studies stated that “[p]reliminary evidence of a reduction in TBARS was seen in the subjects who were studied at the Denver site . . . . TBARS are an important biomarker of oxidative stress. . . . [T]hese pilot studies demonstrate both the safety and efficacy of POMx . . . in humans. However, further studies need to be done to confirm the antioxidant properties of pomegranate ellagitannins administered as a dietary supplement.” (CX0934 at 0003-04).
933. Dr. Heber acknowledged that the published article (F. 931) did not provide all of the results of the San Diego Study, including those concerning antioxidant stress or inflammation. Dr. Heber explained that the San Diego Study was primarily studying safety, “with the idea that we would explore the idea of whether any inflammatory markers or oxidant stress markers were elevated in those subjects.” Dr. Heber further stated that they found that the studied population had a “great deal of variability” at baseline and four-week measurements. Dr. Heber further explained that there was no interest in publishing the results because the findings concerning anti-inflammatory effects were “indeterminate results, not negative results.” (Heber, Tr. 2116-17).

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**iii. Experts' analysis of the Overweight Studies**

934. Drs. Sacks and Stampfer concluded that the methodological shortfalls in the Denver Study – especially the lack of a control group – render its findings unreliable. (CX1291 (Sacks Expert Report at 0035); *see also* Sacks, Tr. 1519-21; Stampfer, Tr. 768-72).
935. Dr. Ornish agreed that there are limitations to the Denver Study and that it was a pilot study, which only provides preliminary findings to justify doing a larger study. Dr. Ornish further opined that the San Diego Study did not demonstrate efficacy since there were no significant changes in biomarkers. (PX0025 (Ornish Expert Report at 0024-25)).
936. Dr. Heber stated in his expert report that the Denver Study demonstrated the efficacy of POMx as an antioxidant. (CX0934 at 0004). At trial, however, he described the Denver Study as a “pilot study . . . not a conclusive demonstration.” (Heber, Tr. 2116). Dr. Heber explained, anti-inflammatory effects “were indeterminate results, not negative results.” (Heber, Tr. 2117).
937. With respect to the lack of statistically significant changes to blood pressure and other biomarkers, such as triglycerides, HDL, LDL, C-reactive protein, and PON, Dr. Sacks acknowledges that the absence of information does not prove the negative. (PX0361 (Sacks, Dep. at 223-24, 238, 243)).

**iv. Determination on the Overweight Studies**

938. The Overweight Studies do not constitute competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 915-937).

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**b. The Diabetes Studies****i. About the Diabetes Studies**

939. Respondents have also sponsored studies evaluating the effect of pomegranate juice and/or its derivatives on persons with diabetes, discussed below, (collectively, “the Diabetes Studies”). (PX0038; PX0127; CX0765).
940. The first of the Diabetes Studies, conducted by Dr. Rock, a member of Dr. Aviram’s team, published as Rock, W, et al., *Consumption of Wonderful Variety Pomegranate Juice and Extract by Diabetic Patients Increases Paraoxonase I Association with High-Density Lipoprotein and Stimulates Its Catalytic Activities*, 56 J. Agric. Food Chem. (2008), looked at the relationship of PON1 and HDL cholesterol activity in 30 diabetic patients who used pomegranate juice or POMx Liquid for four to six weeks. It indicated a reduction in oxidative stress as measured by TBARS and improved PON. All measurements were comparisons to baseline. (PX0127; CX1291 (Sacks Expert Report at 0036-37); PX0192 (Heber Expert Report at 0038-39)).
941. The other two Diabetes Studies were conducted by Dr. Heber and Dr. Hill and were randomized, double-blind, placebo-controlled studies to evaluate the antioxidant effect of pomegranate extract capsule and pomegranate juice, respectively, in diabetic patients. (Heber, Tr. 2048-49, 2054; CX1352 (Heber, Dep. at 124-25); CX0949 at 0007-26 (protocol for diabetes extract study); CX1082 at 0007-21 (protocol for diabetes juice study); CX1284).
942. The POMx protocol called for enrolling 30 diabetics for 12 weeks. (CX949 at 0013). The POM Juice study protocol called for an enrollment of 40 diabetics for 12 weeks. (CX1082 at 0012).
943. The two Diabetes Studies conducted by Dr. Heber and Hill were completed, but the results were not published. (CX1352 (Heber, Dep. at 132-33); CX1342 (Hill, Dep. at 157)).

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**ii. Experts' analysis of the Diabetes Studies**

944. Dr. Sacks testified that the Diabetes Studies do not constitute competent and reliable scientific evidence to support claims that POM Juice or POMx treat, prevent, or reduce the risk of heart disease because they are not RCTs, the study size is too small, and the duration is too limited in scope. (CX1291 (Sacks Expert Report at 0035-37); Sacks, Tr. 1521-24).
945. According to Dr. Heber, the two diabetes studies he conducted did not show a significant change in malondialdehyde, which is a TBARS measure, or in PON, both of which are heart-related biomarkers. (Heber, Tr. 2124 (malondialdehyde), 2137-38 (PON); CX1352 (Heber, Dep. at 161-70)).
946. Dr. Heber did not include the results of his two diabetes studies in his analysis of available human clinical evidence to substantiate heart benefits of POM Products. (PX0192 (Heber Expert Report at 0052-54)).

**iii. Determination on the Diabetes Studies**

947. The Diabetes Studies do not constitute competent and reliable scientific evidence to support claims that the POM Products treat, prevent or reduce the risk of heart disease. (*See* F. 939-946).

**7. Experts' opinions based on the totality of the evidence****a. Summary of Complaint Counsel's experts' opinions**

948. Dr. Sacks and Dr. Stampfer both opined that Respondents' research on pomegranate juice provides no evidence that POMx Pills or POMx Liquid will treat, prevent, or reduce the risk of heart disease or that they are clinically proven to do so. (CX1291 (Sacks Expert Report at 0010, 0038); CX1293 (Stampfer Expert Report at 0017)).

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949. Dr. Stampfer opined: Respondents' human clinical studies, including a large randomized clinical trial, failed to confirm the results of the animal and *in vitro* studies. Although some promising results appear in several of the smaller studies with important design limitations, the weight of the evidence strongly favors the null hypothesis of no effect. . . . The current data does not support the claims for heart disease prevention or treatment. (CX1293 (Stampfer Expert Report at 0022)).
950. Dr. Sacks opined: the evidence is not sufficient to support the conclusion that consumption of POM Juice, POMx Pills, or POMx Liquid treat, prevent, or reduce the risk of heart disease. (CX1291 (Sacks Expert Report at 0038-39)).
951. Dr. Sacks further opined: there is no reliable evidence that POM Juice, POMx Pills, or POMx Liquid reduce or delay the development of arterial plaque; improve blood flow to the heart (or other blood vessels); or reduce blood pressure. (CX1291 (Sacks Expert Report at 0038-39)).
952. Dr. Sacks opined, in addition, that clinical studies, research and/or trials do not prove that drinking POM Juice or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of or treats heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (CX1291 (Sacks Expert Report at 0010)).

**b. Summary of Respondents' experts' opinions**

953. Dr. Heber opined that based on basic scientific studies focusing on the hydrolysable tannins family, especially punicalagins and ellagitannins, POMx Pills and POMx Liquid are equivalent to POM Juice in providing health benefits to humans. (Heber, Tr. 2002-03; *see also* Heber, Tr. 2186-87 (studies show there is no difference between the antioxidant effect in pomegranate juice and that in POMx and that pomegranate juice and POMx have the same impact on oxidative stress)).

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954. Dr. Heber also opined: the body of research on pomegranate juice and extract provides support for potential heart benefits for heart disease. (PX0192 (Heber Expert Report at 0015)).
955. Dr. Heber, in addition, opined that competent and reliable evidence shows that POM and POMx are likely to reduce the risk of cardiovascular disease. (Heber, Tr. 2012, 2087).
956. Dr. Heber further opined: there is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: (1) decreases in arterial plaque; (2) lowering of blood pressure; and (3) improvement of cardiac blood flow, based on the biological mechanism of prolonging the half-life of nitric oxide in the vasculature. (PX0192 (Heber Expert Report at 0044-45)).
957. Dr. Heber also stated in his expert report that he agreed with Dr. Stampfer that “claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease . . . based solely on evidence from large double-blind placebo-controlled trials. . . But the entire body of scientific evidence should be considered when evaluating nutritional science.” (PX0192 (Heber Expert Report at 0044)).
958. Dr. Ornish opined that in evaluating scientific research related to a whole food, as opposed to a drug, it is not necessary to reach statistical significance to convey information about the product; the convention of a finding that there be a five percent or less likely due to chance finding is an arbitrary convention; and that when you have a *p*-value of 0.05, there is a 95 percent probability of validity as opposed to chance and when you have a *p*-value of 0.058, there is a 94 percent validity as opposed to chance. (Ornish, Tr. 2340).
959. Dr. Ornish opined: taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the

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pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. (PX0025 (Ornish Expert Report at 0005)).

960. Dr. Ornish also opined: the universe of existing science provides significant evidence that pomegranate juice is likely to (1) reduce arterial plaque, (2) improve blood flow, and (3) reduce blood pressure. (PX0025 (Ornish Expert Report at 0005); PX0355 (Ornish, Dep. at 42); Ornish, Tr. 2374-75).

**8. Conclusions**

961. In considering whether a conventional food or dietary supplement is likely to have an effect on the risk or treatment of a disease, it is important to first look at the individual items of evidence, to determine whether they are reliable and probative. Then, it is important to look at the evidence as a whole. (CX1291 (Sacks Expert Report at 0038)).
962. There is insufficient competent and reliable scientific evidence to support the conclusion that the POM Products treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart; no clinical studies, research and/or trials prove these effects. (CX1291 (Sacks Expert Report at 0010, 0038-39); CX1293 (Stampfer Expert Report at 0022)).

**H. Substantiation for Respondents' Prostate Cancer Claims****1. Substantiation standard for prostate claims**

963. Because pomegranate juice is derived from a fruit, is known to be safe, and is not a pharmaceutical drug, physicians who treat patients concerned with prostate health would not hold pomegranate juice to the standards

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of safety and efficacy traditionally required by the FDA for approval of a pharmaceutical (performance of a large, randomized, double-blind, placebo controlled clinical trial) before recommending pomegranate juice to their patients. (PX0206 (Miller Expert Report)).

964. A claim that a fruit juice that is known to be safe, treats or prevents prostate cancer, if not offered as a substitute or a replacement for a conventional therapy, can be supported if there is reliable and competent scientific data that support the claimed beneficial effect. (PX0206 (Miller Expert Report at 11); Miller, Tr. at 2201).
965. Experts in the field of prostate health would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice. (deKernion, Tr. 3060; *see also* Miller, Tr. 2201).
966. Experts in the field of prostate health would require that a product be scientifically evaluated through rigorous scientific and clinical studies, and believe that animal and *in vitro* studies alone are not sufficient to conclude that the POM Products treats, prevents, or reduces the risk of prostate cancer or that they have been clinically proven to do so. (CX1287 (Eastham Expert Report at 0006, 0012-15); CX1293 (Stampfer Expert Report at 0009-10)).

## **2. Background facts on prostates and the effects of pomegranates on prostates**

### **a. Prostate function and prostate cancer**

967. The prostate is a gland located in the male pelvis that is an organ of sexual function and fertility. (Eastham, Tr. 1236).
968. Prostate cancer occurs when cells of the prostate, typically the glandular cells, become cancerous, which means they have uncontrolled cell growth. (Eastham, Tr. 1236).
969. Last year about 220,000 men were diagnosed with prostate cancer in the United States. Approximately one in six

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men over the age of 60 will be diagnosed with prostate cancer each year. The average age of prostate cancer diagnosis is in the sixties. About 30,000 men die from prostate cancer each year. (Eastham, Tr. 1237-39).

970. Prostate cancer does not have a typical course. There are many prostate cancers that, while they are seen under the microscope, they do not represent a threat to the life expectancy or the quality of life of the patient. (Eastham, Tr. 1236).
971. Blood levels of prostate specific antigen (PSA) are measured in healthy men to assess their risk of prostate cancer. (Stampfer, Tr. 774).
972. PSA is a protein that is derived almost exclusively from the prostate and is widely used for screening for the risk of prostate cancer. (Stampfer, Tr. 774).
973. PSA is also used after diagnosis of prostate cancer to monitor the progression of disease. (Stampfer, Tr. 774).
974. The two mainstays of cure for prostate cancer are either radical prostatectomy (surgical removal of the prostate) or radiation therapy to the prostate. (Eastham, Tr. 1237; PX0060 at 0001).
975. Although the mainstays described in F. 974 are adequate for permanent disease control in many patients, a significant number of patients relapse and ultimately develop metastatic disease. (PX0060 at 0001).
976. Approximately one third of prostate cancer patients with clinically confined cancer that are treated with radical prostatectomy will develop a biochemical recurrence. (PX0060 at 0001).
977. There are limited treatment options for patients who have undergone primary therapy with curative intent and who have progressive elevation of their PSA without documented evidence of metastatic disease. (PX0060 at 0002).

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978. Androgens are male steroid hormones that regulate prostate cancer cell growth. Hormone-type products increase testosterone levels and, basically, stop the conversion of testosterone to a more potent hormone, androgen. Compounds that contain hormone-type products can impact the PSA if they are used in large quantities. (Stampfer Tr. 773; Eastham Tr. 1242-44).
979. Early initiation of hormonal ablation is associated with significant morbidity and effect on quality of life, including fatigue, hot flashes, loss of libido, decreased muscle mass, and osteoporosis with long-term use. (PX0060 at 0002).
980. Strategies to delay clinical prostate cancer progression and prolong the interval from treatment failure to hormonal ablation would be of paramount importance. (PX0060 at 0002).
981. A combination of epidemiologic and basic science evidence strongly suggests that diet and plant-derived phytochemicals may play an important role in prostate cancer prevention or treatment. (PX0060 at 0002).
982. Epidemiologic studies suggest that a reduced risk of cancer is associated with the consumption of a phytochemical-rich diet that includes fruits and vegetables. (PX0060 at 0002).
983. Fresh and processed fruits and food products contain high levels of a diverse range of phytochemicals of which polyphenols, including hydrolyzable tannins (ellagitannins and gallotannins) and condensed tannins (proanthocyanidins), and anthocyanins and other flavonoids make up a large proportion. (PX0060 at 0002).
984. Several phytochemicals have been proposed as potential chemoprevention agents based on animal and laboratory evidence of antitumor effects. (PX0060 at 0002).
985. Suggested mechanisms of anticancer effects of polyphenols include the inhibition of cancer cell growth

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by interfering with growth factor receptor signaling and cell cycle progression, promotion of cellular differentiation, modulation of phosphodiesterase/cyclooxygenase pathways, inhibition of kinases involved in cell signaling, and inhibition of inflammation. (PX0060 at 0002).

**b. Mechanism of action of pomegranates in the prostate**

986. The pomegranate (*punica granatum* L.) fruit has been used for centuries in ancient cultures for its medicinal purposes. (PX0060 at 0002).
987. Pomegranate fruits are widely consumed fresh and in beverage forms as juice and wines. Commercial pomegranate juice shows potent antioxidant and antiatherosclerotic properties attributed to its high content of polyphenols, including ellagic acid in its free and bound forms (as ellagitannins and ellagic acid glycosides), gallotannins, and anthocyanins (cyanidin, delphinidin, and pelargonidin glycosides) and other flavonoids (quercetin, kaempferol, and luteolin glycoside). (PX0060 at 0002).
988. Atherosclerosis means a build-up of plaque in arteries. (Stampfer, Tr. 700).
989. The most abundant of the polyphenols in pomegranates is punicalagin, an ellagitannin implicated as the bioactive constituent responsible for > 50% of the potent antioxidant activity of the juice. Punicalagin is abundant in the fruit husk and, during processing, is extracted into pomegranate juice in significant quantities reaching levels of > 2g/L juice. (PX0060 at 0002).
990. Ellagic acid and tannins have been shown previously to exhibit *in vitro* and *in vivo* anticarcinogenic properties, such as induction of cell cycle arrest and apoptosis, as well as the inhibition of tumor formation and growth in animals. (PX0060 at 0002).

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**i. *In vivo* research reporting reduced inflammation in prostate tumors**

991. A large body of literature has linked inflammation to prostate carcinogenesis at all stages of the development of prostate cancer from normal tissue to advanced cancer. (PX0192 (Heber Expert Report at 0029); PX0070 at 0001).
992. Inflammation in the human is a key step in prostate cancer progression. (CX1352 (Heber, Dep. at 257-58); PX0070 at 0001).
993. Areas of chronic inflammation are almost universally present in pathologic specimens of the prostate, including biopsy cores in men prior to the diagnosis of prostate cancer, transurethral resection chips, and total prostatectomy specimens. (PX0192 (Heber Expert Report at 0029)).
994. Ninety-eight percent of prostate tumors removed at surgery for cancer have evidence of inflammation. (CX1352 (Heber, Dep. at 257-58); PX0192 (Heber Expert Report at 0029-30)).
995. *In vivo* research has demonstrated that pomegranate polyphenols reduce inflammation in prostate tumors. (CX1352 (Heber, Dep. at 257-58); Heber, Tr. 1992).

**ii. *In vivo* research reporting nuclear factor  $\kappa$ B decreased**

996. One well-established signaling pathway mediating inflammatory responses relevant to cancer is the nuclear factor-*kappa*B (NF- $\kappa$ B) pathway. (PX0192 (Heber Expert Report at 0030); deKernion, Tr. 3046-47; Heber, Tr. 1992; PX0070 at 0001).
997. The unique protein NF- $\kappa$ B was the subject of Nobel Prize-winning research by Dr. David Baltimore who identified the protein's unique ability to both receive a signal from the outside of a cell and translate that signal into genetic

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programming of inflammatory proteins that are secreted by cells (“Dr. Baltimore’s study”). (PX0192 (Heber Expert Report at 0030); Heber, Tr. 1992).

998. Dr. Baltimore’s study involved *in vitro* and animal research. (PX0192 (Heber Expert Report at 0030)).
999. Dr. Baltimore’s study showed that the activity of NF- $\kappa$ B is regulated by another protein inhibitor called I $\kappa$ B, which binds to and sequesters NF- $\kappa$ B family members in the fluid part of the cell away from DNA, called the cytoplasm. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).
1000. Dr. Baltimore’s study showed that when the NF- $\kappa$ B pathway is activated, I $\kappa$ B is chemically modified by an enzyme called I $\kappa$ B kinase, which adds a phosphorus atom at specific amino acids on the I $\kappa$ B protein (serine residues 32 and 36). (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).
1001. Dr. Baltimore’s study showed that once altered, the inhibitory protein I $\kappa$ B is degraded and NF- $\kappa$ B is free to move to the nucleus, where it functions to activate genetic mechanisms after binding to DNA, resulting in the secretion of proinflammatory signaling proteins. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).
1002. Dr. Baltimore’s study showed that while normal activation of NF- $\kappa$ B is temporary in response to a stimulus meant to activate immune function, constant or constitutive activation has been observed in breast cancer, liver cancer, melanoma, Hodgkin’s disease, and cervical cancer. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).
1003. Dr. Baltimore’s study stated that direct genetic evidence in mouse models of colon and liver cancer have established that NF- $\kappa$ B activation within tumor cells or infiltrating inflammatory cells is required for tumor initiation or promotion. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).

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1004. Dr. Baltimore's study reported that activation of NF- $\kappa$ B is observed in primary prostate cancer specimens as evidenced by its presence in the nucleus of cells where the genes reside and represents an independent risk factor for recurrence of prostate cancer after radical prostatectomy. (PX0192 (Heber Expert Report at 0030); PX0070 at 0001).
1005. Dr. Baltimore's study reported that pomegranate extract has been shown to inhibit NF- $\kappa$ B in normal human cells, including chondrocytes, epidermal keratinocytes, and vascular endothelial cells. (PX0192 (Heber Expert Report at 0031); PX0070 at 0002).
1006. Dr. Baltimore's study concluded that pomegranate extract inhibits both continuous (constitutive) and stimulated (cytokine-induced) NF- $\kappa$ B activity in prostate cancer cells *in vitro* and that the NF- $\kappa$ B inhibitory effect of pomegranate extract was necessary for the maximal cell killing effects of pomegranate extract. (PX0192 (Heber Expert Report at 0031); Heber, Tr. 1993; PX0070 at 0002).
1007. Respondents' experts testified that in tumors treated with pomegranate extract, the NF- $\kappa$ B decreased, therefore causing decrease of tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).
1008. Respondents' experts testified that there is an absolute linear connection between the polyphenol mechanisms in pomegranate extract and the decrease in tumor growth. (deKernion, Tr. 3046-47; Heber, Tr. 1993).
1009. The mechanisms of action of the POM Products on inflammation and NF- $\kappa$ B contributes to the total body of research relied upon by Respondents. (PX0161 (deKernion Expert Report at 0011-12); PX0192 (Heber Expert Report at 0031); PX0206 (Miller Expert Report at 12); PX0070).

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**3. Basic science studies****a. Summary of the studies**

1010. Respondents have conducted four *in vitro* studies and four animal studies relating to prostate cancer, according to their January 13, 2009 summary of their prostate cancer research to date. (CX1029 at 0004).
1011. POM's initial studies involved *in vitro* growing of human tumor cells in petri dishes in laboratories, adding POM and POM products and evaluating the effect on the human tumor cells. These initial studies showed a significant decrease in growth, increase in apoptosis, (programmed tumor death), and decrease in inflammation, factors which are all related to cancer. (deKernion, Tr. 3044).
1012. Subsequent research involved *in vivo* study wherein a human tumor was grown in immune deficient mice, an environment, which behaves as though it were in a human. In these studies which used LAPC4, a particular prostate tumor line, researchers demonstrated that when a prostate tumor is grown in mice and pomegranate extract and pomegranate products are added, the tumors markedly decreased. (deKernion, Tr. 3045). These studies were not of animal glands, but were studies of human prostate tissue put in animals. All of these studies indicated that POM had an antitumor effect on human tumors. (deKernion, Tr. 3049).
1013. In 2001, Agensys, a biotech company, performed early preclinical research for POM investigating the effect of pomegranate juice and prostate cancer. Agensys' unpublished research found that *in vitro* pomegranate juice consumption "substantially inhibits the proliferation of prostate cancer cells" and that pomegranate juice consumption "retards the growth of subcutaneous and orthotopic prostate tumors in mice." (deKernion, Tr. 3115; Tupper Tr. 1034; PX0065 at 0036-37).
1014. In a study titled, "*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize*

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*to the Mouse Prostate Gland,”* Doctors Navindra Seeram, Arie Belledegrum, David Heber, and colleagues evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunodeficient mice injected with human prostate cancer cells. The study showed that pomegranate extract significantly inhibited prostate cancer in the mice as compared to the control. Researchers also found that ellagic acid and synthesized urolithins from the pomegranate extract were shown to inhibit the growth of human prostate cancer cells *in vitro*. The researchers concluded that the chemopreventive potential of pomegranate ellagitannins and localization of their bioactive metabolites in mouse prostate tissue suggest that the pomegranate may play a role in prostate cancer treatment and chemoprevention. The researchers also stated “[t]his warrants future human tissue bioavailability studies and further clinical studies in men with CaP [prostate cancer].” (PX0069).

1015. In a study titled, *“Pomegranate polyphenols down-regulate expression of androgen-synthesizing genes in human prostate cancer cells overexpressing the androgen receptor,”* Doctors Hong, Seeram, and Heber examined the effects of pomegranate polyphenols from POMx Pills and POM Wonderful 100% pomegranate juice on the expression of androgen enzymes and androgen receptors. The study stated: recurrent prostate tumors advance to an androgen-independent state where they progress in the absence of circulating testosterone, leading to advanced cancer. The study also stated: during the development of the androgen-independent state, prostate cells are known to increase intracellular testosterone synthesis, which maintains cancer cell growth in the absence of significant amounts of circulating testosterone and that over-expression of androgen receptor to produce testosterone occurs in androgen-independent prostate cancer. The study found that POM polyphenols from either POMx Pills or POM Wonderful 100% pomegranate juice significantly inhibited gene expression and androgen receptors as a potential mechanism for maintaining healthy prostate cells. The researchers concluded that,

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“these results suggest that pomegranate polyphenols may be particularly helpful in the subgroup of patients with androgen-independent prostate cancer.” (PX0068).

1016. A study by Doctors Rettig, Heber, et al., titled, “*Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-kappaB-dependent mechanism,*” evaluated POMx Pills and POM Wonderful 100% pomegranate juice and found that their consumption was linked to reduction in cancer growth and decreased plasma PSA levels. The study found that one of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the NF-kB pathway, which serves as a predictor for recurrence of prostate cancer after radical prostatectomy, and that POMx inhibited NF-kB and cancer cell viability in a dose response fashion *in vitro* and Human LAPC4 prostate cancer xenograft mouse model. Based on the results reported, the researchers concluded “that pomegranate juice could have potential as a dietary agent to prevent the emergence of androgen-independence,” thus potentially prolonging life expectancy of prostate cancer patients, and suggested “that this may be a high priority area for future clinical investigation.” (PX0070).
1017. In a study by Dr. Sartippour, et al., titled, “*Ellagitannin-Rich Pomegranate Extract Inhibits Angiogenesis In Prostate Cancer In Vitro And In Vivo,*” the *in vivo* results showed that POMx Pills inhibit prostate tumor growth compared to control in immunodeficient mice injected with human prostate cancer cells. The mice were given a dose comparable, using caloric demand scaling, to that found in POMx and taken by humans. The study reported that POMx was shown to significantly decrease the overall blood vessel density in mouse tumors. The study also stated that *in vitro* results showed that POMx Pills significantly inhibited proliferation of human prostate cancer cells at low ug/ml. concentrations. The researchers concluded, “these findings strongly suggest the potential of pomegranate ellagitannins for prevention of the multi-focal development of prostate cancer as well as to prolong

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survival in the growing population of prostate cancer survivors of primary therapy.” (PX0071).

**b. Complaint Counsel’s experts’ opinions of basic research on prostate cancer**

1018. Complaint Counsel’s experts testified that to substantiate a claim that a food or dietary supplement is an effective treatment for prostate cancer, experts in the field would require an RCT trial with an appropriate sample population of patients with the stage of the disease targeted by the study, and measuring a proper endpoint. (CX1287 (Eastham Expert Report at 0015)).
1019. Complaint Counsel’s experts reviewed the available *in vitro* and animal research and concluded that RCTs with proper endpoints are needed to confirm the potential antioxidant effect on prostate cancer observed in a test tube or laboratory setting. (CX1293 (Stampfer Expert Report at 0022); CX1287 (Eastham Expert Report at 0021)).

**c. Respondents’ experts’ opinions of basic research on prostate cancer**

1020. Dr. deKernion explained that Respondents’ animal studies were on human prostate tissue inserted in the animals and were not merely a study of animal glands. (deKernion, Tr. 3049).
1021. Dr. DeKernion testified that Respondents’ *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed cancer cells from humans that had been inserted into mice. (deKernion, Tr. 3044-47, 3120; PX0351 (deKernion, Dep. at 110)).
1022. Dr. deKernion testified that while one cannot always extrapolate from *in vitro* and animal results to what the results would be in humans, the pre-clinical studies he reviewed indicated a strong likelihood that, in humans, pomegranate juice would at least inhibit the growth of

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prostate cancer cells. (deKernion, Tr. 3063-64; PX0161 (deKernion Expert Report at 0011-12)).

1023. Dr. deKernion also testified that that even where the animal and *in vitro* evidence is strong and shows that an agent's mechanism of action works, this evidence does not prove that an agent works in humans. (deKernion, Tr. 3063-64).

**d. Determination on Respondents' basic research**

1024. Experts in the field agree that even where the animal and *in vitro* evidence is strong and shows that an agent's mechanism of action works, this evidence alone does not prove that an agent works in humans. (deKernion, Tr. 3063-64; Stampfer, Tr. 722-25 (animal studies do not always correspond with what will occur in humans; one cannot assume that if an *in vitro* assay shows a certain result, the same result will occur in the human body)).

**4. Human clinical studies**

1025. Respondents have one human clinical study completed and published, the Pantuck Phase II Cancer Study (2006), and one ongoing human clinical study, the Carducci Dose Study, according to their January 13, 2009 summary of their prostate cancer research as of that date. (CX1029 at 0004).

**a. Pantuck Phase II Prostate Cancer Study**

**i. Background to the Pantuck Study**

1026. Dr. Allan J. Pantuck is an associate professor of Urology at UCLA Medical School and maintains a clinical practice at UCLA. He attended college at Columbia University, medical school at Robert Wood Johnson Medical School, and has a Masters Degree in Clinical Research from UCLA Medical School. (CX1090 at 0001; CX1341 (Pantuck Dep. at 20-21)).

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1027. Dr. Pantuck's clinical appointments include: Attending Urologist at Harbor-UCLA Medical Center, Attending Urologist Wadsworth Veterans Affairs Medical Center, and Attending Urologist, UCLA Medical Center. (CX1090 at 0004).
1028. Dr. Pantuck's professional societies and memberships include the American Society of Clinical Oncology, American Urological Association, Jonsson Comprehensive Cancer Center, and the Society of Urologic Oncology. (CX1090 at 0002).
1029. Dr. Pantuck served as editor of *Advances in the Management of Renal Cell Carcinoma* and *Proceedings of the Irish Society of Surgical Oncology* (2003). Dr. Pantuck has been a reviewer for medical journals such as the *British Journal of Urology International*, *The Journal of Urology*, *Clinical Cancer Research*, and *Urologic Oncology*. (CX1090 at 0003).
1030. In 2001, Dr. Pantuck wrote a letter to Dr. Dornfeld and Dr. Harley Liker (Respondents' scientific advisors) setting forth his protocol concepts for two clinical studies studying the benefits of pomegranate juice in populations of men with prostate cancer. (CX0544 at 0001). According to the letter, "these pilot studies are designed to provide preliminary data to justify further development of pomegranate juice as a chemopreventative agent for prostate cancer." (CX0544 at 0001). One of the two proposed protocol concepts became the *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer* ("Pantuck Study"). (CX1341 (Pantuck, Dep. at 57)).
1031. The Pantuck Study began in 2003. (CX1128 at 0001). According to the protocol, the study was a single-center, three-year study in which approximately 40 patients with prostate cancer treated by radical prostatectomy or radiotherapy with a rising PSA would receive eight ounces of pomegranate juice daily. (CX0666 at 0004-05).

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1032. By 2006, the Pantuck Study was complete and ready for publication. Dr. Pantuck first submitted the manuscript for the study to the *Journal of Clinical Oncology*. (CX1341 (Pantuck, Dep. at 107)). It was initially rejected. (CX1341 (Pantuck, Dep. at 107)). He subsequently submitted it to *Clinical Cancer Research*. (CX1341 (Pantuck, Dep. at 107)). One peer reviewer called the manuscript “excessively advocatory of pomegranate juice as a treatment for prostate cancer.” (CX0790 at 0001). Dr. Pantuck addressed this concern and other comments by making various changes to the manuscript. (CX0790; CX0786).
1033. The Pantuck Study, titled, “*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer,*” Pantuck, et al., was published in the journal *Clinical Cancer Research* in July 2006. (CX0815).
1034. *Clinical Cancer Research* is an extremely well regarded peer-reviewed journal. The process and rigor for being published in *Clinical Cancer Research* is very high. It is considered one of, if not the, finest clinical cancer journals. (CX1352 (Heber Dep. at 268-69)).
1035. Dr. Heber testified that the Pantuck Study is considered, “a very highly esteemed paper.” (CX1352 (Heber, Dep. at 268)).
1036. The Pantuck Study was the first clinical trial of pomegranate juice in patients with prostate cancer. (CX0815 at 0001).
1037. According to the published study report, the Pantuck Study was “an open-label, single-arm clinical trial,” meaning it was not an RCT and did not have a placebo group. (CX0815 at 0002).
1038. The Pantuck Study cost \$479,236.50. (CX1128 at 0001).

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**ii. About the Pantuck Study**

1039. The Pantuck Study included 46 patients who had been diagnosed with prostate cancer. The majority of the patients (68%) had been previously treated for prostate cancer by undergoing radical prostatectomy. The remainder had been treated by radiation (10%), brachytherapy (10%), a combination of surgery and radiation (7%), or cryotherapy (5%). (CX0815 at 0003).
1040. All 46 patients in the Pantuck Study drank eight ounces of pomegranate juice daily until meeting disease progression endpoints. Clinical endpoints were effect on serum prostate specific antigen (PSA), serum-induced proliferation and apoptosis of prostate cancer cells, serum lipid peroxidation, and serum nitric oxide levels. The primary endpoint was the effect on PSA variables, such as change in prostate specific antigen doubling time (PSADT). (CX0815 at 0002).
1041. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. (deKernion, Tr. 3051).
1042. PSADT is a mathematical expression of the rapidity with which the prostate specific antigen is rising, and an expression of the rapidity of growth and number of prostate tumor cells. (deKernion, Tr. 3050).
1043. Patients in the Pantuck Study had their blood drawn every three months to have their PSA determined. Disease progression was defined as either a greater than 100% increase in PSA (with a minimum value of 1.0 ng/ml.) compared with the best response observed or any documentation of metastatic or recurrent disease. (CX0815 at 0002).
1044. Patients in the Pantuck Study who consumed POM Juice experienced a significant statistical increase in PSADT when compared to their own baseline pre-treatment PSADT. (CX0815 at 0001, 0004).

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1045. In the Pantuck Study, the average pre-treatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was approximately 54 months. Thus, mean PSA doubling time significantly increased from a mean of 15 months at baseline to 54 months post-treatment. (CX1080 at 0004).
1046. The Pantuck Study reported: *in vitro* assays comparing pre-treatment and post-treatment patient serum on the growth of the prostate cancer line LNCaP showed a 12% decrease in cell proliferation and a 17% increase in apoptosis, a 23% increase in serum NO, and significant reductions in oxidative state and sensitivity to oxidation of serum lipids after pomegranate juice consumption versus before pomegranate juice consumption. (CX0815 at 0001).
1047. The Pantuck Study concluded: the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress, warrant further testing in a placebo-controlled study. (CX0815 at 0001).

**iii. Follow up to the Pantuck Study**

1048. In 2008, Dr. Pantuck released the following abstract: Pantuck, AJ, et al., "*Long term follow up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times,*" American Society of Clinical Oncology ("Pantuck Phase II Follow-Up Results") which summarized follow-up results for the Pantuck Study. (PX0061).
1049. The Pantuck Phase II Follow-Up Results reported that fifteen (31%) active patients remained on the study. (PX0061). All of the men who had dropped out of the study did so because their PSA had increased. (CX0918 at 0001). As of June 2010, only 12 patients remained active in the study. (CX1128 at 0001).

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1050. The Pantuck Phase II Follow-Up Results reported that those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice. (PX0061; Eastham, Tr. 1305; CX1341 (Pantuck, Dep. at 136)).
1051. The Pantuck Phase II Follow-Up Results reported: mean PSA doubling time for the entire cohort continued to show a significant increase following treatment, from a mean of 15.4 at baseline to 60 months post-treatment, while the median PSA slope decreased 60% from 0.06 to 0.024. Patients remaining on study (“active”) were compared to those no longer on study (“non-active”). At baseline, mean PSA doubling times were similar between Active and Non-Active patients. However, post-treatment PSADT prolongation was greater and the decline in median PSA slope was larger in active compared to non-active patients. (PX0061).
1052. The Pantuck Phase II Follow-Up Results concluded that long-term follow up of pomegranate juice consumption in men with prostate cancer and rising PSA following primary therapy demonstrates a durable increase in PSA doubling time and stated that a multi-center, randomized phase III study is ongoing to further evaluate the benefits of pomegranate in a placebo-controlled manner. (PX0061).

**iv. Statements by Dr. Pantuck about the  
Pantuck Study**

1053. Dr. Pantuck explained that the design of the study was for subjects to serve as their own control. Patients had a specific PSA doubling time prior to treatment; patients would then be treated and measured for any change in their doubling time after treatment. (CX1341 (Pantuck, Dep. at 78)).
1054. When the Pantuck Study report was released in 2006, Dr. Pantuck was quoted in an American Association for Cancer Research press release, as stating: “[w]e don’t believe we are curing anyone from prostate cancer.” He

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pointed out that “although a third of patients experienced a decrease in PSA during the study, nobody’s PSA went to zero.” Dr. Pantuck further explained: “The PSA doubling time, however, was longer. For many men, this may extend the years after surgery or radiation that they remain recurrence free and their life expectancy is extended. They may be able to prevent the need to undergo additional therapies, such as radiation, hormonal or chemotherapies.” (CX0816 at 0002).

1055. Dr. Pantuck stated that the Pantuck Study did not prove that pomegranate juice prevents or reduces the risk of prostate cancer because all the patients in the study already had prostate cancer, thus his study did not address anything related to causation. (CX1341 (Pantuck, Dep. at 108)).
1056. Dr. Pantuck did not claim that the Pantuck Study proved that pomegranate juice can treat prostate cancer, but explained that the study showed that the doubling time for PSA was prolonged. (CX1341 (Pantuck, Dep. at 108)).
1057. Dr. Pantuck testified that the Pantuck Study showed evidence that the growth of the cancer had been altered by POM Juice. (CX1341 (Pantuck, Dep. at 118-19)).
1058. Dr. Pantuck stated that the feedback from the scientific community with regard to the peer-reviewed published Pantuck Study has primarily been favorable, and that some doctors have discussed the findings with patients. (CX1341 (Pantuck, Dep. at 268-69)).
1059. Dr. Pantuck also stated: “[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical end point.” (CX0815 at 0008). According to Dr. Pantuck, “PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome.” (CX1080 at 0001). Dr. Pantuck has also stated that “although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in

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PSA kinetics arising from therapeutic intervention is meaningful.” (CX1080 at 0001).

1060. Dr. Pantuck testified that the greatest limitation of the Pantuck Study was the lack of a blinded control arm. (CX1341 (Pantuck, Dep. at 110)). In the published study report, Dr. Pantuck specifically pointed to the published study, *Rosiglitazone versus Placebo for Men with Prostate Carcinoma and a Rising Serum Prostate-Specific Antigen Level after Radical Prostatectomy and/or Radiation Therapy*, *Cancer* 2004: 101:1569-74 (“Rosiglitazone Study”). (CX0815 at 0008).
1061. The Rosiglitazone Study was a randomized, double-blind placebo-controlled study examining the effect of rosiglitazone in a population of men similar to the patients studied in the Pantuck Study, namely men who had been treated by radical prostatectomy or radiation with a rising PSA. (PX0172 at 0001; CX0815 at 0001; deKernion, Tr. 3069). The Rosiglitazone Study found that 40% of the placebo group and 38% of the treatment group experienced a prolongation in PSADT. (PX0172 at 0001; deKernion, Tr. 3071).
1062. The Rosiglitazone Study authors stated that “[t]he discordance between baseline and post-treatment PSADT in our placebo group suggests caution is required when using changes in PSADT as an outcome in uncontrolled trials and reinforces the value of randomized, placebo-controlled trials in this setting.” The Rosiglitazone Study authors concluded that, “the current results do not diminish the potential value of changes in PSADT as an outcome variable for the early evaluation of novel therapeutic agents. In randomized studies of similar design, more active agents may demonstrate the value of PSA kinetics as a screen for biologic activity.” (PX0172 at 0006).
1063. Dr. Pantuck stated that the Rosiglitazone Study “highlights the potential limitations of PSA variables in monitoring patients and the need for confirmatory prospective studies using a blinded control arm.” (CX0815 at 0008).

**b. Carducci Study****i. Background to the Carducci Study**

1064. Respondents have also sponsored a human study looking at POMx use in men who have already been treated for prostate cancer. The study is completed and an abstract summarizing the results has been published. *See* M.A. Carducci, et al., *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy* (“Carducci Study”), *J Clin Oncol* 29: 2011 (suppl 7; abstr 11). (PX0175; *see also* CX1174). A final, peer-reviewed study report had not been published at the start of trial in this matter. (*See* Nonparties Johns Hopkins University and Michael A. Carducci, M.D.’s Motion for *In Camera* Treatment, at 5).
1065. The Carducci Study was conducted by Dr. Michael A. Carducci, a professor of oncology and urology at the Johns Hopkins School of Medicine, in Baltimore, Maryland. Within the Cancer Center, he leads two programs, the prostate cancer/genitourinary cancer program and chemical therapeutics. (CX1340 (Carducci, Dep. at 14-15); CX1120).
1066. Dr. Carducci is a graduate of Georgetown University and Wayne State University Medical School. Dr. Carducci did a residency in internal medicine at the University of Colorado in Denver. After completing a year as chief resident at the University of Colorado, he accepted a fellowship in oncology at Johns Hopkins University. (CX1340 (Carducci, Dep. at 13-14)).
1067. Dr. Carducci has conducted 40 to 50 clinical trials relating to prostate cancer and has published approximately 80 articles related to prostate cancer. (CX1340 (Carducci, Dep. at 15-16)).
1068. In 2006, Dr. Carducci began working with Respondents to design the Carducci Study. (CX0806). Dr. Carducci submitted a proposed protocol for the Carducci Study to Respondents for a larger randomized three-arm study, with

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two treatment arms and one placebo arm. (CX1340 (Carducci, Dep. at 28-29; CX0064 at 0002, *in camera*).

1069. Respondents conducted a feasibility and cost analysis and decided that the study proposed by Dr. Carducci was too costly. The placebo arm was dropped from the study due to costs, and, in part, due to poor patient acceptance of a placebo. (CX1340 (Carducci, Dep. at 28-29)).

**ii. About the Carducci Study**

1070. The Carducci Study began in January 2008. (CX1138 at 0002). According to the protocol, the Carducci Study was an 18-month, multi-center, randomized, double-blind, dose-finding study of the effect of two different doses of POMx capsules (one or three capsules) on PSADT in men who had received initial therapy for prostate cancer. (CX1110 at 0007).
1071. An interim analysis of the Carducci Study was conducted in 2009 and shared with Respondents in 2010. (*See* CX1088, *in camera*; CX1102, *in camera*). The final analysis was conducted in August 2010. (CX1146, *in camera*).
1072. In 2011, Dr. Michael Carducci presented the abstract of his clinical research study titled, “*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-specific Antigen Following Primary Therapy*” at the disease specific meeting of the American Society of Clinical Oncology (“Carducci abstract”). (PX0175). Dr. Carducci’s abstract was peer-reviewed prior to being selected for presentation. (CX1340 (Carducci, Dep. at 176)).
1073. The Carducci Study was a multi-center, double blind Phase II randomized trial that studied 104 men with rising PSA and without metastases. They were given either a high or low dose (one capsule or three capsules) of POMx, stratified by baseline PSADT and Gleason score, and with no restrictions for PSADT and no upper limit PSA value. (PX0175).

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1074. In the Carducci Study, men were treated until progression or for 18 months. PSA levels were obtained every three months. (PX0175).

**iii. Results of the Carducci Study**

1075. According to the Carducci abstract, 104 men were enrolled and treated for up to six months (92%), 12 months (70%), and 18 months (36%). There was no significant treatment difference ( $p = .920$ ) in PSADT between the one capsule and three capsule dose groups. (CX1174 at 0001).
1076. The Carducci abstract reported: median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment ( $p < .001$ ), a within group measurement. Thus, it showed that POMx treatment significantly increased the PSA doubling time by over six months in both treatment arms. (CX1174 at 0001).
1077. The Carducci abstract also reported that 13 patients (13%) had declining PSA levels during the study. (CX1174 at 0001).
1078. The Carducci abstract concluded that POMx demonstrates “promising antitumor effects in prostate cancer.” (CX1174 at 0001).

**iv. Statements by Dr. Carducci about the Carducci Study**

1079. Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease state was a scientifically valid way to conduct the study. (CX1340 (Carducci, Dep. at 181-82)).
1080. Dr. Carducci also testified that the endpoint of PSA doubling time is not a standard for regulatory approval of drugs at the FDA level and PSA doubling time as a marker or surrogate has not been proven. (CX1340 (Carducci, Dep. at 89-90)).

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1081. Dr. Carducci stated that the Carducci Study was not designed to use endpoints that were “drug-like,” but was specifically designed for a natural product and that researchers were looking at safety and whether POMx had an effect on rising PSA. (CX1340 (Carducci, Dep. at 50-51)).
1082. Dr. Carducci testified that the Carducci Study results, as designed and planned, were statistically significant. (CX1340 (Carducci, Dep. at 183)).
1083. Dr. Carducci also testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Study is attributable to POMx. (CX1340 (Carducci, Dep. at 95)).
1084. According to Dr. Carducci, the Carducci Study was never designed to prove, and did not prove, that POMx prevents or reduces the risk of prostate cancer. (CX1340 (Carducci, Dep. at 87-88)).
1085. According to Dr. Carducci, the Carducci Study was never designed to prove that POMx treats prostate cancer but the study showed that PSA doubling time increased by over six months in both arms of the study. (CX1340 (Carducci, Dep. at 87)).

**c. Expert opinion on the human clinical studies****i. Complaint Counsel’s experts on the Pantuck Study**

1086. Complaint Counsel’s experts testified that the Pantuck Study fails to provide support for prostate cancer treatment claims for two major reasons: the lack of a placebo control group and the lack of an accepted endpoint marker. (Eastham, Tr. 1295-97; CX1287 (Eastham Expert Report at 0018-19); CX1293 (Stampfer Expert Report at 0024-25); Stampfer, Tr. 782-83).
1087. According to Dr. Stampfer, without a placebo control group in the Pantuck Study, it is not possible to know

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whether the same change in PSADT would have been observed in this patient group if they had never received POM Juice. (Stampfer, Tr. 869-70; CX1293 (Stampfer Expert Report at 0024)).

1088. According to Dr. Eastham, if the Pantuck Study had included a control group, it is possible that *no* statistical difference between groups would have been observed. Without a placebo, there is no way to eliminate confounding factors that may have impacted PSADT – such as changes in diet, exercise, or the reduction of stress. (Eastham, Tr. 1295-97; CX1287 (Eastham Expert Report at 0018)).
1089. The Pantuck Study used mean PSA doubling time as an endpoint. (PX0060). Complaint Counsel’s experts testified that in a prostate cancer treatment trial, PSA doubling time is not a relevant surrogate marker for prostate cancer prevention. Instead, in a prostate cancer treatment trial, overall survival or prostate cancer-specific mortality is the endpoint generally accepted by experts in the field. (CX1293 (Stampfer Expert Report at 0025); Eastham, Tr. 1280; CX1287 (Eastham Expert Report at 0006-09, 0014) (“The primary endpoint in a prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study.”)).
1090. Dr. Eastham criticized the Pantuck Study for the additional reason that the patients studied, with an average pre-treatment PSADT of 15 months, are considered to have a far lower risk of clinical progression, and because of this, it is unclear whether the increase in PSADT observed in the Pantuck Study is clinically significant. (Eastham, Tr. 1297-98).
1091. Complaint Counsel’s experts also testified that the Pantuck Study was designed as a treatment study (*i.e.*, study was conducted in men with prostate cancer) and does not provide any evidence that POM Juice is a

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prostate cancer preventative. (CX1293 (Stampfer Expert Report at 0025); Eastham, Tr. 1294-99).

1092. Dr. Eastham opined that the appropriate sample population for a cancer prevention trial “would involve more than 10,000 healthy men, ages 50 to 65, having no sign of prostate cancer.” (CX1287 (Eastham Expert Report at 0012)).
1093. Dr. Eastham further opined that a “prostate cancer prevention study must be conducted over a long enough period of time to see an effect over time.” CX1287 (Eastham Expert Report at 0014)).
1094. Complaint Counsel’s experts also state that the Pantuck Study on POM Juice cannot provide reliable evidence to support claims about POMx Pills’ or POMx Liquid’s benefit for prostate cancer. (Eastham, Tr. 1306; CX1293 (Stampfer Expert Report at 0025); CX1287 (Eastham Expert Report at 0020)). According to Dr. Eastham, POM Juice is not identical to POMx Pills and POMx Liquid. (CX1287 (Eastham Expert Report at 0020)). POM Juice has more than one active ingredient. Processing may result in eliminating a needed ingredient. (Eastham, Tr. 1306-07). Even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent. (CX1287 (Eastham Expert Report at 0020)).
1095. Dr. Eastham is not an expert in bioavailability and did not review any of the equivalency studies or articles on POM Juice, POMx Pills or POMx Liquid. (PX0358 (Eastham, Dep. at 94)).

**ii. Complaint Counsel’s experts on the Carducci Study**

1096. Complaint Counsel’s experts testified that the Carducci Study cannot provide support for treatment claims because it lacked a placebo-control group and that without a

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placebo-control group, it is not possible to conclude that POMx caused the change in the patients' PSADT. (Eastham, Tr. 1310; CX1287 (Eastham Expert Report at 0022); Stampfer, Tr. 789-90; CX1293 (Stampfer Expert Report at 0028)).

1097. Complaint Counsel's experts testified also that the Carducci Study cannot provide support for treatment claims because the primary endpoint in the study is PSADT, which has not been accepted by experts in the field as a surrogate for overall survival. (Eastham, Tr. 1310; CX1287 (Eastham Expert Report at 0022); CX1293 (Stampfer Expert Report at 0028)).
1098. As found in F. 1075, the Carducci Study showed no difference between a one pill dose and a three pill dose. Complaint Counsel's expert testified that the lack of a dose response despite a three-fold difference in dosage does not support a causal relationship between POMx and change in PSADT. (Stampfer, Tr. 789-90; CX1293 (Stampfer Expert Report at 0028)).
1099. Complaint Counsel's experts also testified that the Carducci Study cannot provide support for prevention claims because it evaluated the effect of POMx in men who already had prostate cancer. (Eastham, Tr. 1309-10; *see also* CX1293 (Stampfer Expert Report at 27)).

**iii. Complaint Counsel's experts on PSA doubling time**

1100. Complaint Counsel's experts testified that in a prostate cancer treatment trial, PSA doubling time is not a relevant surrogate marker for prostate cancer prevention. (Eastham, Tr. 1280; CX1287 (Eastham Expert Report at 0006-09); CX1293 (Stampfer Expert Report at 0025)).
1101. In his testimony, Dr. Eastham stated: modulation of PSA doubling times has not been proven to be of any utility and that no one would propose that changes or modulation of PSA doubling time is a prognostic factor in men with

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biochemical recurrence after primary therapy for prostate cancer. (Eastham, Tr. 1342, 1345).

1102. Dr. Eastham has also written, in an article titled, “*Prostate-specific antigen doubling time as a prognostic marker in prostate cancer*,” *Nature Clinical Practice* (2005): “PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can also be used as a surrogate marker for prostate cancer-specific death.” Dr. Eastham’s article concluded “PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death.” (PX0178 at 0001, 0009).
1103. In his expert report, Dr. Stampfer opined “it is unknown if PSADT predicts overall survival in prostate cancer patients throughout its range.” (CX1293 (Stampfer Expert Report at 0026)).
1104. Dr. Stampfer also testified that PSA doubling time is a “predictor of disease and mortality” and that, if the extension of PSA doubling time is true, it would substantially prolong lives. (Stampfer, Tr. 869, 873).

**iv. Respondents’ experts on both clinical studies**

**(a) PSA doubling time**

1105. Dr. deKernion testified that the presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present and that PSADT provides an expression of how those tumor cells are going to behave. The longer the PSADT, the less dangerous the growth of the cancer. (deKernion, Tr. 3051-52).
1106. Dr. deKernion testified that the Pantuck Study and the Carducci Study showed that POM Juice and POMx,

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respectively, slowed down the growth of the tumor cells as expressed by the longer time it took for those tumor cells to double. (deKernion, Tr. 3057).

1107. Dr. deKernion testified that the Pantuck Study and the Carducci Study both showed a dramatic lengthening of PSA doubling time. (deKernion, Tr. 3052-58).
1108. Dr. deKernion opined that PSA doubling time is used to determine success or failure of prostate cancer treatment and that multiple studies support that PSADT is correlated with the risk of clinical tumor and recurrence and, therefore, must have some association with longevity. (PX0161 (deKernion Expert Report-0004; deKernion, Tr. 3050-58).
1109. Dr. deKernion stated that PSA doubling time is clearly a useful marker in determining risk or outcome in patients following prostate cancer treatment. (deKernion, Tr. 3055).
1110. Dr. deKernion testified that given the understanding of PSA doubling time in predicting risk of clinical recurrence and to some extent survival, it is logical to use changes in PSADT as indicative of an intervention's effectiveness regarding prostate tumor behavior. (PX0161 (deKernion Expert Report at 0007, 0011-12)).
1111. Dr. deKernion also testified that the PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical benefit in chemotherapy trials. (deKernion, Tr. 3096).
1112. Dr. Heber testified that PSA doubling time is a "very important clinically utilized marker of clinical status." (CX1352 (Heber, Dep. at 314)).
1113. Dr. Heber testified that there is a lot of support from the urological community to get the FDA to accept PSA doubling time as a surrogate endpoint and that there is "a lot of feeling in the urological community and scientific

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agreement that [the] rate of rise of PSA is an important biomarker.” (CX1352 (Heber, Dep. at 316-17)).

**(b) Placebo control arm**

1114. Dr. deKernion testified that a control arm is not necessary for an objective Phase II study that is exploratory in nature. Many studies on food and many other categories in science are observational type studies without use of a control—a control is important when there is a high risk that the observed effect could be attributed to something other than the substance being tested. (PX0161 (deKernion Expert Report at 0009); deKernion, Tr. 3059-60, 3066; PX0351 (deKernion, Dep. at 97-99)).
1115. Dr. deKernion testified that in both the Pantuck Study and the Carducci Study, the control was the previous doubling time prior to treatment. The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards, comparing one to the other. This was done in lieu of a separate placebo group. (deKernion, Tr. 3059).
1116. Dr. deKernion testified that a control arm is often used to control for the placebo effect, that one purpose of a placebo control group is to limit confounding factors, and that the use of a placebo group is more important when you have a subjective reporting, as opposed to an objective reporting. (deKernion, Tr. 3059-60, 3066-67; PX0351 (deKernion, Dep. at 97-99)).
1117. Dr. deKernion specifically testified that a placebo control arm is not needed when PSADT is the study endpoint to assess the efficacy of the product or therapy being studied. In the Pantuck Study and the Carducci Study, the researchers were looking and testing objective blood results, and there is no evidence to suggest the placebo effect plays any role in modulating the PSADT of the subject. (deKernion, Tr. 3059-60, 3081; PX0351 (deKernion, Dep. at 97-99)).

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1118. Dr. deKernion also testified that without a placebo, one cannot be certain that the effect on PSA doubling time seen in the Carducci Study is attributable to POMx. (deKernion, Tr. 3103).

**(c) Respondents' experts' conclusions**

1119. Dr. Heber testified that in laboratory studies he conducted, he found no difference in the antioxidant effect between POM Juice and POMx products and that animal studies indicate that the effects of pomegranate juice and POMx Pills on prostate cancer are equivalent. (CX1352 (Heber, Dep. at 336); Heber, Tr. 2002; Heber, Tr. 2186-87).
1120. At trial, Dr. Heber testified that there is competent and reliable science showing that the POM Juice and POMx lengthen the PSA doubling time for men who have had prostate cancer and, thus, it is likely for those men to have a deferred recurrence or death from that disease; and that POM Juice and POMx are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (Heber, Tr. 2012-13).
1121. In his expert report, Dr. Heber opined: the statistically significant prolongation of PSA doubling time, corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress and inflammation, provide strong scientific rationale for the statement that pomegranate juice promotes prostate health. (PX0192 (Heber Expert Report at 0027)).
1122. Dr. deKernion testified that in order to show an effect of POM Products on prostate cancer, the best way to do that research is on patients whose prostate had been removed because the presence of PSA elevation is almost always an indication of remaining cancer. This is how the Pantuck Study and Carducci Study were conducted. (deKernion, Tr. 3057).
1123. Dr. deKernion opined that all "evidence supports that PSA changes including doubling time after failure of definitive therapy truly reflect a change in the tumor cell growth; no

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evidence exists to suggest that a biochemical effect on PSA measurement can account for changes; and no evidence exists that PSA doubling time significantly and spontaneously lengthens in a patient with known biochemical or clinical cancer.” (PX0161 (deKernion Expert Report at 0008)). Therefore, in the Pantuck Study, it is only logical to conclude that the agent causing the change in PSA doubling time is POM Juice, especially given the pre-clinical evidence of the effect of the POM Products on prostate cancer, “and the results of these studies could not be explained otherwise.” (PX0161 (deKernion Expert Report at 0011-12)).

1124. Dr. deKernion opined that POM Products are beneficial to prostate health and although there is not 100% proof that POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies showed, with a “high degree of probability,” that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. (deKernion, Tr. 3119-20, 3126; PX0351 (deKernion, Dep. at 41-42)).
1125. Dr. deKernion testified that there is a high degree of probability that POM Products inhibit the clinical development of prostate cancer cells even in men not diagnosed with prostate cancer. (deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 76-77) (in healthy men, who have never been diagnosed with prostate cancer, POM Juice and POMx could possibly play a role in preventing them from getting prostate cancer).
1126. Dr. deKernion testified that there is a high probability that the POM Products provide a special benefit to men with PSA after radical prostatectomy. (deKernion, Tr. 3126).
1127. Dr. deKernion also testified that the Carducci Study did not follow patients for a long enough time, especially for those with a long PSA doubling time, to prove that POMx will prolong their lives. (deKernion, Tr. 3103).

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**5. Determinations on the human clinical studies****a. PSA doubling time**

1128. Clinicians use PSADT as a prognostic tool at the time of biochemical recurrence of prostate cancer to predict the odds of clinical progression of the disease in prostate cancer patients who have undergone initial treatment. (Eastham, Tr. 1260; PX0351 (deKernion, Dep. at 93)). *See also* PX0178 at 001 (Complaint Counsel's expert writing: "PSA doubling time has emerged as an important factor in the evaluation of men with newly diagnosed prostate cancer or prostate cancer that recurs after treatment. PSA doubling time can also be used as a surrogate marker for prostate cancer-specific death.").
1129. Clinicians accept PSADT as a useful marker in determining risk or outcome in patients following prostate cancer treatment and measuring the likelihood of recurrence of the tumor after a man has had his prostate removed. (deKernion, Tr. 3051, 3055); *see also* CX1341 (Pantuck Dep. at 254-55) (clinicians find PSADT to be clinically important for prostate cancer treatment and one of the most important variables that a doctor can discuss to characterize a prostate cancer patient).
1130. Some published studies demonstrate acceptance of PSA doubling time as a valid predictor of disease:
- In a study titled, "*Does PSADT After Radical Prostatectomy Correlate With Overall Survival?*" in the January 2011 edition of the *Journal of Urology*, Dr. Anna Teeter and her colleagues wrote of the "widespread acceptance" that PSADT after radical prostatectomy predicts prostate cancer mortality; that this has been "well established"; that PSADT is a "useful tool for identifying men at increased risk of all-cause mortality early in their disease course"; and that PSADT is "a powerful predictor of overall survival." (PX0167).

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- In a study titled, “*Stratification of Patient Risk Based on Prostate-Specific Antigen Doubling Time after Radical Retropubic Prostatectomy*” in the April 2007 issue of Mayo Clinic Proceedings, Dr. Tollefson and colleagues wrote that PSADT was “a highly significant and reliable test” to determine the likelihood of disease recurrence and death, an “excellent indicator of clinical disease recurrence” and the only significant factor that predicts clinical progression.” The researchers concluded that, “prostate-specific antigen doubling time is an independent predictor of clinical disease recurrence and mortality after surgical biochemical failure.” (PX0166).
- In a study titled, “*Risk of Prostate Cancer-Specific Mortality Following Biochemical Recurrence After Radical Prostatectomy*,” Dr. Freedland and colleagues used PSADT to “define risk factors for prostate cancer death following radical prostatectomy and to develop tables to risk stratify for prostate cancer-specific survival.” The researchers found that clinical parameters such as PSADT can help risk stratify patients for prostate cancer-specific mortality following biochemical recurrence after radical prostatectomy. (PX0165).
- In a study titled, “*Recurrence Patterns After Radical Retropubic Prostatectomy: Clinical Usefulness of Prostate Specific Antigen Doubling Times and Log Slope Prostate Specific Antigen*” published in the October 1997 edition of the Journal of Urology, Drs. Patel, deKernion, et al., studied the correlation between prostate specific antigen doubling time and clinical recurrence in patients with detectable PSA after radical retropubic prostatectomy and concluded that, after PSA became detectable, PSA doubling time was a

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better indicator of the risk and time to clinical recurrence after radical retropubic prostatectomy than other factors including preoperative PSA. (PX0162).

1131. There are no studies proving that modulating PSADT (*i.e.*, changing the rate of the PSA doubling time) changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. (Eastham, Tr. 1261; CX1287 (Eastham Expert Report at 0011, 0019); PX0161 (deKernion Expert Report at 0004); PX0351 (deKernion, Dep. at 52-53)).
1132. The FDA has not accepted PSADT as a surrogate endpoint for clinical benefit in chemotherapy trials. (deKernion, Tr. 3096; CX1352 (Heber, Dep. at 316-17); CX1340 (Carducci, Dep. at 89-90)).
1133. Respondents acknowledged in a report on their expert panel on prostate cancer: “To date, all POM Wonderful clinical evaluations of pomegranate-derived products in prostate cancer have used PSADT as the primary endpoint. While data obtained using this approach has generated a high degree of interest from patients and urologists, it is unclear whether PSADT is acceptable as a registrational endpoint for a drug designed to prolong the time to disease progression after initial therapy for prostate cancer.” (CX1104 at 0004).
1134. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. (Eastham, Tr. 1297; Stampfer, Tr. 782-83; deKernion, Tr. 3096; CX1287 (Eastham Expert Report at 0010); CX1293 (Stampfer Expert Report at 0025); CX1340 (Carducci, Dep. at 88-90); CX1341 (Pantuck, Dep. at 253-54)). Many men with increases in PSA after initial therapy do not die of prostate cancer. On the other hand, some men succumb to prostate cancer without an increase in PSA. (Stampfer, Tr. 783; Eastham, Tr. 1258; deKernion, Tr. 3088).

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**b. Research results**

1135. There is no clinical study, research or trial that provides 100% proof that the POM Products prevent prostate cancer in humans. (deKernion, Tr. 3062, 3119).
1136. There is no clinical study, research or trial that provides 100% proof that the POM Products reduce the risk of prostate cancer in humans. (deKernion, Tr. 3062-63, 3119).
1137. There is clinical research demonstrating that patients who were given POM Products had their PSA go down, which is significant evidence that something is happening to those tumor cells. (deKernion, Tr. 3065).
1138. Although one cannot make a firm claim that the POM Products are absolutely preventative, given the data presented in the Pantuck Study and the Carducci Study, it is reasonable to state that POM Products have shown an effect on prostate cancer with little or minimal toxicity. (PX0161 (deKernion Expert Report at 0011)).

**6. Conclusions**

1139. Pomegranate consumption can potentially be used to prevent or delay clinical recurrence of prostate cancer once a patient experiences biochemical recurrences (PSA recurrences) after a radical prostatectomy. (PX0192 (Heber Expert Report at 0027)).
1140. No Phase III randomized trial has been completed to prove that POM Products prolong the life of patients who have recurrence of prostate cancer after supposedly curative therapy. Effective trials are ongoing. As reflected by changes in PSA doubling time, the POM Products are a reasonable adjunct for a patient who wishes to help their general health and possibly avoid a clinical recurrence of prostate cancer. (See PX0161 (deKernion Expert Report at 0011)).

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1141. The statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis as well as oxidative stress, and inflammation provides strong scientific rationale for the statement that pomegranate juice promotes prostate health and has led to ongoing phase III clinical trials. (PX0192 (Heber Expert Report at 0027)).
1142. Competent and reliable scientific evidence supports the conclusion that the POM Products support prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. (PX0161 (deKernion Expert Report); (PX0192 (Heber Expert Report at 0027); deKernion, Tr. 3126; PX0351 (deKernion, Dep. at 41-42); Heber, Tr. 2012).
1143. There is insufficient competent and reliable scientific evidence to support the conclusion that the POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical studies, research and/or trials establish these effects. (CX1287 (Eastham Expert Report at 0024-26); Stampfer, Tr. 790-91; CX1293 (Stampfer Expert Report at 0029-30); *see also* Eastham, Tr. 1317-19)); *see also* deKernion, Tr. 3062-63; *see also* PX0161 (deKernion Expert Report at 0011)).

**I. Substantiation for Respondents' Erectile Dysfunction Claims****1. Substantiation standard for erectile dysfunction claims**

1144. Clinical evidence supported by basic scientific evidence is sufficient to support claims that pomegranate juice has a potential benefit for vascular blood flow and the vascular health of the penis. (PX0149 (Burnett Expert Report at 0006)).
1145. Experts in the field of erectile dysfunction would not require RCTs to substantiate health benefit claims for harmless pure fruit products like pomegranate juice.

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(PX0149 (Burnett Expert Report at 0006-07); Burnett, Tr. 2272, 2303; PX0189 (Goldstein Expert Report at 0003); Goldstein, Tr. 2600-02, 2611, 2620).

1146. Experts in the field of erectile dysfunction would not require that pomegranate juice or its derivatives be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function. (PX0149 (Burnett Expert Report at 0006-07); Burnett, Tr. 2272-74, 2303; PX0189 (Goldstein Expert Report at 0003); Goldstein, Tr. 2600-02, 2611, 2620).
1147. Experts in the field of erectile dysfunction would not require that pomegranate juice or derivatives be subjected to RCTs before concluding that pomegranate juice has a potential beneficial effect on erectile dysfunction. (Burnett, Tr. 2272-74, 2303).
1148. Experts in the field of erectile dysfunction would require that a product be scientifically evaluated through rigorous scientific and clinical studies, and believe that animal and *in vitro* studies alone are not sufficient, before concluding that pomegranate juice treats erectile dysfunction in a clinical sense. (Burnett, Tr. 2261-64; 2285-86; 2303).

## **2. Background facts on erectile health and dysfunction**

### **a. Erectile health distinguished from erectile dysfunction**

1149. Erectile health is having a healthy erectile mechanism. (PX0189 (Goldstein Expert Report at 0008)).
1150. Erectile health is promoted when the male practices strategies that encourage endothelial health, such as exercise, use of the Mediterranean diet, and use of endothelial-healthy medications (such as aspirin, statins, and PDE5-inhibitors). (PX0189 (Goldstein Expert Report at 0008); PX0190; PX0352 (Goldstein, Dep. at 148)).

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1151. Erectile health is distinguished from erectile dysfunction. (PX0189 (Goldstein Expert Report at 0008)).
1152. Erectile dysfunction is the consistent or persistent inability to obtain and/or sustain an erection adequate for sexual intercourse. (Burnett, Tr. 2257; PX0189 (Goldstein Expert Report (Goldstein Expert Report at 0008-09))).
1153. Improving ones erectile function may also help improving ones erectile dysfunction. (Burnett, Tr. 2303).
1154. A clinical treatment for erectile dysfunction is different than the concept of something having a potential beneficial effect on erectile tissue function and health. (PX0349 (Burnett, Dep. at 56-57)).
1155. Erectile dysfunction has been estimated to affect up to 30 million men in the United States. (PX0189 (Goldstein Expert Report at 0008-09)).
1156. The most common cause of erectile dysfunction is cardiovascular disease. (PX0189 (Goldstein Expert Report at 0009)).
1157. “Subjects with ED seem to have a vascular mechanism similar to that seen in atherosclerosis [ . . . ] and therefore, a diagnosis of ED may be seen as a sentinel event that should prompt investigation for coronary heart disease (CHD) in asymptomatic men.” (PX0190 at 0002).
1158. Cardiovascular disease is strongly associated with endothelial cell dysfunction. (PX0189 (Goldstein Expert Report at 0009)).
1159. Endothelial cell dysfunction may act to adversely affect the structure and function of the critical arterial inflow mechanism, the critical expandability of the erectile tissue and the critical integrity of the veno-occlusive mechanism. (PX0189 (Goldstein Expert Report at 0009)).
1160. The erectile mechanism is largely dependent on the health, integrity, structure and function of the arterial vascular and

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corporal erectile tissue systems. (PX0189 (Goldstein Expert Report at 0008)).

**b. Physiology of human penile erection**

1161. The penis consists of two corpora cavernosa or erectile chambers and a corpus spongiosum or erectile tissue surrounding the urethra. The corpora cavernosa erectile tissue are contained by a thick and strong fibrous lining called the tunica albuginea that stretches to some extent during penile erection but also acts as a container to provide axial rigidity to the erect penis. (PX0189 (Goldstein Expert Report at 0006); Burnett, Tr. 2245).
1162. The erectile tissue includes numerous interconnecting lacunar spaces that fill with blood during erection, and are lined by vascular endothelial cells. The lacunar spaces are surrounded by vascular smooth muscle and connective tissue such as collagen and elastin. (PX0189 (Goldstein Expert Report at 0006)).
1163. Arterial blood enters the corpora cavernosa via the right and left cavernosal arteries. There are numerous small regulatory arteries off the cavernosal artery called helicine arterioles that open into the lacunar spaces. At the peripheral edge of the erectile tissue, underneath the tunica albuginea, there are small veins called sub-tunical venules that drain blood from the peripheral lacunar spaces through the tunica into draining veins at the side of the penis to eventually return blood back to the heart. (PX0189 (Goldstein Expert Report at 0006); Burnett, Tr. 2245-46).
1164. In the flaccid state, smooth muscle in the helicine arterioles and surrounding the lacunar spaces are contracted allowing only small amounts of blood to enter the erectile chambers. Relaxation of the vascular smooth muscle of the corpora cavernosa leads to penile erection. Dilation of the helicine arterioles increases perfusion of high pressure arterial blood into the lacunar spaces. Relaxation of the smooth muscle surrounding the lacunar spaces results in engorgement of the erectile tissue and

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expansion of the erectile tissue against the tunca albuginea. This erectile tissue expansion results in compression of the sub-tunical venules that restricts blood outflow from the corporal erectile chambers. This venous trapping mechanism is the corporal veno-occlusive mechanism. Due to the hydraulic nature of increasing blood inflow and perfusion pressure and restricting blood outflow, there is an increase in intracavernosal pressure to a value approximating the mean systemic arterial blood pressure. The containment of pressure within the tunica albuginea leads to axial rigidity and penile hardness that enables functional penile penetration. (PX0189 (Goldstein Expert Report at 0006-07); Burnett, Tr. 2246-48).

**c. The role of nitric oxide in human penile erection**

1165. Nitric oxide (“NO”) has a beneficial effect on blood flow. (Heber, Tr. 1969, 2140; Burnett, Tr. 2250).
1166. Blood vessels and the flow of blood to the penis are important to erectile function. (Melman, Tr. 1169).
1167. While many types of molecules participate in the erection process, NO “is the key molecule that governs penile erection,” and is “known to be of paramount importance in the maintenance of good erectile function.” (PX0149 (Burnett Expert Report at 0004); Burnett, Tr. 2249-50, 2276; PX0190 at 0006). Complaint Counsel’s erectile dysfunction expert, Dr. Melman, agreed that NO employs a critical role in the erectile process and that there are men whose erectile dysfunction is caused by the inadequate production of NO. (Melman, Tr. 1169; PX0360 (Melman, Dep. at 32)).
1168. The physiologic mechanism of penile erection involves release of NO in the corpus cavernosum during sexual stimulation. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007)).
1169. The NO is released from shear stress off the endothelial cells in the lacunar spaces within the corpora cavernosa and from autonomic nerves that innervate the erectile

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tissue and are activated during sexual stimulation. (PX0189 (Goldstein Expert Report at 0007); Burnett, Tr. 2248-49; PX0349 (Burnett, Dep. at 88-90)).

1170. Upon its synthesis and release from their cellular sources, NO diffuses to neighboring vascular and trabecular smooth muscle cells lining the lacunar spaces. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007); PX0349 (Burnett, Dep. at 87-90)).
1171. The NO activates the enzyme guanylate cyclase within the vascular smooth muscle cells that results in increased levels of cyclic guanosine monophosphate (cGMP), an effector of smooth muscle relaxation via protein kinase G (PKG) actions. (PX0149 (Burnett Expert Report at 0004-05); PX0189 (Goldstein Expert Report at 0007); PX0349 (Burnett, Dep. at 87-90)).
1172. NO, cGMP and PKG mediate the relaxation of the cavernous smooth muscle and vasodilation of blood vessels. (PX0149 (Burnett Expert Report at 0004); PX0189 (Goldstein Expert Report at 0007)).
1173. Persistent smooth muscle relaxation leads to tissue engorgement within the corpora cavernosa and penile erection. (PX0189 (Goldstein Expert Report at 0007)).
1174. Cyclic guanosine monophosphate is hydrolyzed by the phosphodiesterases, predominantly type 5 ("PDE5"), to inactive 5'-GMP, terminating penile erection. (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 92-93)).
1175. PDE5 inhibitors such as sildenafil (Viagra), vardenafil (Levitra) and tadalafil (Cialis) inhibit PDE5, thereby augmenting cGMP levels. (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 93)).
1176. Endothelial NO function is fundamental to the vascular process of penile erection. (Burnett, Tr. 2290).

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1177. The vascular function of vessels in various parts of the body behave similarly. (Burnett, Tr. 2290).

**d. Antioxidant activity of pomegranate juice**

1178. Oxidative stress molecules in the body, which are produced by various kinds of conditions of inflammatory change, disease states, etc., have deleterious effects throughout the body in the vasculature and in the penis that actually counter-effect the body's NO regulatory mechanism, not just for transient effects to bring about erection, but also to maintain the wellness of the erectile tissue. (PX0349 (Burnett, Dep. at 89-90); Burnett, Tr. 2250-51; Goldstein, Tr. 2604-05; PX0190 at 0006).

1179. Antioxidants are well known to enhance the biological actions of NO by virtue of their capacity to stabilize NO by protecting against the oxidative destruction of NO by oxidative stress molecules. (PX0056 at 0002; PX0059 at 0001, 0004; PX0190 at 0006; PX0149 (Burnett Expert Report at 0005-06); PX0189 (Goldstein Expert Report at 0004-05); Goldstein, Tr. 2604-05).

1180. The antioxidant effect described in F. 1179 results in much higher and more prolonged cellular concentrations of NO, leading to markedly increased biological actions of NO. (PX0056 at 0002; PX0059 at 0001, 0004; PX0149 (Burnett Expert Report at 0005-06)).

1181. Antioxidants play a potential role in preserving erectile tissue health and function. (Burnett, Tr. 2285-86; Goldstein, Tr. 2604-05).

1182. Pomegranate juice possesses potent flavonoid antioxidants. (PX0149 (Burnett Expert Report at 0005-06); Burnett, Tr. 2250-51; PX0189 (Goldstein Expert Report at 0011); PX0056; PX0058; PX0051; PX0004).

1183. Pomegranate juice enhances the production of endothelial NO formation by suppressing the oxidative stress molecules that oppose the endothelial NO synthase function. (PX0149 (Burnett Expert Report at 0005-06);

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PX0349 (Burnett, Dep. at 103, 119); Burnett, Tr. 2251-54).

1184. Pomegranate juice possesses anti-oxidative molecular effects and these effects activate endothelial NO mechanisms in vasculature which serve potential beneficial effects on vascular blood flow and promote vascular biologic health of the penis. (PX0149 (Burnett Expert Report at 0005-06)).

### **3. Erectile dysfunction studies**

1185. Respondents have sponsored two human studies addressing erectile dysfunction-related endpoints and at least six *in vitro* and animal studies looking at NO metabolism in an effort to identify a potential erectile dysfunction benefit from pomegranate juice. (CX1193 at 0001; CX0716 at 0029; PX0051 at 0001; PX0056 at 0001; PX0057 at 0001; PX0059 at 0001; PX0004 at 0001; PX0058 at 0001).

#### **a. Tools for human clinical studies evaluating erectile function**

1186. Both Complaint Counsel's and Respondents' erectile dysfunction experts agree it is important to use a validated tool when conducting a human clinical trial investigating whether a product treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1099; CX1289 (Melman Expert Report at 0010); Burnett, Tr. 2266 (agreeing that experts would rely on a validated tool when conducting a human clinical trial investigating whether a product treats erectile dysfunction)).
1187. A validated tool is "established as measuring erectile dysfunction through rigorous assessments involving reliability testing, validity testing, construct validity, and other criteria." (Burnett, Tr. 2266; *see also* Melman, Tr. 1100 (stating that validation means that a measure has been shown to have statistical reliability)).

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1188. Validation is important because “[r]igorous assessment of patient-reported outcomes is necessary to ensure reliability, responsiveness, and discriminant and predictive validity. These attributes ensure that the instrument measures what it states it measures, and that the results are reproducible and sensitive to change.” (PX0352a02 at 0002; PX0352 (Goldstein, Dep. at 55-56)).
1189. Dr. Melman testified that a study to support a treatment for erectile dysfunction must show that a man can complete intercourse with sexual satisfaction and achieve orgasm. (Melman, Tr. 1141-43). *See also* Melman, Tr. 1146-47 (In the hypothetical case of “a man [that] hasn’t been able to have an erection for five years, then he tries [a] product and he now has an erection and he can penetrate his wife and bring her to sexual satisfaction, but he doesn’t have an orgasm himself,” the maker of the product “can’t tell the public about what [the product has] done.”).

**i. The IIEF**

1190. The International Index of Erectile Function (“IIEF”) is a validated measure for evaluating change in erectile function. (JX0003 ¶ A.9; Melman, Tr. 1099; CX1289 (Melman Expert Report at 0010); Burnett, Tr. 2293; PX0352 (Goldstein, Dep. at 65); CX1193 at 0002; *see also* CX1240 at 0003, *in camera* (stating in a pre-investigational new drug application for POMx that the FDA considered the “erectile function domain of the IIEF . . . as the most appropriate measure of the efficacy of the product for treating erectile dysfunction”)).
1191. The IIEF is a 15 question psychometrically validated instrument designed to assess a man’s overall erectile and sexual function via the individual domains of erectile function, orgasmic function, sexual desire, intercourse satisfaction and overall satisfaction. (PX0189 (Goldstein Expert Report at 0009); Melman, Tr. 1099-1101; CX0686 at 0026-29; CX1193 at 0002 (stating that the “IIEF is a validated questionnaire whose erectile function domain

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score has been demonstrated to correlate with ED [erectile dysfunction] intensity”).

1192. The erectile function domain relates only to erectile performance and does not evaluate orgasm or ejaculation. (Goldstein, Tr. 2604).
1193. The IIEF was designed for evaluating pharmaceuticals, not natural botanical products. (Goldstein, Tr. 2603-04).
1194. Dr. Goldstein, who was at the Pfizer Drug Company meeting where the IIEF was developed for its pharmaceutical product Viagra, testified that the IIEF was originally intended for pharmaceutical products in patients with IIEF scores consistent with erectile dysfunction. (PX0352 (Goldstein, Dep. at 67-69)).
1195. The IIEF has some ambiguous questions. For example, one question asks how often do you get an erection, but does not qualify as to what type of erection, *i.e.*, mild erection; moderate erection, etc. (Goldstein, Tr. 2603). Also, IIEF has deficiencies as it requires patient recall and involves patients’ subjective interpretation of their erection physiology. (Burnett, Tr. 2293-94).

**ii. The GAQ**

1196. The Global Assessment Questionnaire (“GAQ”) is not a validated measure for assessing erectile function. (Melman, Tr. 1118; Burnett, Tr. 2294; PX0352 (Goldstein, Dep. at 73)).
1197. By itself, experts would not consider the GAQ to be a sufficient endpoint in a clinical study evaluating a treatment for erectile dysfunction. (Burnett, Tr. 2294-95) (agreeing that the GAQ was more vague and nonspecific than a validated tool in measuring whether a therapy had an effect on the ability to achieve and maintain erections).
1198. The GAQ is commonly accepted as a standardized instrument among those conducting erectile dysfunction research. The GAQ’s “clinical meaningfulness based on

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its simplicity makes it extremely widely used and very important in assessing erectile function.” (Goldstein, Tr. 2602-03, 2634; Burnett, Tr. 2304; PX0349 (Burnett, Dep. at 127); CX1337 (Forest, Dep. at 79)).

1199. In the development of pharmaceutical products for sexual medicine, the FDA widely approves of non-validated, patient-reported outcomes, such as the GAQ. (PX0352 (Goldstein, Dep. at 57)).
1200. The GAQ does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1120, 1122; CX1289 (Melman Expert Report at 0014)).
1201. The GAQ is a single yes/no question designed to assess the individual self-evaluation of the study treatment (*e.g.*, pomegranate juice consumption versus placebo consumption) effect on the patient’s sexual health concern. (PX0189 (Goldstein Expert Report at 0009); Goldstein, Tr. 2603).
1202. The GAQ is a very easy evaluation and written for a high school educated person to understand. (Goldstein, Tr. 2603; CX1337 (Forest, Dep. at 151-52)).
1203. The GAQ is used in all sexual medicine trials. (Goldstein, Tr. 2603; PX0352 (Goldstein, Dep. at 57)).
1204. The GAQ was used by Pfizer in testing sildenafil (Viagra) and in every vardenafil (Levitra) and tadalafil (Cialis) trial. (Burnett, Tr. 2304; Goldstein, Tr. 2602; PX0352 (Goldstein, Dep. at 57)).
1205. The GAQ is a very “acceptable,” informative,” and “valuable” tool to use for testing pomegranate juice. (Burnett, Tr. 2294, 2304).

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**b. The Forest/Padma-Nathan Study****i. About the Forest/Padma-Nathan Study**

1206. POM sponsored a study by Mr. Christopher Forest, Dr. Harin Padma-Nathan, and Dr. Harley Liker, titled, *Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double-Blind, Crossover Study* (“Forest/Padma-Nathan Study”). (CX1147 at 0004; CX1193 at 0001, 0004). The clinical trial was conducted in 2004 to 2005, and the results were later published in the *International Journal of Impotence Research* in 2007. (CX1193 at 0001; CX1147 at 0004).
1207. Dr. Padma-Nathan, the principal investigator of the Forest/Padma-Nathan Study, received the first fellowship from the American Foundation for Urologic Disease that was awarded in the area of erectile dysfunction. The prestigious fellowship is awarded to two urologists annually. His work involved two years of basic lab and *in vitro* scientific research in smooth muscle pharmacology cosponsored by the Department of Urology and the Department of Cardiology at Boston University. (CX1338 (Padma-Nathan, Dep. at 23, 32-33)). Dr. Padma-Nathan is a man of repute in the field of urology. (Heber, Tr. 2000).
1208. Mr. Forest, at the time of the Forest/Padma-Nathan Study, was Physician Assistant and Director of Clinical Trials, working for Dr. Padma-Nathan. (CX1337 (Forest Dep. at 20)).
1209. Dr. Liker, POM’s medical director, was involved with the design and conduct of the Forest/Padma-Nathan Study. (See CX 1350 (Liker, Dep. at 191); CX0637 at 0001; CX0622 at 0001; CX0704 at 0001; CX0644 at 0001-02; CX0834 at 0001-02). Dr. Liker also reviewed and approved changes to the article prior to publication. (CX0881 at 0001-02; *see also* CX0856 at 0001) (sending revised draft of manuscript to Dr. Liker)).

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1210. The Forest/Padma-Nathan Study was a randomized, double-blinded, placebo-controlled pilot study that examined the efficacy of POM Juice versus placebo in improving erections in 53 men with mild to moderate erectile dysfunction. (CX1193 at 0001; CX1289 (Melman Expert Report at 0012-13)).
1211. The Forest/Padma-Nathan Study used a crossover design, and the 53 participants who completed the study received a different beverage during the two 28-day treatment periods. (CX1289 (Melman Expert Report at 0012-13); CX1193 at 0002-03). Participants in cohort one consumed POM Juice in period one and then switched to the placebo beverage in period two. (CX1193 at 0002-03). Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. (CX1193 at 0002-03).
1212. The Forest/Padma-Nathan Study used the GAQ as the primary outcome measure and the IIEF as the secondary outcome measure. (CX1337 (Forest, Dep. at 84); CX1193 at 0002; Melman, Tr. 1120; CX0686 at 0008).
1213. The Forest/Padma-Nathan Study hypothesized that treatment of the participants with POM Juice would produce: 1) statistically significant positive GAQ scores when compared to placebo-controlled patients, and 2) changes in the erectile function domain of the IIEF when the values are compared with the baseline and between the two groups. (CX0686 at 0008).
1214. The Forest/Padma-Nathan Study's GAQ asked participants the following yes or no question: "While using the study beverage, did you feel that your erections improved?" (CX0686 at 0025).
1215. Dr. Padma-Nathan, the lead researcher, testified that while the GAQ is not a validated measure for measuring erectile function, "it's not unreasonable to have it as a single question, to try to capture a signal for any evidence of [erectile] treatment effect." (CX1338 (Padma-Nathan Dep. at 90-91, 94)).

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1216. The erectile function domain questions of the IIEF have graded response scales and ask specific questions relating to erectile function, such as “Over the last month, when you attempted sexual intercourse, how often were you able to penetrate (enter) your partner?” and “Over the last month, during sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?” (CX0686 at 0026-27; *see also* Melman, Tr. 1123).
1217. Dr. Padma-Nathan testified that the IIEF was a validated measure and the “gold standard.” (CX1338 (Padma-Nathan, Dep. at 90)).
1218. Dr. Padma-Nathan considered the Forest/Padma-Nathan RCT Study “a scientifically rigorous study.” (CX1338 (Padma-Nathan Dep. at 196-97)).
1219. A study as scientifically rigorous as the Forest/Padma-Nathan RCT Study is almost unheard of in the food industry. (Goldstein, Tr. 2601-02, 2613-14).
1220. Dr. Goldstein, indicated that as editor in chief of the *International Journal of Impotence Research*, the Forest/Padma-Nathan Study “is the first and only nutraceutical clinical trial that is randomized and double-blind that [he has] ever come across in [the] field.” (Goldstein, Tr. 2598).

**ii. Results of the Forest/Padma-Nathan Study**

1221. Of the 53 participants who completed the Forest/Padma-Nathan Study, a total of 42 subjects demonstrated improved GAQ scores, 25 after drinking pomegranate juice. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).
1222. In the pomegranate juice–placebo sequence, 56% demonstrated improvement of GAQ score versus 33% in the placebo-pomegranate juice sequence. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).

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1223. In the placebo–pomegranate juice sequence, 38% versus 29% reported improvement in GAQ score. (PX0189 (Goldstein Expert Report at 0012-13); CX0908).
1224. Overall, the GAQ scores demonstrated that pomegranate juice drinkers enjoyed a nearly 50% better improvement in erections over the placebo drinkers. (CX0908 at 0003; PX0352 (Goldstein, Dep. at 109, 144); CX1338 (Padma-Nathan, Dep. at 191-92)).
1225. The Forest/Padma-Nathan Study’s GAQ results achieved a probability value (“*p*-value”) of 0.058, which is not statistically significant, as it is slightly above the statistical significance measure of 0.050. (PX0189 (Goldstein Expert Report at 0012-13); CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598). This means the study had a 94%, rather than 95%, probability of being valid and not the result of chance. (Heber, Tr. 1978; Goldstein, Tr. 2599; Burnett, Tr. 2305).
1226. The Forest/Padma-Nathan RCT Study’s IIEF erectile function domain results achieved a *p*-value of 0.72, which is not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297 (agreeing that a *p*-value of 0.72 is “nowhere near approaching statistical significance”); PX0352 (Goldstein, Dep. at 65); CX1193 at 0003; CX1213 at 0001 (comparing the change from baseline for the treatment group versus the control group)).
1227. The Forest/Padma-Nathan Study report noted the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193 at 0004). *See also* Melman, Tr. 1125, 1127; CX1289 (Melman Expert Report at 0014) (the study not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function).
1228. Dr. Padma-Nathan also testified that the Forest/Padma-Nathan RCT Study was “[u]nder-powered to achieve statistical significance . . . [but] that shouldn’t be misconstrued to mean that the study was a deficient one.” (CX1338 (Padma-Nathan, Dep. at 106, 108)). Dr. Padma-

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Nathan further testified that he did not think they were “trying to achieve [statistical significance] and didn’t believe [they would] get statistical significance.” (CX1338 (Padma-Nathan, Dep. at 106)).

1229. Dr. Padma-Nathan testified that the study concluded that there was a potential for pomegranate juice to have beneficial effects on erectile dysfunction, with the caveat of the need for further studies to confirm. (CX1338 (Padma-Nathan, Dep. at 184)).
1230. Dr. Padma-Nathan and Mr. Forest testified that the study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66)).
1231. After the Forest/Padma-Nathan Study was submitted for publication, a peer reviewer for the *International Journal of Impotence Research* stated that it was “a negative study, not a positive study, and should be presented that way.” (CX0856 at 0001).
1232. A published review by Dr. Jacob Rajfer, Professor of Urology at UCLA, *Pomegranate Juice: Is It the New, All-Natural Phosphodiesterase Type 5 Inhibitor?*, 10 Rev. Urol. 168-69 (2008), also stated that the Forest/Padma-Nathan Study had negative results. (CX1290 at Ex. C; Melman, Tr. 1128-29; CX1289 (Melman Expert Report at 0016)).

**iii. Expert opinion on the Forest/Padma-Nathan Study**

1233. Dr. Melman testified that the GAQ is not a validated measure for assessing erectile function; has not been tested for statistical reliability; and does not measure the degree of improvement, indicate how often a study participant experienced improved erections, or show whether he was able to complete sexual intercourse. (Melman, Tr. 1118-22; CX1289 (Melman Expert Report at 0014)). Dr. Melman further testified that without the ability to show

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meaningful change of erectile function, the GAQ does not provide clinically significant information. (Melman, Tr. 1118-22; CX1289 (Melman Expert Report at 0014)).

1234. Dr. Melman had not heard of the term GAQ until being involved as an expert in this case and he formed his opinions about the GAQ after being involved in this case. (Melman, Tr. 1180-81).
1235. Dr. Melman testified that the Forest/Padma-Nathan Study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function. (Melman, Tr. 1125, 1127; CX1289 (Melman Expert Report at 0014)). Dr. Melman further opined that experts in the erectile dysfunction field would require that a study be conducted over an appropriate duration because, even if there is improvement in the quality of erection, a treatment is not efficacious when the participant is still unable to complete intercourse. (CX1289 (Melman Expert Report at 0011-12)).
1236. Dr. Melman testified that the Forest/Padma-Nathan Study's IIEF erectile function domain results achieved a *p*-value of 0.72 and GAQ results achieved a *p*-value of 0.058, which are not statistically significant. (Melman, Tr. 1120-21). Dr. Melman further testified that nearly achieving statistical significance is insufficient to prove a product's efficacy in treating, preventing, or reducing the risk of erectile dysfunction in humans. (Melman, Tr. 1103, 1121).
1237. Dr. Melman also testified that based on the results of an animal study and one study on 11 men, Dr. Melman has made public statements that a gene-transfer therapy for erectile dysfunction called hMaxi-K would help erectile dysfunction. (Melman, Tr. 1148, 1150, 1155).
1238. Respondents' experts testified that even though the statistical significance was not reached, the Forest/Padma-Nathan Study "provides very valuable information" regarding erectile health and function and is absolutely "clinically significant" because "it supports the conclusion

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that the positive results in the basic science are borne out in human function.” (Goldstein, Tr. 2598-99, 2605, 2608; PX0352 (Goldstein, Dep. at 34-47, 105-09)).

1239. Dr. Goldstein testified that the results of the Forest/Padma-Nathan Study showed that “there were 50 percent more people than the placebo who thought that there was erectile benefit from using this drug. And I will call that clinically significant in conjunction with the fact that there are no deaths, no priapisms, no heart attacks, no strokes, no flushing, no nasal congestion, none of the traditional side effects seen by PDE5 inhibitors. No need for stents, drug-eluting stints, no need for surgery. No need for penile prosthetic procedures.” (PX0352 (Goldstein, Dep. at 109)).
1240. Dr. Goldstein also testified that the Forest/Padma-Nathan Study “is of extreme relevance to the clinician and consumer” and is “suggestive evidence that use of pomegranate juice would benefit [a] patient with erectile dysfunction.” (PX0189 (Goldstein Expert Report at 0014); Goldstein, Tr. 2605; PX0352 (Goldstein, Dep. at 34, 105-06)).
1241. Dr. Goldstein opined that the short treatment period in the Forest/Padma-Nathan Study “actually resulted in less favorable findings such that one would anticipate that a more robustly designed study would certainly have obtained statistically significant results.” (PX0189 (Goldstein Expert Report at 0013); PX0352 (Goldstein, Dep. at 80)).
1242. Dr. Burnett testified that the results of the Forest/Padma-Nathan Study provide support that pomegranate juice “may be an intervention that would complement conventional ED treatment, and [he] would support its use by patients.” (Burnett, Tr. 2298).
1243. Dr. Burnett opined that the Forest/Padma-Nathan Study supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function, and is “a potential treatment for ED.” (PX0149

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(Burnett Expert Report at 0006); Burnett, Tr. 2255-56, 2270; PX0349 (Burnett, Dep. at 103, 112, 116-18, 138-39, 142)).

1244. Dr. Heber opined that the Forest/Padma-Nathan Study showed that consumption of POM juice created a marked improvement in erectile function among men who had experienced erectile dysfunction, and it had major clinical significance in showing a benefit from pomegranate juice despite barely missing statistical significance. (Heber, Tr. 1830-31, 1979).
1245. Dr. Heber testified that the Forest/Padma-Nathan Study “could [not] be disregarded” and that “it is a positive in providing important scientific information consistent with the basic science that pomegranate juice may be helpful for men with erectile dysfunction.” (Heber, Tr. 2001).

**iv. Determinations on the Forest/Padma-Nathan Study**

1246. The GAQ is an adequate tool for testing a product like pomegranate juice. (Burnett, Tr. 2303-04).
1247. The Forest/Padma-Nathan Study’s IIEF erectile function results of a *p*-value of 0.72 is not statistically significant. (Melman, Tr. 1120-21; Burnett, Tr. 2297).
1248. The Forest/Padma-Nathan Study’s GAQ results of a *p*-value of 0.058 was a few thousandths of a percentage point short of the 95% threshold, and thus not “statistically significant.” (PX0189 (Goldstein Expert Report at 0012-13); CX0908; Heber, Tr. 1978; Goldstein, Tr. 2598-99; Burnett, Tr. 2305).
1249. As noted in the Forest/Padma-Nathan Study itself, the treatment period was a limitation because it might not have been long enough to allow for a clinical response. (CX1193 at 0004).
1250. Despite the limitations stated in F. 1247-1249, the Forest/Padma-Nathan Study has clinical significance in

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showing a benefit from pomegranate juice on erectile tissue physiology and health. (PX0189 (Goldstein Expert Report at 0013); PX0149 (Burnett Expert Report at 0006); CX0908; Heber, Tr. 1979, 2001; Goldstein, Tr. 2598-99; PX0352 (Goldstein, Dep. at 108-09); Burnett, Tr. 2256; PX0349 (Burnett, Dep. at 138-39)).

1251. The Forest/Padma-Nathan Study supports the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function. (PX0149 (Burnett Expert Report at 0006); Burnett, Tr. 2255-56; PX0349 (Burnett, Dep. at 103, 112, 116-18, 138-39, 142)).
1252. The Forest/Padma-Nathan Study supports the conclusion that pomegranate juice is a potential treatment for erectile dysfunction. (PX0349 (Burnett, Dep. at 142); CX1338 (Padma-Nathan, Dep. at 184)).
1253. The Forest/Padma-Nathan Study does not support the conclusion that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. (CX1338 (Padma-Nathan, Dep. at 157-58); CX1337 (Forest, Dep. at 165-66); PX0349 (Burnett, Dep. at 142)).

**c. Davidson BART/FMD Study**

1254. A subset of 27 participants from the Davidson BART/FMD Study, a randomized, double blind, and placebo-controlled cardiovascular study funded by Roll (discussed in F. 903), also completed the IIEF questionnaire. (CX1065 at 0001; CX0716 at 0029; CX0684 at 0001, 0014). This analysis was planned for in the protocol for the Davidson BART/FMD Study. (CX0716 at 0029).
1255. The Davidson BART/FMD Study was primarily a cardiovascular study and therefore its protocols did not include any of the type of inclusion or exclusion criteria one would expect to see in a basic erectile dysfunction clinical trial. (CX0716; PX0019; Melman, Tr. 1092).

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1256. The unpublished IIEF results from the Davidson BART/FMD Study were not statistically significant for the intent to treat population. (Melman, Tr. 1130-31; CX1289 (Melman Expert Report at 0017); CX1336 (Davidson, Dep. at 88-89)). The  $p$ -value was 0.7887 when comparing the intent to treat population's change in IIEF erectile function domain scores for the treatment group versus the control group. (CX0684 at 0014).
1257. The erectile dysfunction findings in the Davidson BART/FMD Study were flawed since one of the two study sites was unable to collect any data for the baseline IIEF measurement. (CX0654 at 0001 ("IIEF data not collected on most subjects at site 2; Mary Sue was aware of this and site staff reported that subjects are uncomfortable completing this questionnaire in the office (close quarters) so they tried to send it to them prior to their visit for them to bring in completed, yet it still was incomplete. Unfortunately, this baseline data will be missing.")).
1258. Neither Dr. Burnett nor Dr. Goldstein reviewed the IIEF data from the Davidson BART/FMD Study. (PX0352 (Goldstein, Dep. at 142); PX0349 (Burnett, Dep. at 170)).
1259. The IIEF results from Davidson BART/FMD study do not support the conclusion that drinking eight ounces of POM Juice daily treats, prevents, or reduces the risk of erectile dysfunction. (Melman, Tr. 1130-31; CX1289 (Melman Expert Report at 0017)).

**d. Nitric oxide studies****i. Studies sponsored by Respondents**

1260. Respondents have sponsored at least six *in vitro* and/or *in vivo* studies investigating the effects of pomegranate juice on NO levels, including:
- *Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in*

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*Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice*, by Dr. Aviram;

- *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants*, by Dr. Azadzo;
- *Effects of a Pomegranate Fruit Extract Rich in Punicalagin on Oxidation-Sensitive Genes and eNOS Activity at sites of Perturbed Shear Stress and Atherogenesis*, by Dr. de Nigris;
- *The Influence of Pomegranate Fruit Extract in Comparison to Regular Pomegranate Juice and Seed Oil on Nitric Oxide and Arterial Function in Obese Zucker Rats*, by Dr. de Nigris;
- *Beneficial Effects of Pomegranate Juice on Oxidation-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress*, by Dr. de Nigris; and
- *Pomegranate Juice Protects Nitric Oxide Against Oxidative Destruction and Enhances the Biological Actions of Nitric Oxide*, by Dr. Ignarro.

(PX0051at 0001; PX0056 at 0001; PX0057at 0001; PX005 9at 0001; PX0004 at 0001; PX0058 at 0001).

1261. Respondents' *in vitro* and *in vivo* studies are "basic science" or "pre-clinical." (PX0149 (Burnett Expert Report at 0005-06); PX0189 (Goldstein Expert Report at 0010-13) (describing the de Nigris, Aviram, Ignarro, and Azadzo studies as *in vitro* or *in vivo*); CX0982 at 0011-14 (describing the de Nigris, Aviram, Ignarro, and Azadzo studies as "pre-clinical" studies)).

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**(a) Dr. Aviram's Study**

1262. Dr. Aviram is a distinguished professor of biochemistry and researcher at the Technion Faculty of Medicine and the Rambam Medical Center in Haifa, Israel, and head of the Lipid Research Laboratory. (PX0004; CX1358 (Aviram, Dep. at 7-8)).
1263. Dr. Melman, described Technion Institute in Haifa, Israel as a "terrific" institution. (Melman, Tr. 1168).
1264. For over 30 years, Dr. Aviram's major research focused on antioxidants in general, and on its dietary role in cardiovascular disease. (CX1358 (Aviram, Dep. at 5)).
1265. Dr. Aviram has concluded, based on his medical research, that pomegranate juice had greater antioxidant potencies than red wine, which he believed at the time possessed the most potent antioxidant. (CX1358 (Aviram, Dep. at 5-6)).
1266. Dr. Aviram's Study, titled, *Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice*, reported that dietary supplementation with nutrients rich in antioxidants was associated with inhibition of atherosclerosis. (PX0189 (Goldstein Expert Report at 0012); PX0004).
1267. Dr. Aviram and his colleagues studied, in healthy male volunteers and in atherosclerotic apolipoprotein E-deficient mice, the effect of consumption of pomegranate juice on such outcomes as lipoprotein oxidation, aggregation and retention, macrophage atherogenicity, platelet aggregation and atherosclerosis. (PX0189 (Goldstein Expert Report at 0012); PX0004).
1268. Dr. Aviram and colleagues found that in humans, pomegranate juice consumption decreased low-density lipoprotein ("LDL") susceptibility to aggregation and retention and increased an high-density lipoprotein ("HDL") associated esterase that can protect against lipid

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peroxidation. (PX0189 (Goldstein Expert Report at 0012); PX0004).

1269. Similar positive anti-atherosclerosis effects were seen in the E-deficient mice. (PX0189 (Goldstein Expert Report at 0012); PX0004).
1270. Dr. Aviram and colleagues concluded that pomegranate juice had potent antiatherogenic effects in humans (and atherosclerotic mice) that may be attributable to its antioxidative properties. (PX0189 (Goldstein Expert Report at 0012); PX0004).
1271. Dr. Goldstein noted that Dr. Aviram's Study is "a very fascinating and very important piece of information." (PX0352 (Goldstein, Dep. at 127)).

**(b) Dr. Azadzoï's Study**

1272. Dr. Azadzoï is a distinguished research professor of urology and pathology at the Boston University School of Medicine and Director of Urology Research at the Veterans Affairs Boston Healthcare System. (PX0051).
1273. Dr. Azadzoï, along with Dr. Goldstein, developed an atherosclerotic animal model for erectile dysfunction. (Goldstein, Tr. 2595).
1274. Dr. Azadzoï has published extensively on studies using atherosclerotic animal models with erectile dysfunction. (Goldstein, Tr. 2595).
1275. Dr. Azadzoï's Study, titled, *Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants*, studied the antioxidant properties of various fruit juices, such as orange juice, blueberry juice, and cranberry juice, and other known antioxidant beverages such as green tea and red wine, and reported that pomegranate juice possessed the highest free radical scavenging capacity. (PX0189 (Goldstein Expert Report at 0011-12); PX0051; PX0352 (Goldstein, Dep. at 123-24); Goldstein, Tr. 2595).

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1276. Dr. Azadzoi and colleagues examined that effect of various antioxidant beverages on arteriogenic erectile dysfunction in rabbits that demonstrated decreased intracavernous blood flow, erectile dysfunction, loss of smooth muscle relaxation, decreased endothelial NO synthase, and neuronal NO synthase, diffuse cavernosal fibrosis and increased cavernous levels of the oxidative product isoprostane 8 – epi – prostaglandin F 2 alpha. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).
1277. Dr. Azadzoi and colleagues found that long term pomegranate juice intake increased intracavernosal blood flow, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. (PX0189 (Goldstein Expert Report at 0011-12); PX0051; PX0352 (Goldstein, Dep. at 123); Goldstein, Tr. 2595-97).
1278. Dr. Azadzoi and colleagues concluded that arteriogenic erectile dysfunction accumulates oxidative products in erectile tissues and that oxidative stress may be of great importance in the pathophysiology of erectile dysfunction. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).
1279. Dr. Azadzoi and colleagues found that antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction. (PX0189 (Goldstein Expert Report at 0011-12); PX0051).

**(c) Dr. de Nigris Study One**

1280. Dr. de Nigris, of the Department of General Pathology and Excellence Research Center on Cardiovascular Diseases of the 1st School of Medicine at the II University of Naples, Italy, and colleagues, including Dr. Louis Ignarro, evaluated the effects of intervention with pomegranate juice on oxidation-sensitive genes and endothelial NO synthase expression induced by high shear stress *in vitro* and *in vivo*. (PX0059). The study was titled, *Beneficial effects of pomegranate juice on oxidation-sensitive genes and endothelial nitric oxide synthase activity at sites of perturbed shear stress*, and is referred to herein as “de Nigris Study One.” (PX0059).

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1281. Cultured human coronary artery endothelial cells exposed to high shear stress *in vitro* and hypercholesterolemic mice were used in the de Nigris Study One. (PX0059).
1282. Dr. de Nigris and colleagues found that pomegranate juice concentrate reduced the activation of redox-sensitive genes and increased endothelial NO synthase expression in cultured human coronary artery endothelial cells and hypercholesterolemic mice. (PX0059; Burnett, Tr. 2290).
1283. Dr. de Nigris and colleagues also found that oral administration of pomegranate juice to hypercholesterolemic mice at various stages of disease reduced significantly the progression of atherosclerosis. (PX0059).
1284. The de Nigris Study One indicates that polyphenolic antioxidants contained in pomegranate juice can contribute to the reduction of oxidative stress and atherogenesis. (PX0059; Burnett, Tr. 2290).

**(d) Dr. de Nigris Study Two**

1285. In a study titled, *Effects of a Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis*, (referred to herein as de Negris Study Two), Dr. de Nigris and colleagues showed that atherosclerosis is enhanced in arterial segments exposed to perturbed shear stress as a result of increased expression of oxidation-sensitive responsive genes. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).
1286. The authors of the de Nigris Study Two studied the effect of pomegranate fruit extract and pomegranate juice antioxidant activity on reduction of oxidative stress and atherogenesis during disturbed shear stress flow using cultured human coronary artery endothelial cells. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).
1287. The de Nigris Study Two showed that pomegranate fruit extract and pomegranate juice reduced the activation of

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oxidation-sensitive genes and increased endothelial NO synthase expression. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).

1288. The de Nigris Study Two also showed that pomegranate fruit extract and pomegranate juice increased cyclic GMP levels. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).
1289. The de Nigris Study Two further showed that administration of pomegranate juice reduced the progression of atherosclerosis in hypercholesterolemic mice. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).
1290. The authors of the de Nigris Study Two concluded that the proatherogenic effects of perturbed shear stress can be reversed with chronic administration of pomegranate fruit extract. (PX0189 (Goldstein Expert Report at 0010-11); PX0056).
1291. The authors of the de Nigris Study Two also stated that some large clinical trials for different antioxidants have failed to show any beneficial effect in terms of preventing major cardiovascular events. (PX0056 at 0008).

**(e) Dr. Ignarro's Study**

1292. Dr. Louis Ignarro has won a Nobel prize for his discoveries concerning NO. Dr. Ignarro conducted an *in vitro* study, titled, *Pomegranate juice protects nitric oxide against oxidative destruction and enhances the biological actions of nitric oxide, to evaluate pomegranate juice's capacity to protect nitric oxide against oxidative destruction*. (PX0189 (Goldstein Expert Report at 0011); PX0058; Goldstein, Tr. 2593-95; Heber, Tr. 1995-96; Burnett, Tr. 2252-53).
1293. Dr. Ignarro has tested pomegranate juice for its capacity to protect NO against oxidative destruction and found that pomegranate juice was around 5,000 times more potent than the other antioxidants he has tested and possesses

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more antioxidant activity than grape juice, blueberry juice, red wine and ascorbic acid. (PX0189 (Goldstein Expert Report at 0011); Goldstein, Tr. 2594-95; Heber, Tr. 1967; Burnett, Tr. 2253; PX0058).

1294. Based on a series of studies that were performed on vascular endothelial cells, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of NO against oxidative destruction, thereby augmenting the biologic actions of NO. (PX0189 (Goldstein Expert Report at 0011); PX0058).
1295. Dr. Goldstein testified that the “Ignarro study is another part of the sequence of evidence that supports that a nutraceutical, specifically pomegranate juice, has incredible vascular-sparing properties that ultimately, when you follow this path leads to the improvement of erectile function in men with erectile health issues.” (PX0352 (Goldstein, Dep. at 133)).
1296. Dr. Goldstein testified also that “you have to study humans to make statements about humans.” (PX0352 (Goldstein, Dep. at 124)).
1297. Complaint Counsel’s expert, Dr. Melman, recognizes that Dr. Ignarro is highly respected and that UCLA School of Medicine, where Dr. Ignarro is a professor in molecular and medical pharmacology, has a good reputation. (Melman, Tr. 1167-68).

**ii. Expert opinions on the basic science relied upon by Respondents**

1298. Dr. Burnett, offered the following expert opinions regarding the basic science relied upon by Respondents:
- “basic scientific evidence exists that establishes that pomegranate juice possesses potent antioxidative molecular effects and these effects operate by activating endothelial NO mechanisms in vasculature [structures involved

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in human penile erection].” (PX0149 (Burnett Expert Report at 0005-06));

- basic science alone “support[s] the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health.” (PX0149 (Burnett Expert Report at 0004-05); PX0349 (Burnett, Dep. at 103, 112, 116-18 )); and
- on the basis of animal studies or *in vitro* studies, pomegranate juice has a “potential benefit . . . to likely improve one’s erection physiology.” (Burnett, Tr. 2262-63).

1299. Dr. Goldstein provided the following expert opinions regarding the basic science relied upon by Respondents:

- “pomegranate juice has excellent basic science both in animal tissue and human tissue and excellent animal model data.” (PX0352 (Goldstein, Dep. at 51-52)); and
- POM’s “strong *in vitro* and *in vivo* studies . . . suggest a probable benefit of pomegranate juice on erectile health,” and that “in and of itself it has shown huge pieces of information that will be helpful in understanding how it would work in humans . . . .” (PX0189 (Goldstein Expert Report at 0013); Goldstein, Tr. 2644).

1300. Dr. Goldstein also provided the following expert opinions:

- competent and reliable scientific evidences shows that pomegranate juice provides a benefit to erectile function. (Goldstein, Tr. 2605); and
- competent and reliable scientific evidence exists upon which clinicians who treat men with erectile health concerns would rely in

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concluding that pomegranate juice promotes erectile health. (PX0189 (Goldstein Expert Report at 0014)).

1301. Dr. Melman provided the following expert opinions regarding the basic science relied upon by Respondents:

- basic research studies about antioxidants' effects on NO levels may relate to the biochemical process for erectile function. (CX1289 (Melman Expert Report at 0017-18)); and
- basic research studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. (CX1289 (Melman Expert Report at 0017-18)).

1302. Notwithstanding Dr. Melman's opinion in F. 1301, Dr. Melman also testified that based on the results in an animal model testing gene therapy erectile dysfunction product (*see* F. 653), he was "personally satisfied" that it would also work in humans. (PX0360 (Melman, Dep. at 56-57)).

#### 4. Determinations

1303. There is no true preventative intervention for erectile dysfunction. There are a wide variety of interventions believed to have some potential benefit, anything from dietary changes to weight loss and perhaps things that are still being evaluated, although the role played is not sure. Because these interventions seem to be potentially beneficial and do not necessarily have harms, physicians feel comfortable in promoting them. (PX0349 (Burnett Dep. at 79); Burnett, Tr. 2301, 2272-73).

1304. "[T]reatment can have different meanings . . . . [T]reatment in the context of a pharmaceutical drug that is approved by the FDA as an intervention for a disease may

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have a different meaning . . . than the broad term of treatment, which is to intervene for a condition.” (Burnett, Tr. 2312).

1305. Pomegranate juice “could be a treatment [to erectile dysfunction] in the sense that it offers some potential health benefits.” (Burnett, Tr. 2312).
1306. Urologists would recommend pomegranate juice as a management tool to promote erectile health in men who are aware that their erectile function is declining but who do not yet meet the clinical definition of erectile dysfunction under the IIEF and therefore do not qualify for pharmacologic treatment. (PX0189 (Goldstein Expert Report at 0014-0015); PX0352 (Goldstein, Dep. at 42-45); Goldstein, Tr. 2609).
1307. Urologists would recommend pomegranate juice as a complement to conventional erectile dysfunction treatment. (Burnett, Tr. 2298, 2313; PX0349 (Burnett, Dep. at 78-79)) (“To the extent that any intervention out there has some potential benefit of a better benefit than harm that meets some level of safety, I would support that intervention, at least as a complimentary intervention and not a mainstay of ED treatment.”) (PX0352 (Goldstein, Dep. at 80) (there are patients in whom there are erectile dysfunction and/or erectile health problems related to inflammatory endothelial dysfunctions, and . . . pomegranate juice has a logical context in the treatment of those patients.”).
1308. Dr. Goldstein “would strongly suggest and encourage” use of pomegranate juice to treat erectile dysfunction in a subpopulation of men who have had an insufficient response to PDE5 inhibitors (like Viagra, Levitra and Cialis) and who wish to reestablish erectile function without invasive or mechanical technology or therapies. (PX0352 (Goldstein, Dep. at 37-42, 46)). Dr. Goldstein opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs designed to treat erectile dysfunction and who are unwilling to consider invasive or mechanical

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therapies for treatment of their erectile dysfunction. (PX0189 (Goldstein Expert Report at 0005); PX0352 (Goldstein, Dep. at 37-42); Goldstein, Tr. 2605, 2641).

1309. Pomegranate juice costs far less than Viagra and there are no side effects to drinking pomegranate juice. (PX0352 (Goldstein, Dep. at 44)).

### 5. Conclusions

1310. The available body of scientific literature – including *in vitro*, *in vivo*, and preliminary clinical trials – suggests that consuming pomegranate juice promotes erectile health. (PX0189 (Goldstein Expert Report at 0003)).
1311. The use of pomegranate juice to promote erectile *health* is a separate and distinct concept from the use of this nutraceutical as a safe and effective treatment for the medical condition of erectile *dysfunction* such as with a PDE5 inhibitor. (PX0189 (Goldstein Expert Report at 0004) (emphasis in original)).
1312. Competent and reliable scientific evidence shows that pomegranate juice provides a benefit to promoting erectile health and erectile function. (Goldstein, Tr. 2605, 2608; PX0189 (Goldstein Expert Report at 0014); PX0149 (Burnett Expert Report at 0006); Burnett, Tr. 2255-56).
1313. There is insufficient competent and reliable scientific evidence to show that pomegranate juice prevents or reduces the risk of erectile dysfunction or has been clinically proven to do so. (Burnett, Tr. 2274, 2300-01; CX1289 (Melman Expert Report at 0018)).
1314. There is insufficient competent and reliable scientific evidence to show that pomegranate juice treats erectile dysfunction in a clinical sense or has been clinically proven to do so. (Burnett Tr. 2285, 2300; Goldstein, Tr. 2611; CX1289 (Melman Expert Report at 0018)). *See also* Burnett, Tr. 2261-64).

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**J. Materiality****1. Overview**

1315. Mrs. Resnick believes that part of the intrinsic value of pomegranate juice is that it has been shown to reduce arterial plaque and factors leading to atherosclerosis and was shown to have a “powerful effect against prostate cancer.” (L. Resnick, Tr. 75-76).
1316. Mr. Resnick testified that POM communicates to consumers the “[company’s] belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product.” (CX1372 (S. Resnick, Tropicana Dep. at 45)).
1317. Mr. Resnick acknowledged that the kinds of benefits revealed by POM’s research results are the primary reason people buy pomegranate juice. (CX1372 (S. Resnick, Tropicana Dep. at 31)). Mr. Resnick also acknowledged that consumers buy pomegranate juice “because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death.” (CX1376 (S. Resnick, Ocean Spray Dep. at 217)).
1318. Mr. Resnick expressed his belief that a great deal of consumers are buying POM Juice because they believe “that we’ve proven that . . . [POM Juice] really does prolong people’s lives if they are getting the onset of prostate cancer.” (CX1376 (S. Resnick, Ocean Spray Dep. at 218-19)).
1319. According to a draft creative brief for POMx dated October 12, 2006, the concept behind communicating the amount of money the company spent on research is: “We don’t just say our product is great, we have clinical studies that prove its efficacy.” (CX0409 at 0057).
1320. POM was aware that among those purchasing the POM products were “people that have heart disease or prostate cancer in their family, or have a fear of having it

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themselves.” (CX1368 at 17 (L. Resnick, Welch Dep. at 67)).

1321. According to a September 2006 press article, Ms. Posell, POM’s then vice president of corporate communications, said “every time new research is released touting” a health benefit of pomegranate juice, “there is a spike in sales. The study . . . linking the consumption of pomegranate juice to a reduction in prostate cancer was especially helpful, she said. . . Pom Wonderful can see the results in increased sales every time a new study surfaces.” (CX0433 at 0004).
1322. According to a July 2004 e-mail from John Regal, POM’s head of marketing at the time, with the subject line “POM Medical research timing and advertising”, POM’s goal for its 2-page *Prevention* “advertorial” (CX0029, F. 297-305, *supra*) was to convey “how POM is particularly good for clean & healthy arteries. We also wanted to highlight the new Aviram study regarding plaque reduction in humans.” (Leow, Tr. 437; CX0667 at 0001).
1323. In evaluating how copy dense or medically oriented to make a planned POMx Pill advertisement, Ms. Kuyoomjian, Senior Vice President of Marketing for POM from 2008 to 2009, reminded Mrs. Resnick in a January 2009 e-mail: “you’ll recall that a previous ad test with less copy did not generate as many orders. That would suggest we keep the research info in the new ad, which would make it information dense as well.” (CX1357 (Kuyoomjian Dep. at 22); CX0266 at 0002).
1324. Mr. Perdigao, the head of Fire Station, Roll’s in-house advertising agency used by POM (F. 134, 138), noted in an e-mail dated June 11, 2009, that the “consumer benefit” of proposed advertisements that did not reference prostate health or heart health was less compelling than more general references to POM being good for you because it offers antioxidants that reduce free radicals. As Mr. Perdigao explained, less specific advertising is generally less provocative. (CX0320 at 0002; L. Resnick, Tr. 90; *see also* Perdigao, Tr. 670-73).

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1325. A creative brief (*see* F. 145-151) for the POM Wonderful website, from June 2008, stated the objective for the assignment was to “tell the story (health benefits, research & how POM fits).” For the “Health Benefits” section of the POM Wonderful website, the creative brief further stated that, to engage viewers, the page should identify “What are the health benefits?”, including “heart health,” “prostate health,” and “E.D.”; “How does it work?”, including antioxidant and anti-inflammatory properties, the “commitment” to research; “What the experts say,” on such matters as heart and prostate, and a “comprehensive research database,” searchable by subject matter, including heart and prostate, and by results. The directed tone and manner included “authoritative.” (CX0200 at 0001-02).
1326. Ms. Leow, a creative director for Roll, stated that scientific information in advertising and marketing material helps sell the products, because the scientific information provided the consumer with a “reason to believe.” (Leow, Tr. 512-13; CX0095).
1327. A creative brief for POMx Pills, dated September 1, 2006, included the sentence in an opening narrative paragraph, as a bullet point: “main creative focus is prostate cancer.” (CX0409 at 0023).
1328. A creative brief for POMx Pills, dated September 5, 2006, stated under “benefit,” in bold type, “Main creative focus for 1<sup>st</sup> round is prostate cancer. (The benefits are from the studies – which showed a decrease in the doubling time of PSA levels).” The “benefit” section continued: “The other versions of the creative [brief] should definitely focus on the other benefits of POM – antioxidant, anti-aging, heart health, etc.” (CX0409 at 028).
1329. Respondents’ marketing expert, Dr. David Reibstein, stated that it was indeed possible, and he would expect that, consumers in POM’s target audience who were concerned about heart disease would find a claim that drinking a bottle of POM Juice a day prevents or treats heart disease to be important, that those concerned about prostate cancer would find a prostate cancer prevention or

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treatment claim important, and that those concerned about erectile dysfunction would find an erectile dysfunction prevention or treatment claim important. (PX0356 (Reibstein, Dep. at 117-19)).

**2. OTX A&U Study and Zoomerang survey**

1330. In the ordinary course of business, POM conducted consumer research to understand the characteristics, attitudes and usage habits of their customers and to identify barriers and opportunities for increasing consumption, particularly *vis-à-vis* other brands of pomegranate juice. (CX0370 at 0002; CX0292; CX0136; CX0453 at 0004).
1331. In June 2009, OTX, a consumer research firm, conducted an Attitudes and Usage consumer survey (“OTX A&U Study”) on POM’s behalf. (CX0370 at 0002, 0004; PX0227). The A&U Study’s sample included current and former POM Juice drinkers, other pomegranate juice drinkers and users of other antioxidant fruit juices. (CX0370 at 0003).
1332. In the OTX A&U Study, among other things, current pomegranate juice users, including users of POM Juice, were asked why they drink pomegranate juice, and were given a list of options, including: “It’s healthy/good for my health,” “I like the taste,” “I like pomegranates,” “it’s all natural,” or “Other (specify)”, and were directed to select all that applied. (PX0227 at 0006). Among the POM Juice drinkers, 85% said they drank pomegranate juice because “it’s healthy good for my health,” 75% said “I like the taste,” 59% said “I like pomegranates,” 50% said “it’s all natural,” 29% said “it’s new/interesting food trend,” and 4% said “other.” (CX0370 at 0011).
1333. Those in the OTX A&U Study that responded, “It’s healthy/good for my health,” were asked a follow-up question, “Which specific health reasons below describe why you personally drink pomegranate juice?” and were presented with a list of reasons, depending on whether

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they were male or female. (CX0370 at 0012; PX0227 at 0006; Reibstein, Tr. 2558-59; Mazis, Tr. 2682-84).

1334. The choices given to the survey respondents identified in F. 1333 were: helps promote heart health; helps protect against prostate cancer [for males only]; helps protect against other cancers (besides prostate); contains naturally occurring antioxidants; will help me live longer; helps improve thinking and memory; good for bone and joint health; helps protect against urinary tract infections; provides immunity from colds and flu; promotes healthy pregnancy [for females only]; promotes menstrual health [for females only] and “[o]ther (specify).” (PX0227 at 0006).
1335. Among the POM Juice drinkers responding to the question in F. 1334, 91% said “contains naturally occurring antioxidants,” 57% said “helps promote heart health,” 47% of men said “helps protect against prostate cancer,” 45% said “provides immunity from colds and flu,” 43% said “helps protect against other cancers (besides prostate); 38% said “helps protect against urinary tract infections,” 28% said “will help me live longer,” 28% said “good for bone and joint health,” 25% said “helps improve thinking and memory,” 14% said “promotes menopausal/post-menopausal health,” 6% said “promotes healthy pregnancy,” and 2% said “other.” The percentages attributed for the different responses attributable to non-POM Juice and other antioxidant beverage drinkers were slightly less. (CX0370 at 0012).
1336. POM’s Senior Vice President of Marketing, Ms. Kuyoomjian, was not surprised by the OTX A&U Study result that, for 47% of male POM users, part of the reason they drink POM Juice is because they believe it helps protect against prostate cancer. (CX1357 (Kuyoomjian, Dep. at 259-60)).
1337. Dr. Reibstein reviewed the OTX A&U Study and concluded that although it presented some information contradictory to the conclusions he drew from his own survey (*see* F. 1344-1372), the OTX A&U Study had

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methodological flaws, cannot be relied upon, and does not invalidate the results of Dr. Reibstein's survey. (PX0223 (Reibstein Expert Report at 0021)).

1338. In rebuttal to the opinion of Respondents' expert Dr. Reibstein, that the OTX A&U Study was not reliable or relevant (F. 1337), Complaint Counsel's expert, Dr. Mazis, reviewed the OTX A&U Study and expressed his opinion that the OTX A&U Study was highly relevant and demonstrated that the heart disease and prostate cancer claims are important to consumers, and are reasons that POM Juice users choose to purchase POM Juice. (Mazis, Tr. 2688-89, 2760; CX1297 (Mazis Expert Report at 0012-13)).
1339. Dr. Mazis testified that, with respect to the likely importance that the challenged claims would have on consumers' purchase or use decisions, he finds the OTX A&U Study more reliable than the Reibstein Survey (*see* F. 1344-1372; Mazis, Tr. 2689).
1340. In Dr. Reibstein's opinion, the OTX A&U Study used closed-ended questions, in that it provided respondents with a list of five choices as to why they drink pomegranate juice, and that this method "cues" the survey respondent to certain answers, excludes other potential answers that were not included on the list of choices, and inflates results. (PX0227 at 0006; Reibstein, Tr. at 2518-20).
1341. Dr. Mazis opined that, when studying purchase motivations, the use of closed-ended questions have an advantage because it allows the researcher to get some specificity, and, therefore, closed-ended questions tend to be used in most of these types of studies. Although closed-ended questions have a disadvantage in that they may lead to some upward bias, in a study like the OTX A&U Study, one accounts for this by giving a long list of choices, as was done in the OTX A&U Study, and examining the relative ranking of responses. (Mazis Tr. 2662-63).

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1342. In August 2007, Respondents commissioned a Zoomerang online survey of the general public, “to better understand pomegranate and non-pomegranate juice consumers,” with respect to, among other things, “importance of certain health benefits.” The survey included 287 heavy pomegranate juice drinkers. Six health benefits were listed and these respondents were asked to rank which health benefit was the most important to them personally. For heavy pomegranate juice drinkers, the number one response, for both males and females was “cardiovascular,” and the number two choice for men was “prostate.” (*See* CX0292 at 0025; CX0136 at 0001, 0003, 0006).
1343. For members of the general public responding to the Zoomerang survey question regarding ranking of health benefits (F. 1342), 60% ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefit, and approximately 18% of males did so for erectile dysfunction. (CX0136 at 0002, 07-08; CX0453 at 0004).

**3. Reibstein Survey**

1344. The Reibstein Survey was conducted on behalf of POM Wonderful in connection with this litigation, by an independent market research company, Horizon Consumer Science (“HCS”) under the direction of Dr. David J. Reibstein. (PX0223 (Reibstein Expert Report at 0001, 0003); F. 266-275).
1345. HCS maintains an online panel of over one million subjects. From this population, a stratified sample of 2,164 was drawn from the United States population. (PX0223 (Reibstein Expert Report at 0004)).
1346. The Reibstein Survey sought to reveal (i) a buyer’s motivation for purchasing pomegranate juice; (ii) whether having previously seen POM Juice advertisements in the normal sequence of viewing advertisements and not in an artificial setting, the advertisements affected the buyer’s

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motivations for buying pomegranate juice; and (iii) whether the buyer's awareness of the legal issues around the case might have affected their motivation for buying pomegranate juice. (PX0223 (Reibstein Expert Report at 0005); Reibstein, Tr. 2487; PX0356 (Reibstein Dep. at 11, 38-39, 51)).

1347. The Reibstein Survey was conducted in October 2010. (Reibstein, Tr. 2541).
1348. Dr. Reibstein's Survey did not address POMx or the purchase motivations of POMx purchasers, and Dr. Reibstein did not undertake to extrapolate the results of his survey to POMx purchasers. (Reibstein, Tr. 2565-66).
1349. To qualify for the Reibstein Survey, respondents had to meet the following criteria: (i) purchased pomegranate juice in the six months prior to the survey; (ii) had not completed any online survey within the 3 months prior to the survey for any beverage products; (iii) did not work in any of the following industries: advertising, public relations, beverages, marketing or market research; and (iv) was over 18 years old. This was accomplished through a series of screening questions. (PX0223 (Reibstein Expert Report at 0004); PX0237 at 0001-02; PX0356 (Reibstein, Dep. at 50-51, 57-58)).
1350. Of the 2,164 panelists that completed the online Reibstein Survey, 750 of them met the qualification criteria, and actually completed the survey. (PX0223 (Reibstein Expert Report at 0004)).
1351. The Reibstein Survey surveyed two groups, 406 respondents who purchased POM Juice in the past six months ("POM Juice consumers") and 344 respondents who purchased brands of pomegranate juice other than POM in the past six months. (PX0223 (Reibstein Expert Report at 0004); Reibstein, Tr. 2493-94).
1352. The Reibstein Survey employed two types of controls. The first control was to draw a sample of non-POM Juice buyers and ask them the same questions as the POM Juice

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buyers to see if these buyers had different motivations for purchasing pomegranate juice. The second control was to compare the responses of people who had seen POM advertisements against those who had not seen any POM advertisements. (PX0223 (Reibstein Expert Report at 0004-05); Reibstein, Tr. 2488-89, 2493; PX0356 (Reibstein, Dep. at 73-74)).

1353. For the sample of 406 POM Juice consumers, the Reibstein Survey asked three primary open-ended questions in Questions E through G, set forth below in F. 1354-1356. (PX0223 (Reibstein Expert Report at 0005)).
1354. Question E asked “Why did you purchase POM Wonderful 100% Pomegranate Juice? *Please include as many specific details.*” (PX0237 at 0002 (italics in original); PX0223 (Reibstein Expert Report at 0006)).
1355. Question F asked “Would you consider purchasing POM Wonderful 100% Pomegranate Juice again?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would?*
2. No a. Why not? *Please include as many specific details as to why you would not?* 3. Don't know.”

(PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0007)).

1356. Question G asked “Would you recommend POM Wonderful 100% Pomegranate Juice to a friend?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would?*
2. No a. Why not? *Please include as many specific details as to why you would not?*

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3. Don't know.”

(PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0008)).

1357. For the 344 non-POM Juice pomegranate juice consumers, the Reibstein Survey asked three primary open-ended questions in Questions H through J, set forth below in F. 1358-1360. (PX0223 (Reibstein Expert Report at 0005)).

1358. Question H asked “You indicated that you have purchased pomegranate juice. *Please include as many specific details as to why you purchased it. Please be as detailed as possible.*” (PX0237 at 0002 (emphases in original); PX0223 (Reibstein Expert Report at 0006)).

1359. Question I asked “Would you consider purchasing pomegranate juice again?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would again?*

2. No. a. Why not? *Please include as many specific details as to why you would not again?*

3. Don't know.”

(PX0237 at 0003 (emphases in original)).

1360. Question J asked “Would you recommend pomegranate juice to a friend?

(SELECT ONE ONLY)

1. Yes a. Why? *Please include as many specific details as to why you would?*

2. No. a. Why not? *Please include as many specific details as to why you would not?*

3. Don't know.”

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(PX0237 at 0003 (emphases in original)).

1361. A summary of the results of the responses to Questions E-J was set forth by Dr. Reibstein in Figure 5 in his expert report. Figure 5 is set forth below:

Question	Percentage of POM Wonderful Juice Buyers whose response mentions a specific disease reference n=406	Percentage of Pomegranate Juice Buyers whose response mentions a specific disease reference n=344
E/H (Why did you purchase?)	1.0% (4/406)	.9% (3/344)
F/I (Why would you purchase/not purchase again?)	.5% (2/406)	0% (0/344)
G/J (Why would/would not recommend?)	.3% (1/406)	.9% (3/344)
<b>NET</b>	<b>1.48% (6/406)</b>	<b>1.74% (6/344)</b>

(PX0223 (Reibstien Expert Report at 0020)).

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1362. The “specific disease” references, as reported by respondents to the Reibstein Survey (F. 1361) included: heart disease, getting rid of plaque, cancer, urinary tract infections, bowel movements, diabetes, kidney stones, and arthritis pain. (PX0223 (Reibstein Expert Report at 0011-12)).
1363. The above findings (F. 1361-1362) reflect 12 unique survey respondents, because one participant responded to both Question E and Question F with a disease reference. This respondent is counted only once in the “net” results. (PX0223 (Reibstein Expert Report at 0011, 0020 n.1-6)).
1364. Questions E through J of the Reibstein Survey were in open-ended format, to reduce any biasing of the survey respondents. (PX0223 (Reibstein Expert Report at 0005); PX0356 (Reibstein Dep. at 84-85)).
1365. In response to questions E and H of the Reibstein Survey, respectively, 35.2% of POM Juice purchasers stated that they purchased or would repurchase POM Juice because it was “healthy” and 46.8% stated that they would recommend it to a friend because it was “healthy.” In addition, 43.6% of POM Juice purchasers stated they purchased because of the taste, and 74% stated they would repurchase because of the taste. (PX0223 (Reibstein Expert Report at 0006-07)).
1366. Question K asked respondents: “Have you ever seen a POM Wonderful 100% Pomegranate Juice advertisement?”

(SELECT ONE ONLY)

1. Yes a. Please include as many specific details as to what you remember about the ad. *Please be as detailed as possible.*
2. No
3. Don’t know.”

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(PX0237 at 0003 (emphases in original); PX0223 (Reibstein Expert Report at 0016); Reibstein, Tr. 2507, 2567).

1367. In response to Question K of the Reibstein Survey, 39.6% of people (297 out of 750) who consumed pomegranate juice in the prior six months had seen a POM advertisement. (PX0223 (Reibstein Expert Report at 0009, 0016); PX0233 at 0028; Reibstein, Tr. 2536).
1368. In response to Question K of the Reibstein Survey, while 20% of the respondents reported “healthy,” none of the respondents who saw a POM advertisement responded that they remember the advertisement making a specific disease claim. Other common details reported by POM Juice purchasers were bottle appearance (22.4%); people or objects in the advertisement (20.6%); and “don’t know/no response” (20%). (PX0223 (Reibstein Expert Report at 0009); PX0233 at 0029).
1369. In the Reibstein Survey, among the 12 unique respondents out of 750 total respondents, including non-POM Juice buyers, who mentioned a specific disease as a reason for purchasing or recommending pomegranate juice, 4 reported having seen a POM advertisement at some point and 8 reported not ever having seen an advertisement. (PX0223 (Reibstein Expert Report 0009, 0016-19)).
1370. Based on the Reibstein Survey findings, Dr. Reibstein, expressed the opinion that POM advertisements had no impact on buyers’ purchase motivations. (PX0223 (Reibstein Expert Report at 0020)).
1371. Dr. Reibstein did not expose consumers to the Challenged Advertisements. (Reibstein, Tr. 2494).
1372. Based on the Reibstein Survey results, Dr. Reibstein, expressed the opinion that there is a very small percentage of people that bought, would buy again, or would recommend POM Juice to a friend because they believe that it cures or prevents a specific disease. (PX0223 (Reibstein Expert Report at 0020)).

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1373. In rebutting the opinions of Dr. Reibstein, Dr. Mazis opined that the Reibstein Survey did not employ a valid measure of materiality of the challenged claims in this case because the survey was a general assessment of consumer motivations but did not assess whether any one of the challenged claims in the complaint would be important in the decision to purchase or to use POM Juice. According to Dr. Mazis, what a consumer might identify as a motivation for purchasing a product is not the same thing as assessing whether, if a consumer knew of a claim, that claim would be important in his or her decision to purchase the product. (CX1297 (Mazis Expert Report at 0008); Mazis, Tr. 2673).
1374. According to Dr. Mazis, in order to do a survey on materiality, “you don’t have to show them the ad, but you have to give them a statement about what the claim was and you have to ask them how important they think that claim would be in their potential purchase decision.” (Mazis, Tr. 2728).
1375. Dr. Mazis further opined that Dr. Reibstein’s methodology was flawed because he asked only open-ended questions but did not follow-up with questions probing further what the respondents meant when referring to POM Juice being “healthy” or having “health benefits” as their motivation for purchasing. According to Dr. Mazis, the Reibstein Survey should have explored what survey respondents meant by their “healthy” response and whether there were specific reasons or benefits that underlay “healthy” responses. (Mazis, Tr. 2756-57, 2707-09; PX0296 (Mazis Expert Report at 0009-10)).
1376. Dr. Mazis agreed that open-ended questions make it “significantly less likely that the respondents will be led into giving a particular answer.” (Mazis, Tr. 2732).
1377. Dr. Mazis expressed the opinion that “the impact of advertising on beliefs about a product is not an appropriate measure of materiality or ad claim communication.” (CX1297 (Mazis Expert Report at 0009)).

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**K. Remedy****1. Roll Global and POM entities**

1378. Roll Global (“Roll”) is an approximately \$2 billion corporation that includes under its umbrella the companies Teleflora, Fiji Water, Paramount Farms (which sells Wonderful Pistachios and Wonderful Almonds), Paramount Citrus (which sells Cuties), Justin Vineyards and Winery, and Suterra. (JX0003 ¶ B.3; S. Resnick, Tr. 1629-30; Perdigao, Tr. 593-94).
1379. POM manufactures, advertises, and sells other products containing pomegranate, including various POM Juice blends, Lite POM Juice, POMx bars, POMx iced tea and iced coffee, and a POMx sports recovery beverage. (JX0003 ¶ B.8).
1380. POM is headquartered in the same building as Roll, in many cases with employees of both companies occupying the same floor. For example, Mr. Perdigao, the president of Roll’s in-house advertising agency, Fire Station and Roll’s Corporate Communications department (F. 134, 138), and Ms. Leow, Fire Station’s Creative Director, are located on the same floor as the offices of Mrs. Resnick, Mr. Resnick, and Mr. Tupper, among other POM employees. (Tupper, Tr. 888; Leow, Tr. 418; PX0277 at 0002-03).
1381. Mrs. Resnick describes Roll as “the umbrella company for all of our businesses” and others that work for Respondents describe Roll similarly and consider POM to be part of Roll. (CX0001 at 00011; Posell, Tr. 298, 305; Tupper, Tr. 894; Perdigao, Tr. 593).
1382. Mr. and Mrs. Resnick each maintain a business address at 11444 West Olympic Blvd., 10th Floor, Los Angeles, CA 90064, which is also the business address for POM and Roll. (PX0277 at 0002-03; *see also* PX0276 at 0002).

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1383. Mrs. Resnick does not have a specific corporate title at POM. (L. Resnick, Tr. 287-88; CX1359 (L. Resnick, Dep. at 37)).
1384. Although Roll's affiliated companies' pay Roll for certain provided services, including advertising (F. 13-14), not all expenses, such as advertising and marketing services, provided to POM were reimbursed. Roll has provided various services over the years to POM relating to POM Juice, POMx Pills, and POMx Liquid "with some portion charged back to POM . . . ." (CX1383 at 0014; CX1357 (Kuyoomjian, Dep. at 235)). For example, the former Vice President of Corporate Communications at Roll testified she was not required to keep track of her time based on whether she was working on a POM project or a project for another Roll company. (Posell, Tr. 325). In addition, Roll provides risk management, human resources, consulting, and travel services to POM without any reimbursement. (CX1354 (Bryant, Dep. at 41-42, 48-50, 55-64)).
1385. When Fire Station acts as Roll's in-house advertising agency, Fire Station bills POM and other Roll entities separately, and each client pays for advertising and marketing expenses incurred. (CX1376 (S. Resnick, Ocean Spray Dep. at 24-25); L. Resnick, Tr. 88-89; CX1359 (L. Resnick, Dep. at 26); Perdigao Tr. 616-17).
1386. The Resnicks have had ultimate say over all business functions of Roll and POM. They have set policy and supervised the senior executives of both companies, disregarding corporate formalities. For example, Mrs. Resnick has had complete oversight over POM's business, despite lacking any formal position with the company. (CX1368 at 0002-03 (L. Resnick, Welch Dep. at 8-9); CX1362 at 0012 (L. Resnick, Coke Dep. at 45-46); CX1374 (Tupper, Ocean Spray Dep. at 18-19); S. Resnick, Tr. 1631 (stating that Mrs. Resnick is very involved in setting POM's marketing and advertising budget); L. Resnick, Tr. 184 (stating that she has interviewed candidates for the chief marketing officer or other senior vice president positions at POM); JX0001 ¶ 18 (showing

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overlapping officers between POM and Roll); Posell, Tr. 321, 325 (stating that while Vice President of Corporate Communications, Ms. Posell reported to Mr. Tupper and Mrs. Resnick)).

1387. For accounting purposes, Roll and its affiliated companies, including POM, were represented as being under common control or ownership and have been included together on consolidated financial and tax statements. (CX1354 (Bryant, Dep. at 23, 27, 52-53), *in camera*; *see also* CX1355 (Hemmati, Dep. at 52-54) (stating that Roll provided information about the Resnick Trust's payments for medical research to POM); CX1276 at 0003).
1388. POM's Consumer Affairs representative would typically respond to consumer complaints; however, "if necessary, [they] might get escalated" to others at POM or Roll, such as Roll's Corporate Communications, which may respond directly to the consumer. (CX1357 (Kuyoomjian, Dep. at 204-10))
1389. Roll also interacts with POM for the purposes of joint cash management, as noted by Roll's Chief Financial Officer, Robert Bryant, who stated that Roll "pool[s] together the cash from each one of [its] operating companies and will invest that cash . . . overnight for purposes of investments . . . [o]r if [Roll has] debt outstanding on [its] working capital lines, then [Roll] will use that cash to pay down those working capital . . . lines." (CX1354 (Bryant, Dep. at 67)).
1390. POM's medical research program was sponsored and funded by various Resnick entities (*e.g.*, Roll, POM, and the Resnick Trust). (CX1118 at 0001; CX0604 at 0022 (stating that "Roll Int'l will reimburse Technion [Institute] directly," even though POM was listed as the research sponsor); CX0628 at 0001 (describing a study on pomegranate juice as the "Roll Beverage Study"); *see also* F. 1391).

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**2. The Resnicks**

1391. The Stewart and Lynda Resnick Revocable Trust entered into contracts to fund research; however, regardless of which Resnick-controlled organization has paid for pomegranate research, the money ultimately comes from the Resnicks. (CX0610; S. Resnick, Tr. 1657, 1675-76, 1722-23; CX1363 at 0016 (S. Resnick, Coke Dep. at 61) (whether a study is sponsored by Roll or POM, “[t]he money comes out of the same pockets”); *see also* CX1376 (S. Resnick, Ocean Spray Dep. at 229-30 (the \$34 million referenced in a POM advertisement is ultimately “our money, however it comes”)); L. Resnick, Tr. 198-99).
1392. Mr. Resnick has been directly involved in the development of POM’s scientific research program by engaging and communicating with scientific consultants, participating in scientific advisory board meetings, and convening company-sponsored research summits. (CX1360 (S. Resnick, Dep. at 85, 110-12); Tupper, Tr. 1027-28; Liker, Tr. 1880, 1889, 1891; CX0589).
1393. With regard to the medical research budget, Mr. Resnick reviews and approves the POM research budget annually, and when necessary if any changes occur during the year. (CX1376 (S. Resnick, Ocean Spray Dep. at 227)).
1394. Mr. Resnick reviews the results of the scientific research he sponsors, and has seen the results of all the important tests and also some of the draft manuscripts before they were published. (S. Resnick, Tr. 1656-57).
1395. Mr. Resnick meets with POM and its scientific advisors about POM-sponsored research ten to twelve times a year “officially” and three to four additional times to review what has been learned and where the company’s research may go. (CX1376 (S. Resnick, Ocean Spray Dep. at 223-24)).
1396. Mrs. Resnick participated in POM’s business on almost a daily basis in the company’s early years, and on a weekly or biweekly basis thereafter and through 2010. (L.

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Resnick, Tr. 93, 157-58; *see also* CX1375 (L. Resnick, Tropicana Dep. at 19-22, 78); CX1359 (L. Resnick, Dep. at 108)).

1397. If there were disputes or issues to resolve regarding advertising decisions, the final authority was either Mr. or Mrs. Resnick. As the overseer of all branding and marketing, Mrs. Resnick had the “final word” on advertising content and concepts. (CX1365 (Perdigao, Coke Dep. at 36-37)); CX1368 at 0003 (L. Resnick, Welch’s Dep. at 9); L. Resnick, Tr. 93; CX1347 (Glovsky, Dep. at 36); CX1357 (Kuyoomjian, Dep. at 84)).
1398. Mrs. Resnick has participated in the hiring and firing of heads of marketing at POM. (L. Resnick, Tr. 183-84, 227-28).
1399. Mrs. Resnick has had a principal role in approving advertising content since POM’s inception. For example, Mrs. Resnick requested that copies of all advertising campaigns be submitted to her for final approval including the headlines used in POM’s advertisements. (CX1368 at 0003 (L. Resnick, Welch Dep. at 9); *see also* CX1357 (Kuyoomjian, Dep. at 56-57, 77, 127); CX1346 (Rushton, Dep. at 42 (approval of website designs)); CX0147).
1400. At LRR Meetings (F. 141) and during other interactions with POM Marketing and Fire Station, Mrs. Resnick would approve a general direction for POM’s advertising and also approved the lion’s share of POM’s advertising concepts. (*see* F. 143).
1401. Mrs. Resnick was “very involved” in developing the POMx brochure, identified as CX1426, Exhibit I “Antioxidant Superpill” package insert, when it was first produced. (L. Resnick, Tr. 246; *see* F. 328-342).
1402. Mrs. Resnick was involved in the approval of the print advertisement identified as CX0029 (“10 OUT OF 10 PEOPLE DON’T WANT TO DIE”) (CX0471 at 0007-08; L. Resnick, Tr. 158; CX0029; *see* F. 299-305).

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1403. Mrs. Resnick approved the headline for the POMx print advertisement headlined “The Only Antioxidant Supplement Rated X.” (L. Resnick, Tr. 266; *see* CX0351 and CX0355; *see* F. 321-327)).
1404. Mrs. Resnick approved the print advertisement identified as CX0031 (“Floss your arteries” print advertisement); CX0471 at 0010; L. Resnick, Tr. 158-59; CX0031; *see* F. 440-448).

**3. Matthew Tupper**

1405. Mr. Tupper has never had any ownership interest in POM Wonderful and has no expectation of ever having such an interest. (CX1353 (Tupper, Dep. at 14-15); Tupper, Tr. 2973).
1406. Mr. Tupper had no more authority at POM than was delegated to him by Mr. Resnick. Mr. Resnick delegated to Mr. Tupper the authority to decide which advertisements should run. (S. Resnick, Tr. 1870).
1407. When Mrs. Resnick reduced her day-to-day involvement in POM’s business beginning in 2007, Mrs. Resnick felt confident that Mr. Tupper would be able to take care of the marketing aspects of the business, as she had previously done. (L. Resnick, Tr. 229).
1408. Mr. Tupper reviewed work on each of POM’s large advertising campaigns at the concept stage, before they were shown to Mrs. Resnick. (Leow, Tr. 459-60).
1409. With respect to health benefit advertising, Mr. Tupper was the “connecting piece” or “liaison” between the marketing vision and the communication of the science. (Tupper, Tr. 2975-76).
1410. Mr. Tupper led meetings to review advertising copy from a scientific perspective prior to its dissemination. (Dreher, Tr. 530).

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1411. Mr. Tupper was engaged in the medical research aspect of POM's business from the time he first joined POM full-time in 2003. Beginning in late 2006 or early in 2007, he became more engaged as the "connecting piece" between research and marketing. (Tupper, Tr. 2975-77; *see* F. 1409).
1412. As POM's president, Mr. Tupper attended most of the marketing review meetings with Mrs. Resnick, which included discussions of POM's scientific research. (Tupper, Tr. 929-30; CX1351 (McLaws, Dep. at 33-34); CX1347 (Glovsky, Dep. at 149-50)).
1413. Mr. Tupper was significantly involved in the research aspects of POM's business, the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. (Tupper, Tr. 895-96, 906; *see also* CX0770; CX0779; CX0800; CX0919; CX0920).
1414. POM's former Senior Vice President of Marketing, Ms. Diane Kuyoomjian, relied on her conversations with Mr. Tupper to understand the content in POM's advertising regarding the relationship between POM advertisements and the scientific support for these advertisements. She relied on Mr. Tupper to be the "arbiter" of whether people felt POM's advertising was accurate. (CX1378 (Kuyoomjian, Ocean Spray Dep. at 71-72)).
1415. Ms. Kuyoomjian, "would never do something [Mr. Tupper] wasn't involved in. He was [her] boss." (CX1357 (Kuyoomjian, Dep. at 51)).
1416. As one of the senior leaders at POM, Mr. Tupper organized meetings to review advertising copy from a scientific perspective. (Dreher, Tr. 530).
1417. Mr. Tupper reviewed and gave direction to POM's marketing staff on parts or elements of creative briefs. (Tupper, Tr. 924).

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1418. According to POM's former Senior Vice President of Marketing, Ms. Kuyoomjian, Mr. Tupper was the primary person from whom she received information on POM's medical research, including information that would appear in consumer advertising copy, and Mr. Tupper in general would provide input as to how to describe the medical research used in advertisement copy. (CX1357 (Kuyoomjian, Dep. at 164-66); *see also* CX0906 at 0001-02 (providing guidance on what types of studies should be used in newsletters and websites)).
1419. Mr. Tupper participated in meetings in which Fire Station and POM personnel presented and reviewed advertising concepts and advertising. (L. Resnick, Tr. 91-92; Tupper, Tr. 929).
1420. Mr. Tupper reviewed advertising copy (including headlines), made changes to copy, and, depending on the project, had final say over POM advertising content and which advertisements should or should not run. (L. Resnick, Tr. 87; Leow, Tr. 423-24, 464-66; Tupper, Tr. 925-27; S. Resnick, Tr. 1870; CX1357 (Kuyoomjian, Dep. at 141-42)).
1421. Sometimes, Mr. Tupper would provide the specific words to use when presenting medical research facts, and in other instances, POM Marketing or Fire Station employees would "take a stab at writing [this information] and send it to [Mr. Tupper] to approve." (CX1357 (Kuyoomjian, Dep. at 169-70)).
1422. On average, Mr. Tupper has interacted with Mr. Perdigao, head of Fire Station creative agency, once a week. (Perdigao, Tr. 613).
1423. During periods when the position of head of marketing at POM was vacant, Mr. Tupper would step in to some extent, and if the subject matter required a high level person, Mr. Tupper would take the lead in communicating with Fire Station. (L. Resnick, Tr. 185; Perdigao, Tr. 611-12).

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1424. Mr. Tupper had direct contact with research scientists who were working on POM's products, including substantive discussions of the underlying science. (Tupper, Tr. 899, 914).
1425. Mr. Tupper worked with Dr. Dreher in preparing summaries of POM's research portfolio. Mr. Tupper offered the business perspective by drafting the "where do we go from here" sections of POM's medical research summaries. He also edited the research summaries. (Dreher, Tr. 555-56, 558; CX1015 at 0001; CX1029).
1426. Mr. Tupper, along with Mr. Resnick, would meet on occasion with Dr. Liker, POM's Medical Director, to communicate the scientific research areas that POM was interested in exploring. (Liker, Tr. 1880).
1427. Mr. Tupper's responsibilities included keeping up to date on the status of medical research on POM's products, as well as reviewing the unpublished and published data that resulted from studies on POM's products. (Tupper, Tr. 913-14, 941; S. Resnick, Tr. 1720-21).
1428. Mr. Tupper, along with Mr. Resnick, participated in meetings with POM's scientific advisors to review research summaries, discuss research results, and come up with future plans for additional research. (Liker, Tr. 1889, 1915, 1925; Dreher, Tr. 555-56). Some of these scientific research meetings also included POM's scientific director at the time (either Risa Schulman, Dr. Dreher, or Dr. Gillespie), Dr. Liker, Dr. Heber, or Dr. David Kessler ("Dr. Kessler"), an advisor to POM. (Liker, Tr. 1889; Heber, Tr. 2068, 2072; Heber, Tr. 2072; S. Resnick, Tr. 1859).
1429. Mr. Tupper participated in regular research summits, which were meetings with scientists that helped POM interpret the results of scientific research and facilitated discussions about future research. (Liker, Tr. 1890-92).
1430. Mr. Tupper reviewed press releases prior to issuance. (Posell, Tr. 368; CX0062; CX0127).

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1431. Mr. Tupper participated in drafting the *Time* magazine cover wraps found herein to have made the claims alleged in the Complaint (*see* F. 308-320, 581; CX1378 (Kuyoomjian, Ocean Spray Dep. at 88-90)).

### III. ANALYSIS

#### A. Burden of Proof

The parties' burdens of proof are governed by Rule 3.43(a) of the Federal Trade Commission's Rules of Practice, Section 556(d) of the Administrative Procedure Act ("APA"), and case law. Pursuant to Commission Rule 3.43(a), "[c]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto." 16 C.F.R. § 3.43(a). Under the APA, "[e]xcept as otherwise provided by statute, the proponent of a rule or order has the burden of proof." 5 U.S.C. § 556(d).

It is well established that the preponderance of the evidence standard governs Federal Trade Commission ("FTC") enforcement actions. *In re Telebrands Corp.*, No. 9313, 140 F.T.C. 278, 426, 2004 FTC LEXIS 154, at \*76 (Sept. 15, 2004) (Initial Decision), *aff'd*, 140 F.T.C. 278, 2005 FTC LEXIS 178 (Sept. 19, 2005), *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Automotive Breakthrough Sciences, Inc.*, No. 9275, 1998 FTC LEXIS 112, at \*38 n.45 (Sept. 9, 1998) (holding that each finding must be "supported by a preponderance of the evidence in the record"); *In re Adventist Health System/West*, No. 9234, 117 F.T.C. 224, 1994 FTC LEXIS 54, at \*28 (Apr. 1, 1994) ("[e]ach element of the case must be established by a preponderance of the evidence"); *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, at \*143 (Sept. 28, 1979) (Initial Decision) (stating that complaint counsel has "the burden of proving by a preponderance of credible evidence that the challenged advertising claims have not been established or did not have a reasonable basis"), *aff'd*, 1983 FTC LEXIS 21, at \*242 (July 5, 1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984). *See also Steadman v. SEC*, 450 U.S. 91, 102 (1981) (holding that the APA establishes preponderance of the evidence standard of proof for formal administrative adjudicatory proceedings).

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The Complaint in this case alleges that Respondents disseminated advertising and promotional materials representing that the consumption of eight ounces of POM Juice, one POMx Pill, or one teaspoon of POMx Liquid (the “POM Products”) daily “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 9, 10, 19. The Complaint further alleges that Respondents represented that they possessed and relied upon, but in fact did not possess or rely upon, a reasonable basis substantiating such claims, and thus, Respondents’ representations were false or misleading. Complaint ¶¶ 19-21. In addition, the Complaint alleges that Respondents have disseminated advertising and promotional materials representing that “clinical studies, research, and/or trials prove” that consuming the POM Products “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction, Complaint ¶¶ 9, 10, 12, 14, 16, but that these representations were false or misleading because clinical studies, research, and/or trials do not in fact prove that consuming the POM Products, “prevents or reduces the risk of” or “treats” heart disease, prostate cancer or erectile dysfunction. Complaint ¶¶ 13, 15, 17, 18. Complaint Counsel has the burden of proving each of the foregoing factual issues by a preponderance of credible evidence. *In re Bristol-Myers Co.*, 1983 FTC LEXIS 64, at \*143-44. *See also FTC v. QT, Inc.*, 448 F. Supp. 2d 908, 959 (N.D. Ill. 2006), *aff’d*, 512 F.3d 858 (7th Cir. 2008).

**B. Jurisdiction**

Section 5 of the Federal Trade Commission Act (“FTC Act”) grants the Federal Trade Commission the authority to “prevent unfair or deceptive acts or practices in or affecting commerce” by “persons, partnerships, or corporations.” 15 U.S.C. § 45(a)(1)-(2) (2012). Section 4 of the FTC Act defines “corporation,” in part, as “any company, trust, so-called Massachusetts trust, or association, incorporated or unincorporated, which is organized to carry on business for its own profit or that of its members, and has shares of capital or capital stock or certificates of interest . . . .” 15 U.S.C. § 44.

POM Wonderful (“POM Wonderful” or “POM”) is a limited liability company. F. 1. Roll International Corporation, which was reorganized at the end of 2010 and is currently known as Roll

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Global (“Roll”), is a separate corporation. F. 7-8. POM Wonderful is one of several separate operating businesses under Roll’s ownership umbrella. F. 11. Mr. Stewart Resnick (“Mr. Resnick”) and Mrs. Lynda Resnick (“Mrs. Resnick”) are the sole owners of Roll and its affiliated companies, including POM Wonderful. F. 12. Mr. Resnick is the Chairman and President of Roll and the Chairman and Chief Executive Officer of POM Wonderful. F. 19-21. Mrs. Resnick is Vice Chairman of Roll. F. 27-28. She is the chief marketing person at POM, with responsibilities for marketing, branding, public relations, and product development. F. 29-31. Mr. Matthew Tupper was the President of POM and managed the day-to-day operations of POM Wonderful, including the POM marketing team, prior to his retirement in 2011. F. 37-38, 40, 44. Thus, POM Wonderful and Roll Global are partnerships or corporations and Mr. and Mrs. Resnick and Mr. Tupper are individuals over which the FTC has jurisdiction.

POM Wonderful is currently in the business of selling fresh pomegranates and pomegranate-related products, including 100% pomegranate juice (“POM Juice”) and pomegranate extract products known as POMx Pills and POMx Liquid (“POMx”). F. 6. Respondents began selling POM Juice in 2002. F. 5, 95. POM Juice is sold in supermarkets nationally and is a major seller in the premium juice category. F. 95. POM’s U.S. Sales of 100% POM Juice, from September 2002 to November 2010, totaled approximately \$247,739,776. F. 96. Respondents admit that “[t]he acts and practices of respondents alleged in this complaint have been in or affecting commerce, as ‘commerce’ is defined in Section 4 of the Federal Trade Commission Act.” Answer ¶ 8. In addition, Respondents promoted the POM Products through various methods, including print advertisements in magazines, freestanding inserts in newspapers, out of home media such as billboards and bus shelters, posters in health clubs and doctors’ offices, Internet websites, online banner advertisements, press releases, and television advertisements. F. 171. The acts and practices charged in the Complaint in this matter are in or affecting commerce within the meaning of the FTC Act, as amended. 15 U.S.C. § 41 *et seq.* Accordingly, the Commission has jurisdiction over the conduct challenged in the Complaint, pursuant to Sections 4 and 5 of the FTC Act. 15 U.S.C. §§ 44, 45.

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### C. Scope of Challenged Advertisements in this Case

#### 1. “Advertisements”

The Complaint charges Respondents with violating Sections 5 and 12 of the FTC Act. Complaint ¶ 22. Section 5(a) of the FTC Act provides that “unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful.” 15 U.S.C. § 45(a)(1). Section 12 of the FTC Act prohibits the dissemination of “any false advertisement” in order to induce the purchase of “food, drugs, devices, services, or cosmetics.” 15 U.S.C. § 52(a)(2). For the purposes of Section 12, “false advertisement” is defined as “an advertisement, other than labeling, which is misleading in a material respect[.]” 15 U.S.C. § 55(a).

The interrelation between Section 5(a) and Section 12 of the FTC Act was recently described by the Court of Appeals for the First Circuit as follows:

[T]he FTC statute . . . provides that both “unfair or deceptive acts or practices in or affecting commerce” (15 U.S.C. § 45(a)(1)) and “disseminat[ing], or caus[ing] to be disseminated, any false advertisement . . . in or having an effect upon commerce” (15 U.S.C. § 52(a)) are “unlawful.” 15 U.S.C. § 55 defines the term “false advertisement” as “an advertisement, other than labeling, which is misleading in a material respect . . . .” Given the strong similarity between the terms “deceptive” and “misleading,” it is no surprise that sections 45 and 52 are sometimes applied in tandem as the basis for an FTC action against an alleged false advertiser; indeed, such a tandem reading is expressly allowed by 15 U.S.C. § 52(b).

*FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 7-8 (1st Cir. 2010).

Complaint Counsel in this case has challenged 43 items, which Complaint Counsel describes as “Respondents’ ads and promotional pieces,” as violating Sections 5 and 12 of the FTC Act. CCB at 19; CCB Appendix A, Tables 1 and 2 (hereafter, “CCB Appendix A”). Specifically, Complaint Counsel challenges print advertisements, newsletters, website advertising,

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and “public relations” promotional pieces, including press releases and press interviews. CCB Appendix A; *see also* CCB at 13. Complaint Counsel asserts that all of the challenged promotional pieces constitute “advertisements” within the scope of Section 12 of the FTC Act, 15 U.S.C. § 52, and deceptive acts or practices within the scope of Section 5 of the FTC Act, 15 U.S.C. § 45. CCB at 14.

Respondents contend that the following four challenged items do not constitute “advertisements” in violation of Sections 5 and 12 of the FTC Act<sup>5</sup>:

1. Mrs. Resnick’s November 2008 television appearance on *The Martha Stewart Show*, during which she shared personal recipes for a POMtini cocktail and Thanksgiving stuffing, (CX1426 (Compl. Ex. E-6));
2. Mrs. Resnick’s February 2009 television appearance on *The Early Show*, during which she shared some marketing ideas for POM and FIJI Water, (CX0472 at 0003);
3. an interview of Mrs. Resnick in *Newsweek* magazine, dated March 20, 2009, discussing the economy, her business acumen, and promoting the sale of her book, *Rubies in the Orchard*, (CX1426 (Compl. Ex. F)); and
4. a June 2008 television interview of Mr. Tupper on FOX Business discussing the newest “hot” wave in foods – the pomegranate – and the pomegranate juice industry, (CX1426 (Compl. Ex. E-7)).

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<sup>5</sup> Respondents also assert that an April 2009 discussion by Mrs. Resnick at USC’s Annenberg School of Communication with Dean Ernest J. Wilson III, on “How to Uncover the Hidden Gems in Your Business,” (CX0472 at 0002), does not constitute “advertising.” RB at 92-95. Complaint Counsel responds that it does not challenge CX0472 at 0002 as deceptive under the FTC Act. CCRB at 43, n.41; CCRFF ¶ 2546. Accordingly, an analysis of that exhibit is not undertaken. Except as described in this section, Respondents do not dispute that the other advertisements and promotional materials challenged in this case are “advertisements” for purposes of Sections 5 and 12 of the FTC Act.

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Respondents assert that these four interviews are not actionable under the FTC Act because they do not constitute “advertising.” RB at 92. Complaint Counsel charges that these media appearances constitute “advertisements” within the scope of Section 12, CCB at 14, and contends that neither Section 5 nor Section 12 limits the FTC’s reach to paid for advertising. CCRB at 44. Complaint Counsel further argues that the Commission’s authority to regulate advertising is circumscribed only by its statutory authority and the limits of the commercial speech doctrine. CCRB at 44 (citing *In re R.J. Reynolds Tobacco Co.*, No. 9206, 111 F.T.C. 539, 542 (Mar. 4, 1988)).

The term “advertisement” is not defined in the FTC Act. However, in *R.J. Reynolds Tobacco*, the Commission made clear that it “understands[] [the term advertisement] to mean a notice or announcement that is publicly published or broadcast and is paid-for.” *R.J. Reynolds Tobacco Co.*, 1988 FTC LEXIS 9, at \*20. Complaint Counsel does not contend and has not pointed to any evidence to support a conclusion that Respondents paid anyone for their participation in the interviews or to allow them to speak about their products. See CCF 570-577. Moreover, these media interviews were conducted by individuals working with *The Martha Stewart Show*, *The Early Show*, *Newsweek*, and FOX Business – entities other than the Respondents – and were not sponsored by Respondents. See F. 575-578. By contrast, the radio program that was found to constitute an “advertisement” in *Daniel Chapter One* ran on a radio network founded and funded by respondents, was titled “Daniel Chapter One HealthWatch,” and was co-hosted by the individual respondents who were responsible for its content. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 157, \*21-22, 48, 163, 169-70 (Aug. 5, 2009) (Initial Decision), *aff’d*, 2009 FTC LEXIS 259 (Dec. 24, 2009).<sup>6</sup> See also *In re Witkower Press, Inc.*, 57 F.T.C. 145, 1960 FTC LEXIS 186, \*157 (July 19, 1960) (finding “respondents’ newspaper advertisements, book jackets and the television shows

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<sup>6</sup> In a case it brought against a telemarketer, the FTC, as prosecutor, acknowledged the distinction between “an independent television program,” and an infomercial, which was a “paid advertisement.” *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d 285, 304-05 (D. Mass. 2008).

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*sponsored by them* unquestionably constitute commercial advertising”) (emphasis added).

Complaint Counsel has cited no cases where the Commission charged a respondent with violating Section 12 of the FTC Act based on public statements that were not paid for or sponsored by the respondent. *E.g.*, *In re R. J. Reynolds Tobacco Co.*, 1988 FTC LEXIS 9, \*1 (“This case involves an advertisement, entitled ‘Of Cigarettes and Science,’ allegedly disseminated by Reynolds in the course of its business of manufacturing, advertising and selling cigarettes.”); *FTC v. Nat’l Comm’n on Egg Nutrition*, 517 F.2d 485, 487-88 (7th Cir. 1975) (“[P]ublished and broadcast statements, in the form of paid advertisements, representing in substance that there is no scientific evidence that eating eggs increases the risk of heart disease or a heart attack . . . were advertisements within the meaning of that term as used in the [FTC] Act, because they were representations concerning the qualities of a product and promoting its purchase and use.”); *Nat’l Comm’n on Egg Nutrition v. FTC*, 570 F.2d 157, 159 (7th Cir. 1977) (enforcing, in part, order imposed on industry association which “mounted an advertising and public relations campaign to convey the message that eggs are harmless and are needed in human nutrition”).

The only case found involving statements made in a public speaking engagement, cited by Respondents and addressed by Complaint Counsel, is *FTC v. Koch*, 206 F.2d 311 (6th Cir. 1953). The court there, without addressing whether promotional materials must be paid for to constitute advertising, found that a challenged book, which “set forth primarily matter of opinion,” did “not fall within the provisions of the statutes involved here.” *Id.* at 317. The court explained:

We also think that if these provisions of the statutes were construed so as to prohibit dissemination of such a book they would violate the First Amendment to the Constitution of the United States. It was not error for the Commission to consider this book and to quote extracts from it as throwing light upon the existence or non-existence of facts supporting the charge in the complaint, for the book was introduced by the respondents. However, we hold that it is not an advertisement covered

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by Sections 5, 12, or 15(a). We make a similar conclusion with reference to Dr. Koch's address before the College of Physicians and Surgeons of Quebec in 1939. If the record contained only these two exhibits, the Commission would not have jurisdiction in this proceeding.

*Id.*

Complaint Counsel has offered no authority to support a conclusion that publicly disseminated information that is not paid for or sponsored by Respondents constitutes "advertisements" within the scope of Section 12 of the FTC Act. Under the Commission's precedent regarding the statutory term "advertisement," the media appearances and interviews by Respondents in this case do not constitute "advertisements" within the scope of Section 12 of the FTC Act because they were not paid for or sponsored by Respondents. Therefore, the issue of whether the media interviews constitute constitutionally protected speech need not be, and is not, decided. Because the following exhibits – CX1426 (Compl. Ex. E-6) (Mrs. Resnick's November 2008 television appearance on *The Martha Stewart Show*); CX0472 at 0003 (Mrs. Resnick's February 2009 television appearance on *The Early Show*); CX1426 (Compl. Ex. F) (interview of Mrs. Resnick in *Newsweek* magazine); and CX1426 (Compl. Ex. E-7) (television interview of Mr. Tupper on FOX Business) – do not constitute "advertisements," this Initial Decision does not evaluate whether Respondents made any of the alleged claims in those exhibits. Moreover, the term, "Challenged Advertisements," as used herein, does not include these four media appearances and interviews.

**2. "Food" or "drug"**

The FTC Act defines the words "food" and "drug" broadly for purposes of Section 12. 15 U.S.C. § 55(b), (c) (defining "food" as, among other things, "articles used for food or drink for man," and defining "drug" as, among other things, "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man"). Courts have repeatedly held that these definitions of "food" or "drug" cover dietary supplements. *In re Daniel Chapter One*, 2009 FTC LEXIS 157, at \*171-73 (Initial Decision) (citing *FTC v. Natural Solution, Inc.*, 2007 U.S. Dist.

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LEXIS 60783, at \*11-12 (C.D. Cal. 2007); *FTC v. Nat'l Urological Group*, 645 F. Supp. 2d 1167, 1190 (N.D. Ga. 2008); *Direct Marketing*, 569 F. Supp. 2d at 300-03). POM Juice is a juice derived from pomegranate fruits. F. 57-58. POMx Pills and Liquid are extracts derived from the pomegranate. F. 67, 70-71, 89-90. Accordingly, each of the POM Products are a “food” or “drug” (F. 60, 61, 67, 70-71, 89-90) as defined in Section 12 of the FTC Act.

**D. Overview of Applicable Law**

An “advertisement is deceptive under the [FTC] Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect.” *Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992) (citing *In re Thompson Medical Co.*, No. 9149, 104 F.T.C. 648, 788, 1984 FTC LEXIS 6, at \*311 (Nov. 23, 1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986)); *In re Cliffdale Assocs.*, No. 9156, 103 F.T.C. 110, 164-66, 1984 FTC LEXIS 71, at \*104 (Mar. 23, 1984)). The determination of whether Respondents disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondents disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314; *FTC v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994); *Direct Marketing*, 569 F. Supp. 2d at 297. Each of these elements is addressed below.

**E. Whether Respondents Disseminated Advertisements Conveying the Alleged Claims****1. General principles**

“The Commission will deem an advertisement to convey a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message.” *Thompson Medical*, 104 F.T.C. at 788; *Cliffdale Associates, Inc.*, 103 F.T.C. at 164-66; *Federal Trade Commission Policy Statement on Deception*, appended to *Cliffdale Associates, Inc.*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at \*176-77 (1984) (the “*Deception Statement*”); *In re Kraft, Inc.*, 114 F.T.C. 40, 1991 FTC LEXIS 38, at \*10 (1991).

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Advertising claims may be conveyed either expressly or impliedly. Express claims directly state the representation at issue. *Kraft*, 970 F.2d at 319 n.4; *Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at \*311; *Cliffdale*, 1984 FTC LEXIS 71, at \*108 (1984). Because the claim is stated unequivocally, the statement itself establishes its meaning, and it is, therefore, reasonable to interpret such advertisement as making the alleged claim. *Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at \*311-12. Implied claims are made in an oblique or indirect way. *Kraft*, 970 F.2d at 319 n.4.

An interpretation of an advertisement may be reasonable even though it is not shared by a majority of consumers. *Kraft*, 1991 FTC LEXIS 38, at \*14; *Deception Statement*, 1984 FTC LEXIS 71, at \*177 n.20. A reasonable interpretation is one that would be shared by a “significant minority” of reasonable consumers. *Id.*; *In re Novartis Corporation*, No. 9279, 127 F.T.C. 580, 1999 FTC LEXIS 63, at \*22-23 (May 13, 1999); *Kraft*, 1991 FTC LEXIS 38, at \*14; *see also Telebrands Corp.*, 140 F.T.C. at 291 (“An ad is misleading if at least a significant minority of reasonable consumers are likely to take away the misleading claim.”).

“[F]indings with respect to what representations are made in advertisements are factual. *See, e.g., Thompson Medical v. FTC*, 791 F.2d 189, 197 (D.C. Cir., 1986) (quoting from the FTC’s brief); *AHP [American Home Products]*, 695 F.2d [681,] 686 [(3rd Cir. 1982)]; *Beneficial Corp. v. FTC*, 542 F.2d 611, 617 (3d Cir. 1976).” *Removatron Int’l Corp. v. FTC*, 884 F.2d 1489, 1496 (1st Cir. 1989). In the instant case, it has been found as a fact that none of the Challenged Advertisements expressly (*i.e.*, unequivocally and directly) states that “drinking eight ounces of POM Juice daily” or “taking one POMx Pill daily,” or “taking one teaspoon of POMx Liquid daily” (1) “treats,” “prevents,” or “reduces the risk” of “heart disease,” including by reducing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart, or that these effects are “clinically proven”; (2) “treats,” “prevents,” or “reduces the risk” of “prostate cancer,” including by prolonging prostate-specific antigen doubling time, or that these effects are “clinically proven”; or (3) “treats,” “prevents,” or “reduces the risk” of erectile dysfunction, or that these effects are “clinically proven.” F. 586. Thus, the issue is whether any of the Challenged Advertisements made the alleged

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claims implicitly; that is, whether a significant minority of consumers, acting reasonably in the circumstances, would interpret any of the Challenged Advertisements to convey the claims alleged in the Complaint. The methodology used in making this factual determination is further explained in below.

**a. Facial analysis**

To determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement itself (a “facial analysis”). *Thompson Medical*, 1984 FTC LEXIS 6, at \*313; *Cliffdale*, 1984 FTC LEXIS 71, at \*108. A proper facial analysis requires “an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.” *Deception Statement*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at \*172. The advertisement must be viewed as a whole “without emphasizing isolated words or phrases apart from their context.” *Removatron*, 884 F.2d at 1496 (quoting *AHP*), 695 F.2d at 687; see also *FTC v. Sterling Drug, Inc.*, 317 F.2d 669, 674 (2d Cir. 1963) (“The entire mosaic should be viewed rather than each tile separately.”). “But the Commission may not inject novel meanings into ads and then strike them down as unsupported; ads must be judged by the impression they make on reasonable members of the public.” *In re Bristol-Meyers Co.*, No. 8917, 102 F.T.C. 21, 1983 FTC LEXIS 64, \*249 (July 5, 1983), *aff’d*, 738 F.2d 554 (2d Cir. 1984).

“If, after examining the interaction of all the different elements in the ad, the Commission can conclude with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the advertisement conveys the claim. See *Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.” *In re Stouffer Foods Corp.*, No. 9250, 118 F.T.C. 746, 1994 FTC LEXIS 196, at \*9 (Sept. 26, 1994). However, the alleged claim must be reasonably clear or conspicuous from the face of the advertisement. *Kraft*, 970 F.2d at 319 (holding that the Commission can rely on its own reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement “so long as those claims are reasonably clear from the face of the advertisement”); accord *Nat’l Urological Group*, 645 F. Supp. 2d

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at 1189 (holding that facial analysis is sufficient basis to find alleged claim was made if claims are “clear and conspicuous” or “apparent” on the face of the advertisement); *QT, Inc.*, 448 F. Supp. 2d at 958 (“Where implied claims are conspicuous and reasonably clear from the face of the advertisements, extrinsic evidence is not required.”).

If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, “the Commission will not find the ad to have made the claim unless extrinsic evidence allows the conclusion that such a reading of the ad is reasonable. *Kraft*, 114 F.T.C. at 121; *Thompson Medical*, 104 F.T.C. at 789.” *Stouffer*, 1994 FTC LEXIS 196, at \*10. In all cases, however, if extrinsic evidence has been introduced, that evidence “must be considered by the Commission in reaching its conclusion on the meaning of the advertisement.” *Bristol-Meyers*, 1983 FTC LEXIS 64, at \*247-48; see *Deception Statement*, 1984 FTC LEXIS 71, at \*172-73; *Thompson Medical*, 1984 FTC LEXIS 6, at \*324-25 (holding that because Thompson offered extrinsic evidence, the Commission was “obliged to consider it”). The Commission will carefully consider any extrinsic evidence that is introduced, taking into account the quality and reliability of the evidence. See *Kraft*, 114 F.T.C. at 122, 1991 FTC LEXIS 38, at \*14; *Stouffer*, 1994 FTC LEXIS 196, at \*10.

**b. Extrinsic evidence**

Extrinsic evidence includes, but is not limited to, “reliable results from methodologically sound consumer surveys.” *Kraft*, 114 F.T.C. at 121, 1991 FTC LEXIS 38, at \*13; *Cliffdale*, 103 F.T.C. at 164-66, 1984 FTC LEXIS 71, at \*108-09. In determining whether a consumer survey is methodologically sound, the Commission will look to whether it “draws[s] valid samples from the appropriate population, ask[s] appropriate questions in ways that minimize bias, and analyze[s] results correctly.” *Thompson Medical*, 104 F.T.C. at 790, 1984 FTC LEXIS 6, at \*315. “The Commission does not require methodological perfection before it will rely on a copy test or other type of consumer survey, but looks to whether such evidence is reasonably reliable and probative. See *Bristol-Myers Co.*, 85 F.T.C. 688, 743-44 (1975). Flaws in the methodology

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may affect the weight that is given to the results of the copy test or other consumer survey.” *Stouffer*, 1994 FTC LEXIS 196, at \*10-11.

In addition to consumer surveys, another type of extrinsic evidence the Commission will look at is:

evidence not specifically showing how consumers understood the advertisements at issue before us, but showing how consumers might ordinarily be expected to perceive or understand representations like those contained in the ads we are reviewing. For example, we might look at the dictionary definition of a word to identify the word’s common usages. Or we might look at principles derived from market research, as expressed by marketing experts, which show that consumers generally respond in a certain manner to ads that are presented in a particular way, and presume that consumer reactions to a particular ad before us would be consistent with the general response pattern. Where we apply such marketing principles, we will derive them from research presented in references generally accepted as reliable in the field of marketing. Such references may be cited by marketing experts called to testify in the proceeding.

*Thompson Medical*, 1984 FTC LEXIS 6, at \*315-16.

A third type of evidence the Commission “will consider if offered is the opinion of expert witnesses in the proceeding as to how an advertisement might reasonably be interpreted. For example, we might consider the opinion of a marketing expert who stated his or her view that consumers would interpret an advertisement in a particular manner. However, where the opinions voiced by experts are not adequately supported we ordinarily give them little weight.” *Thompson Medical*, 1984 FTC LEXIS 6, at \*316-17.

Whether examining the advertisement itself, extrinsic evidence, or both, the Commission considers the overall, common-sense, net impression made by the advertisement in determining whether the alleged claim may reasonably be ascribed to it. *FTC v. Tashman*, 318 F.3d 1273, 1283 (11th Cir.

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2003); *Kraft*, 114 F.T.C. at 122; *Thompson Medical*, 104 F.T.C. at 790; *Stouffer* 118 F.T.C. 746, 1994 FTC LEXIS 196, at \*11. Ultimately, “[t]he meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is fundamentally a question of fact. . . . This question of fact may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey.” *Nat’l Urological Group*, 645 F. Supp. 2d at 1189; *QT*, 448 F. Supp. 2d at 957-58; *see also Removatron*, 884 F.2d at 1497 (holding that findings with respect to what representations are made in advertisements are factual).

**c. Intent of the advertiser**

Complaint Counsel urges that the evidence shows that Respondents intended to make the claims alleged in the Complaint. Citing *Telebrands Corp.*, 140 F.T.C. at 304 and *Novartis Corp.*, 127 F.T.C. at 683, Complaint Counsel argues that such intent constitutes extrinsic evidence that the Challenged Advertisements in fact conveyed the claims alleged. Respondents deny any intent to make the disease claims alleged in the Complaint. This Initial Decision need not, and does not, determine whether or not Respondents intended to make the disease claims alleged in the Complaint because the evidence is sufficient to conclude that Respondents disseminated advertisements containing the alleged claims, without regard to Respondents’ alleged intent. *See* Section III.E.2, *infra*. Moreover, to the extent Complaint Counsel is arguing that advertiser intent alone can support interpreting an advertisement to contain an alleged claim, absent a facial analysis and/or other extrinsic evidence demonstrating that such claim was made, that argument is rejected, as more fully explained below.

It is well established that liability under Section 5 of the FTC Act does not require proof of intent to deceive. *FTC v. World Travel Vacation Brokers, Inc.*, 861 F.2d 1020, 1029 (7th Cir. Ill. 1988); *Chrysler Corp. v. FTC*, 561 F.2d 357, 363 & n.5 (D.C. Cir. 1977); *Kraft*, 114 F.T.C. at 121. Similarly, it is no defense to an action for deceptive advertising that the advertiser did not intend to make the claim alleged. *World Travel Vacation Brokers*, 861 F.2d at 1029; *FTC v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill.

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1998). It would be incongruous, at best, if intent could be used as a sword but not a shield.

Moreover, the law is clear that the goal of advertising interpretation is to determine whether reasonable consumers would interpret an advertisement to convey an alleged claim. *See, e.g., Thompson Medical*, 104 F.T.C. at 788, 1984 FTC LEXIS 6, at \*311 (holding that an advertisement conveys a claim if consumers, acting reasonably under the circumstances, would interpret the advertisement to contain that message); *Nat'l Urological Group*, 645 F. Supp. 2d at 1189 (question of advertisement's meaning "may be resolved by the terms of the advertisement itself or by evidence of what consumers interpreted the advertisement to convey"). Complaint Counsel's suggested approach is contrary to law because it would have the analysis of the Challenged Advertisements focus on the perspective of the advertiser, based on the intent of a respondent, rather than focus on the perspective of the audience, *i.e.*, the consumer who sees or hears the advertisement. It is also noteworthy that, while extrinsic evidence of consumer interpretation is appropriate to consider, advertiser "intent" is not mentioned among the types of extrinsic evidence that is considered in determining how consumers would interpret an advertisement. As the Commission explained in the *Deception Statement*, extrinsic evidence "can consist of expert opinion, consumer testimony (particularly in cases involving oral representations), copy tests, surveys, or any other reliable evidence of consumer interpretation." 1984 FTC LEXIS 71, at \*173 n.8 (emphasis added); *see also Thompson Medical*, 1984 FTC LEXIS 6, at \*315-16.

In *Telebrands*, upon which Complaint Counsel relies, the Commission held: "Based on our own review of the challenged advertising, we conclude that consumers would reasonably interpret respondents' Ab Force ads to mean that the device (1) causes loss of weight, inches, or fat; (2) creates well-defined abdominal muscles; and (3) is an effective alternative to regular exercise . . . ." 140 F.T.C. at 301. The Commission further held that "other considerations," including "ample evidence that respondents intended to convey the challenged claims," provided further support for the conclusions of the facial analysis. *Telebrands Corp.*, 140 F.T.C. at 304. Similarly, in *Novartis*, 127

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F.T.C. at 683, also cited by Complaint Counsel, the Commission stated that “evidence of intent to make a claim may support a finding that the claims were indeed made.” The Commission held, however, similar to *Telebrands*, that the challenged claim was “plain from a facial analysis of the challenged ads alone” and that the “extrinsic evidence” indicating respondent intended to make the challenged claim “provide[d] additional support for [the] finding that the superiority claims” were made. *Novartis*, 127 F.T.C. at 683-84. Indeed, in *Novartis*, “the issue of whether the claim was made [was] not a close one.” *Id.* at 683.

Thus, while *Telebrands* and *Novartis* indicate that evidence of an advertiser’s intent to make a claim can bolster or confirm a finding that a claim was in fact made, the law does not indicate that advertiser intent alone is a valid basis for finding that a claim was made, absent a facial analysis and/or other extrinsic evidence demonstrating that such claim was made. In the instant case, the evidence is sufficient to conclude that Respondents disseminated advertisements containing the alleged claims, and it is, therefore, not necessary to determine, or rely upon, Respondents’ alleged intent.

**d. Target audience**

Complaint Counsel argues that the Challenged Advertisements must be interpreted from the perspective of the target audience for POM Product advertising which, according to Complaint Counsel, consists of “consumers concerned about preventing or reducing their risk of illness.” CCB at 18. See *Telebrands*, 140 F.T.C. at 291 (stating that “[i]f an ad is targeted at a particular audience, the Commission analyzes ads from the perspective of that audience” (citing *Deception Statement*, 1984 FTC LEXIS 71, at \*178-79)); *Thompson Medical*, 1984 FTC LEXIS 6, \*321 n.15 (recognizing precedent that persons with health-related problems can be a target audience). In support of the argument that consumers concerned about preventing or reducing their risk of illness constitute a “target audience” for purposes of interpreting the Challenged Advertisements, Complaint Counsel relies principally on certain “creative briefs” prepared by POM Marketing and provided to the in-house advertising agency, Fire Station, which served to guide Fire Station’s work in developing advertising for POM Juice, POMx

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Pills and Pomwonderful.com. CCF 299-308; CX0409; F. 145-152. These creative briefs include a section titled, “target audience,” which, for the purpose of these documents, meant the audience to whom the advertisement would appeal. F. 148, 175. Complaint Counsel also notes that Respondents placed advertising in health-oriented magazines, such as *Prevention* and *Men’s Fitness*, in health clubs, on prescription drug bags, and on medical-oriented websites (e.g., WebMD). CCB at 19.

Respondents dispute that the creative briefs or POM’s alleged focus on health-conscious consumers are probative in this matter, and further note that the POM Products were advertised in a wide variety of local and national publications that are not devoted to health. RRB at 49-50. Respondents do not appear to dispute, however, that health-conscious consumers are among POM’s target consumers.

The creative briefs, as well as the fact that Respondents sought to reach health-conscious consumers by placing advertising in such magazines as *Health Magazine*, *Men’s Health*, and *Men’s Fitness*, and in health clubs, on prescription drug bags, and on medical-oriented websites (e.g., WebMD), show that Respondents endeavored to reach educated, affluent, and health-conscious individuals. F. 171, 179, 181.<sup>7</sup> Although at least one creative brief for POM Pills specifically included within the “target audience,” among others, middle-aged men or seniors who are concerned or “scared” about prostate cancer, e.g., F. 178, Complaint Counsel’s extrapolation from such evidence that POM’s target group was “consumers concerned about preventing or reducing their risk of illness” in general is unpersuasive and is, therefore, rejected. Moreover, the evidence shows that Respondents’ advertising was also directed to a more general audience. F. 169-171. In particular, the evidence shows that the Challenged Advertisements were disseminated in a wide variety of locally and nationally distributed publications, well beyond health-oriented publications, including the *Chicago Tribune*, *Details*, *Rolling Stone*, *InStyle*, *Town and Country*, *Fortune*, the

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<sup>7</sup> Complaint Counsel’s assertion that advertisements were distributed in the reception area of urologists’ offices is not supported by the evidence cited by Complaint Counsel. See CCF 226.

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*New York Times*, *Discover*, *Popular Science*, and *Time*. F. 169-170.

In any event, even if Respondents' advertising sought to appeal to educated, affluent, and health-conscious individuals, this conclusion has no practical utility in the instant case. As the Commission stated in *Thompson Medical*, with respect to "target audiences": "[A]most all advertising is targeted at some demographic group, such as farmers, housewives, or residents of a particular area. This alone does not mean that we apply a standard different from our customary one." *Thompson Medical*, 1984 FTC LEXIS 6, \*321 n.15. The term, "target audiences," for purposes of interpreting advertising, refers to "special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or a distinctive reaction to particular advertising claims[.]" *Id.* Complaint Counsel does not cite to any evidence in the record indicating how, if at all, "educated, affluent, health-conscious consumers" would be more capable or more likely than ordinary consumers to infer the alleged disease claims from the Challenged Advertisements. *See* CCB at 18-19. In fact, what little evidence there is on the characteristics of this group indicates, if anything, that educated, affluent, health-conscious consumers are more likely to be more discerning and careful readers of an advertisement, and more likely to better understand an advertisement, F. 521-522, all of which weigh against a conclusion that such consumers would be more susceptible to inferring disease claims.

In addition, the only evidence of a "distinctive reaction to particular advertising claims" among educated, affluent, health-conscious consumers is the opinion of Complaint Counsel's rebuttal expert on, *inter alia*, advertising and consumer behavior, Dr. David Stewart (*see* F. 285, 288), that such consumers are more likely to be "more attentive to health claims" and more likely to "draw pragmatic inferences" about the benefits of the POM Products. F. 517. However, Dr. Stewart defined such "pragmatic inferences" as meanings that are neither expressed in the advertisements, nor implied by the advertisements, and may or may not even follow, logically. F. 517. Finally, as Dr. Stewart also noted, consumers are not simply passive recipients of messages, but are active processors, and in determining how a

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consumer would interpret an advertisement, it is critical to consider prior beliefs, prior knowledge, what the consumer may regard as relevant, how the consumer will process the information, and generally what the consumer brings to the viewing situation. F. 542-543. Complaint Counsel introduced no evidence on these considerations cited by Dr. Stewart.

In summary, while the evidence shows that Respondents' advertising may have been geared, at least in part, toward educated, affluent, health-conscious consumers, Complaint Counsel has failed to prove that this group would be more likely to interpret, or in fact did interpret, the Challenged Advertisements differently than ordinary consumers, or in what manner that group would do so. Accordingly, to meaningfully analyze the Challenged Advertisements from the perspective of the asserted target group would require unacceptable speculation, because what constitutes such perspective, or how such perspective would be applied to the group's interpretation of advertising, has not been proven.

## **2. Respondents disseminated advertisements making the claims alleged in the Complaint**

### **a. Summary of findings**

As noted above, the determination of what claims are made in an advertisement is a factual one. *Removatron Int'l Corp.*, 884 F.2d at 1496; *AHP*, 695 F.2d at 686; *Nat'l Urological Group*, 645 F. Supp. 2d at 1189; *QT*, 448 F. Supp. 2d at 957-58. In *Thompson Medical*, the Administrative Law Judge ("ALJ") described the approach that he employed in making such determination as follows:

In determining the meaning of individual advertisements, I have primarily relied on my knowledge and experience to determine what impression or impressions an advertisement as a whole is reasonably likely to convey to a consumer. When my initial determination is confirmed by the expert testimony of complaint counsel or respondent, I rested. When my initial determination disagreed with that of expert testimony, which was often conflicting, I reexamined the advertisement in question,

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and further considered other record evidence such as copy tests and other consumer research before reaching a final determination. I have not relied on such extrinsic evidence when, after careful study and reflection, I found it to be unpersuasive and contrary to the weight of evidence.

*Thompson Medical*, 1984 FTC LEXIS 6, \*82-83 (Initial Decision).

Employing and applying the above methodology, based upon a facial analysis and having considered all applicable extrinsic evidence, this Initial Decision finds that certain Challenged Advertisements disseminated by Respondents made the claims alleged in the Complaint. F. 579-584. Therefore, Complaint Counsel has satisfied the first element of its deceptive advertising claim. *See Kraft*, 970 F.2d at 314. Detailed findings of fact are set forth in Section II.D, *supra* and summarized, as applicable, in the following analysis. *See also* Initial Decision Appendix (containing advertisements found to have made the alleged claims). The reasoning for these findings is further explained below. The evidence upon which Respondents rely to argue that none of the Challenged Advertisements should be interpreted as making the challenged claims, including the opinions of their linguistics expert, Dr. Ronald Butters (F. 259-263), have been fully considered. F. 579. With respect to those Challenged Advertisements found to have made the alleged claims, such evidence fails to outweigh the evidence demonstrating that the claims were in fact made, including the overall net impression of the advertisements themselves. F. 584. Respondents' arguments are further addressed in Section III.E.2.f, *infra*.

As to those of the Challenged Advertisements that were not found to have made the challenged claims, this Initial Decision finds that such claims were not reasonably clear or conspicuous on the face of the advertisements, and that considering the interplay of all the elements of such advertisements, it could not be concluded with confidence, on the face of the advertisements alone, that a significant minority of reasonable consumers would interpret the advertisements to make the claims alleged in the Complaint. F. 585, 587. Among other reasons, these advertisements: do not mention heart disease, prostate cancer, or

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erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a connection for the reader, such as through associated explanatory text, between health benefits, or study results, and effectiveness for heart disease, prostate cancer, or erectile dysfunction. F. 588; *see also* F. 585. *See In re Sterling Drug, Inc.*, No. 8919, 102 F.T.C. 395, 1983 FTC LEXIS 66, at \*477-78 (July 5, 1983) (holding that claim that Bayer aspirin relieved tension was not apparent in advertisement depicting Bayer relieving a headache caused by tension). In the context of these advertisements, the nature of the transaction, *i.e.*, the purchase of a food product, or a supplement derived therefrom, as opposed to the purchase of a drug (F. 57, 65-68, 70-72), further weighs against interpreting such advertisements as making the alleged claims. *See Deception Statement*, 103 F.T.C. 110, 1984 FTC LEXIS 71, at \*172 (noting that in evaluating whether implied claim was made, the Commission will consider, among other factors, the nature of the transaction). To this extent, the facial analysis is confirmed by the opinion of Respondents' expert, Dr. Butters, that an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim, than an advertisement promoting a drug. F. 491-492.

Furthermore, as to those of the Challenged Advertisements, described above, for which the alleged claims are not reasonably clear from a facial analysis, the weight of the applicable extrinsic evidence also fails to demonstrate that such advertisements would be reasonably interpreted to make the claims alleged in the Complaint. F. 589; *see also* F. 585. For example, Complaint Counsel relies on the Bovitz Survey, a 2009 study of billboard headlines, commissioned by Respondents to assess the impact of their advertising campaigns. F. 544-548; *see* CCF 588. In particular, Complaint Counsel relies on the fact that forty-three percent of survey respondents in POM's general target audience and forty-eight percent of those survey respondents that were POM Juice users, when shown an advertisement picturing a POM Juice bottle saying, "I'm off to save PROSTATES!" and a sub-headline "The Antioxidant Superpower," said the advertisement's

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main idea was “good for prostates.” F. 557. However, this vague and general interpretation is not persuasive evidence that a significant minority of reasonable consumers would draw the further inference, when viewing an advertisement containing such language and imagery, that the POM Products treat, prevent, or reduce the risk of “prostate cancer.” *See also* F. 524 (In linguistic terms, “I’m off to save prostates” would not imply that a product will protect or rescue one from disease). Similarly, Complaint Counsel relies on the fact that fourteen percent of survey respondents in POM’s general target audience, when shown an advertisement picturing a POM Juice bottle inside a blood pressure cuff, with the headline “Decompress” and a sub-headline “POM Wonderful Pomegranate Juice[ ] The Antioxidant Superpower,” said the advertisement’s main idea was “helps/lowers blood pressure.” F. 555. This vague and ambiguous conclusion is not enough to support a finding that a significant minority of reasonable consumers would draw the further inference, when viewing an advertisement containing this language and imagery, that the POM Products treat, prevent, or reduce the risk of “heart disease.” None of the survey respondents in the Bovitz Survey answered that the main idea of these billboard advertisements was prevention, risk reduction, or treatment of any specific disease. F. 555-558, 572. The most common “main idea” communicated (at least 90%) was that POM Juice had general health benefits. F. 572. Moreover, the Bovitz Survey examined only advertisement headlines and images, as shown on the billboard advertisements. F. 547. Thus, the Bovitz Survey did not examine the headlines, images and text, as shown on any of the Challenged Advertisements. F. 547. As Complaint Counsel’s rebuttal expert, Dr. Stewart, acknowledged, other text that is added in a lengthier print advertisement might modify a message communicated by the image and headline of a billboard. F. 561. For this reason as well, the findings of the Bovitz Survey are entitled to little weight.

Complaint Counsel also places too much weight on opinions that Complaint Counsel obtained from Dr. Butters on cross-examination that phrases such as “prostate health” and “heart health” would be interpreted to mean the absence of disease. F. 538-539. While the meaning of “health” may well include the absence of disease, the meaning of “health” is surely not so

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limited as to include only treatment, prevention or reduction of the risk of disease, and to the extent Dr. Butters opined as such, that opinion is rejected.

Accordingly, because, as to certain Challenged Advertisements, the alleged claims are not reasonably clear or conspicuous on the face of the advertisements themselves, and because the applicable extrinsic evidence of the meaning of those advertisements is insufficient or unpersuasive, this Initial Decision finds that the evidence fails to demonstrate that such advertisements made the claims alleged in the Complaint. F. 587-590; *see also* F. 585. *See Sterling Drug*, 1983 FTC LEXIS 66, at \*477-78 (stating Commission was “unwilling in the absence of extrinsic evidence to find that consumers infer from these ads that Bayer will relieve tension” where such claim was “not apparent . . . from a careful examination of the ads”); *Thompson Medical*, 104 F.T.C. at 339-40 (holding that Commission “cannot find the ad to convey” implied claim that Aspercreme contained aspirin where Commission was unable to “conclude with adequate confidence” based on the advertisement itself “whether or not one message conveyed to consumers” was that Aspercreme contained aspirin and where extrinsic evidence was insufficient to find such claim). It is worth emphasizing that this is not a finding that the advertisements *do not* convey the alleged claims, but merely that the evidence was insufficient to conclude that they do. As the Commission stated in *Thompson Medical*:

Here we merely say that complaint counsel failed to provide extrinsic evidence demonstrating that [the advertisements] created a net impression which did [make the challenged claim]. We do not attempt to use our judgment to reach any substantive conclusion. Where the implied meanings of an advertisement are unclear absent extrinsic evidence, our expertise is no more reliable in permitting conclusions that an interpretation is unreasonable than that it is reasonable.

*Thompson Medical*, 1984 FTC LEXIS 6, at \*371.

To be clear, Complaint Counsel has demonstrated, based on a number of the Challenged Advertisements, that Respondents *did*, in fact, disseminate some advertisements making the claims

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alleged in the Complaint. It is not necessary to find that all the Challenged Advertisements made the alleged claims in order to warrant injunctive relief for deceptive advertising. *Bristol-Meyers*, 1983 FTC LEXIS 64, at \*250-51 (disagreeing with ALJ findings that certain advertisements made the challenged claims, and stating: “Although we find a smaller number of violative ads than did the ALJ, there is certainly an adequate number to support the order . . . .”); *Fedders Corp.*, No. 8932, 85 F.T.C. 38, 71-72, 1975 FTC LEXIS 282, \*72 (Jan. 14, 1975) (“The Commission has previously issued orders in cases involving no more than one or a few deceptive advertisements.”).

**b. “Establishment” claims vs. “efficacy” claims**

Advertisements that claim a certain type or level of support are considered “establishment claims.” *Thompson Medical*, 791 F.2d at 194. An establishment claim includes a claim that the effectiveness of a product has been shown by clinical proof. *Removatron*, 884 F.2d at 1492 n.3. As the Commission stated in *Thompson Medical*: “There is no conceptual or practical reason to single out such claims [ ] for special treatment. They are but one example of an express or implied claim that an advertiser possesses a particular level of substantiation.” 1984 FTC LEXIS 6, at \*387 n.59; *see also Bristol-Meyers*, 1983 FTC LEXIS 64, at \*253 (noting that a claim of clinical proof can be express or implied). A claim that a product is effective, without expressly or impliedly representing a particular level of support, is not an establishment claim, but is an efficacy claim. *Removatron*, 884 F.2d at 1491 n.3.

The majority of the Challenged Advertisements that have been found herein to have made the claims alleged in the Complaint represented that clinical studies supported the claimed effectiveness of the POM Products, and, therefore, are referred to herein as “establishment claims.” The remainder of the Challenged Advertisements found to have made the claims alleged in the Complaint made non-establishment, “efficacy” claims.

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**c. Heart disease claims**

The evidence shows that Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease and, in many of these same advertisements, are clinically proven to do so, by lowering blood pressure, reducing arterial plaque, and/or increasing blood flow to the heart. F. 580, 583. Respondents made these claims indirectly and obliquely, typically by presenting, through words and images, a logical syllogism that: free radicals cause or contribute to heart disease; the POM Products contain antioxidants that neutralize free radicals; and, therefore, the POM Products are effective for heart disease. F. 294-295, 301-303, 348, 374, 394-396, 398, 407, 414, 444, 452-453, 460-462. Against this background, many of the advertisements further state or represent that the POM Products have been shown in one or more clinical, medical, or scientific studies, to reduce plaque, lower blood pressure, and/or improve blood flow to the heart, in a context where it is readily inferable that the referenced study results involve heart disease risk factors and, therefore, constitute clinical support for the effectiveness claim. F. 295, 301, 303, 349, 373, 376, 379, 395-397, 400, 407, 414, 420.

For example, in April 2009, the “Cardiovascular” section of the health benefits webpage of pomwonderful.com had a “read more” link that took the viewer to text stating that “heart disease” is a leading killer of men and women in the United States, that “atherosclerosis,” which is defined for the reader as too much “plaque,” is a leading factor in “heart attacks,” and further describes the role of antioxidants in reducing LDL (defined as “bad” cholesterol) oxidation. F. 373-374. The “read more” links from this page connect to a 2005 study on the effect of pomegranate juice on myocardial perfusion published in the *American Journal of Cardiology*; a 2004 study on reduction of carotid intima-media thickness, blood pressure (CIMT-BP) and LDL oxidation; and a 2001 study on reduction of systolic blood pressure. F. 374. The “Cardiovascular” section of the health benefits webpage of pomwonderful.com also advised the reader that POM Juice was shown in one study to improve blood flow to the heart in “coronary heart disease” “patients”; and, in another

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study, to reduce arterial plaque. F. 373. In this context, asserting clinical proof of a beneficial effect on the underlying conditions of the body (blood flow, arterial plaque, CIMT-BP, and LDL) would reasonably be interpreted as representing clinical proof of effectiveness for heart disease. F. 373-375, 381.

Another example is the Heart Newsletter (CX1426 (Compl. Ex. M); F. 346-350), which states or represents that (1) “58.8 million Americans suffer from some form of heart disease”; (2) supplementation with antioxidants is “your ally” in fighting “heart disease”; (3) antioxidants fight free radicals and help prevent cell and tissue damage that lead to “disease”; (4) POM Juice and POMx have polyphenol antioxidants, which are unique and superior; and (5) POMx provides antioxidant supplementation without adding the calories of POM Juice. F. 348. The Heart Newsletter further states that POM’s “scientists have found” that POM Juice “may help counteract factors leading to arterial plaque buildup, as well as inhibit a number of factors associated with heart disease.” F. 349. The text then proceeds to describe these findings, from “new research,” including (1) a “pilot” study involving 19 “patients” with “clogged arteries” which found a “30% decrease in arterial plaque” among those drinking eight ounces of POM Juice daily; and (2) a study involving 45 “patients” with “impaired blood flow to the heart,” showing “17% improved blood flow” among those who consumed eight ounces of POM Juice daily. F. 349. By connecting POM-provided antioxidants to benefits for “heart disease,” and by further connecting the study results to heart disease risk factors, the advertisement implies that the POM Products are effective for heart disease, and that such effectiveness is based upon clinical testing. F. 350. *See also* F. 301 (CX0029 print advertisement representing, *inter alia*, that “heart attacks are due to . . . plaque in the arteries” and “scientific research shows” that POM Juice prevents LDL oxidation and reduces plaque); F. 414 (CX0473 Ex. E-1 (pomegranatetruth.com)), representing that “atherosclerosis,” which is defined for the reader as too much “plaque,” is a leading factor in “heart attacks” and linking to research studies on the effects of pomegranate juice on myocardial perfusion, reduction of carotid intima-media thickness, blood pressure, and LDL oxidation); F. 339-340, 419-420.

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The Challenged Advertisements that were not found to have made establishment claims, as alleged by Complaint Counsel, but which were found to have made heart disease efficacy claims only, either do not reference any clinical testing or refer to clinical testing in such a way, and in such context, that it cannot be concluded with confidence that a significant minority of reasonable consumers would take away the message that the efficacy claim is “clinically proven.” See F. 440-448 (CX0031 (“Floss your arteries”)); F. 456-468 (CX0034 (“Amaze your cardiologist”)). For example, CX0031 represents that “clogged arteries lead to heart trouble,” free radicals cause “artery clogging plaque,” and that drinking eight ounces of POM Juice a day “can reduce plaque up to 30%!\*” F. 444. While this advertisement makes an efficacy claim, the only reference to any scientific support is in very small print, at an asterisk at the bottom of the page, which states: “Aviram, M. Clinical Nutrition, 2004. Based on a clinical pilot study.” F. 447. CX0034 is a similar advertisement. F. 466.

As the Commission stated in *Bristol Meyers*, not “every reference to a test necessarily gives rise to an establishment claim. The key, of course, is the overall impression created by the ad.” 1983 FTC LEXIS 64, at \*253. In CX0031 and CX0034, this small print, single reference to a study, particularly in the context of a qualified assertion that POM Juice “can” reduce plaque, is insufficient to conclude with confidence that a significant minority of reasonable consumers would interpret these advertisements to be claiming that POM Juice is “clinically proven” to be effective for heart disease. F. 446-447, 466-467. Moreover, the applicable extrinsic evidence does not support a conclusion that consumers would interpret these advertisements to be making a “clinically proven” claim. F. 579, 585. Accordingly, the evidence fails to demonstrate that these advertisements, which do make efficacy claims, convey the additional message that POM Juice’s efficacy is demonstrated by clinical proof. F. 448, 468, 585.

**d. Prostate cancer claims**

The evidence shows that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent, or reduce the risk of

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prostate cancer, by prolonging prostate-specific antigen (“PSA”) doubling time. F. 581. These advertisements typically communicate the claim by juxtaposing statements and representations that prostate cancer is a leading cause of death in men; antioxidants, such as those provided by the POM Products, may help prevent cancer; that PSA is an indicator of prostate cancer; that PSA doubling time is an indicator of prostate cancer progression; and that the POM Products have been shown in clinical testing to slow PSA doubling time. F. 310-318, 332, 334-336, 352-353, 371, 381, 389-392, 398, 400-405, 409, 429-430. Thus, similar to those advertisements found herein to have made heart disease claims, these advertisements specifically refer to prostate cancer, and connect both POM-provided antioxidants, and the study results, to effectiveness for prostate cancer. *Id.*

For example, CX1426 (Compl. Ex. I) (POMx Pill package insert) juxtaposes statements and representations that: (1) antioxidants fight free radicals, which may be linked to “serious health threats like cancer . . .”; (2) “Prostate cancer is the most commonly diagnosed cancer . . . and the second-leading cause of cancer death” among men in the United States; (3) POMx is a “time pill” because “stable levels of PSA,” which is defined for the reader as “prostate-specific antigens,” “are critical for men with prostate cancer,” and “[p]atients with quick PSA doubling times are more likely to die from their cancer”; (4) “[a]ccording to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. 83% of those who participated in the study showed a significant decrease in their cancer regrowth rate”; and (5) “basic studies” indicate POMx may have the same effects as POM Juice. F. 332, 334.

Similarly, the Prostate Newsletter (CX1426 (Compl. Ex. N)) states and represents that: (1) “Prostate cancer is the second leading cause of cancer related death in men in the United States . . . .”; (2) “risk factors” for prostate cancer include “diet,” and advises a diet that includes, among other things, “fruits rich in antioxidants”; (3) a “preliminary UCLA medical study” on 46 men treated for prostate cancer, showed that a majority of those consuming eight ounces of POM Juice daily “experienced a significantly extended PSA doubling time. Doubling time is an

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indicator of prostate cancer progression – extended doubling time may indicate slower disease progression”; testing on “patient” blood serum showed a decrease in “cancer cell proliferation,” and “increase in cancer cell death”; (4) in another study, “in vitro laboratory testing at UCLA showed that POMx significantly decreased human prostate cancer cell growth and increased cancer cell death”; and (5) POMx has the same active ingredients in POM Juice. F. 352-353. *See also* F. 311 (regarding CX0314, CX0372, CX0379, CX0380, representing, *inter alia*, that according to a published study on men treated for prostate cancer, those consuming POM Juice “experienced significantly slower” “PSA doubling times,” and that PSA “is a biomarker that indicates the presence of prostate cancer. ‘PSA doubling time’ is a measure of how long it takes for PSA levels to double. A longer doubling time may indicate slower progression of the disease”); F. 371, 380-381, 403-404, 409, 430.

**e. Erectile dysfunction**

The evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent or reduce the risk of erectile dysfunction (“ED”). F. 582. Respondents disseminated print advertisements that stated and represented, for example, that: (1) the superior antioxidants in the POM Products protect against free radicals, which can damage the body; (2) powerful antioxidants enhance the actions of nitric oxide in vascular endothelial cells, showing potential for management of “ED”; and (3) a preliminary study on “erectile function” showed that men who consumed POM Juice reported “a 50% greater likelihood of improved erections,” as compared to a placebo. F. 323-324. Similarly, in April 2009, the “Erectile Function” section of the health benefits webpage on pomwonderful.com reported that a 2007 “pilot” study, published in the *Journal of Impotence Research*, involving 61 male subjects with “mild to moderate erectile dysfunction,” showed that those men drinking eight ounces of POM Juice daily for four weeks were “50% more likely to experience improved erections.” F. 372. *See also* F. 380-381, 433-437. Presenting a study on “erectile function” showing “improved erections” is reasonably read to imply effectiveness for erectile dysfunction, particularly when juxtaposed to an express reference to

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management of “ED.” F. 323-325. *See also* F. 408 (response to the FAQ “Erectile Dysfunction” “Can pomegranate juice benefit men with erectile dysfunction?” stating, “Initial results linking POM Wonderful 100% Pomegranate Juice and erectile performance are promising. In a soon-to-be-published clinical study on men with erectile dysfunction, the group who consumed 8oz. of POM Juice daily experienced better erectile performance than the group who drank a placebo”). Moreover, as Respondents’ expert, Dr. Butters, acknowledged, contemporary speakers of American English could interpret the phrase “erectile function” to relate to the ability of men to achieve and maintain erections. Erectile function and the absence of erectile dysfunction are closely related. F. 537.

**f. Respondents’ arguments as to advertisement interpretation**

As noted above, the determination of whether any of the Challenged Advertisements conveyed the implied claims alleged in the Complaint is a question of fact. *Removatron*, 884 F.2d at 1496; *AHP*, 695 F.2d at 686; *Nat’l Urological Group*, 645 F. Supp. 2d at 1189; *QT*, 448 F. Supp. 2d at 957-58. As to those Challenged Advertisements found herein to have made the challenged claims, this factual question has been resolved against Respondents. This determination is based upon all the evidence, including full consideration and weighing of all the evidence, inferences, and arguments raised by Respondents in opposition to finding that the challenged claims were made. As to those Challenged Advertisements found herein to have made the challenged claims, Respondents’ opposing evidence, inferences and arguments, have been rejected as unpersuasive, unsupported, or otherwise outweighed by other evidence, including the overall net impression of the advertisements themselves. Respondents’ contentions that require further elaboration are discussed below.

Respondents contend that the challenged claims are not reasonably clear or conspicuous on the face of any of the Challenged Advertisements, and that Complaint Counsel failed to present any reliable extrinsic evidence showing that reasonable consumers would interpret the advertisements to make the alleged claims. Therefore, Respondents argue, Complaint Counsel failed to meet its burden of proving that the challenged claims were

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made. *See, e.g.*, RB at 71-74. Respondents accurately assert that Complaint Counsel did not offer a copy test on the Challenged Advertisements. Complaint Counsel also did not proffer any expert opinion or analysis of the Challenged Advertisements to demonstrate that reasonable consumers would interpret the Challenged Advertisements as making the alleged claims. F. 513. As to those Challenged Advertisements for which the alleged claims were not reasonably clear or conspicuous on the face of the advertisements alone, *see* F. 587-588; *see also* F. 585, such a copy test or expert analysis provided by Complaint Counsel might have made a material difference. However, the failure of Complaint Counsel to proffer such extrinsic evidence is not fatal to Complaint Counsel's case because, for those Challenged Advertisements found to have made the alleged claims, the claims are, in fact, apparent from the overall, common-sense, net impression, of the words and images of the advertisements themselves. F. 293, 299, 310, 325, 331, 338, 346, 351, 368, 387, 411, 417, 422, 429, 433, 443, 455, 463, 474. Moreover, Complaint Counsel adduced some extrinsic evidence relevant to consumer interpretation, albeit on cross-examination and rebuttal, which has also been considered. F. 579; *see, e.g.*, F. 527, 533-537, 540-541.

Respondents further contend that the Challenged Advertisements must be interpreted in the context of the purchase of food, or a food-derived product, as opposed to the purchase of a drug, and that when viewed from this perspective, the advertisements are not reasonably interpreted, including by a facial analysis alone, as conveying the claim that the POM Products "prevent," "treat," or "reduce the risk" of any disease. *See, e.g.*, RB at 72, 78-82. Respondents argue in the alternative that, to the extent consumers would interpret the Challenged Advertisements as claiming that the POM Products "may help prevent" or "reduce the risk" of heart disease, prostate cancer or erectile dysfunction, it is in the same sense that broccoli, a healthy diet, or exercise "reduce the risk" of disease, and not in the sense of a drug, with a single target of action. *Id.*; *see also* RRB at 20-22. Further, Respondents argue that to the extent reasonable consumers would interpret the Challenged Advertisements as making a "treatment" claim, it would not be in the sense of a substitute for medical treatment. RB at 72. Respondents fail to

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explain how such a limited interpretation is legally significant since such claims would still appear to be within the scope of the claims alleged in the Complaint. In any event, Dr. Butters, whose testimony Respondents cite, did not testify to the interpretation urged by Respondents. RB at 73-74, 78-82 (citing Butters, Tr. 2817-18, 2821). In the cited testimony, Dr. Butters opined that what people might infer with respect to a food product might be different than what they might infer with respect to a drug; that an advertisement promoting the consumption of food is far less likely to be interpreted by a reasonable consumer as conveying a treatment claim; and that the word “treatment” means medical treatment. *See* F. 491-492. Dr. Butters simply did not opine that consumers would interpret the Challenged Advertisements in the manner claimed by Respondents. Moreover, as noted above, the nature of the transaction (*i.e.*, the purchase of a food product or food-derived supplement) has been considered in determining the meaning of the Challenged Advertisements. With respect to those of the Challenged Advertisements for which the challenged claims were not reasonably clear or conspicuous on the face of the advertisements themselves, the opinions of Dr. Butters, set forth above, have been taken into account. As to other advertisements, the nature of the POM Products as food, or food-derived, was insufficient to outweigh the overall net impression that such advertisements conveyed the alleged claims. *See, e.g.*, F. 296, 305.<sup>8</sup>

Respondents argue that the Challenged Advertisements are not reasonably interpreted as making “broad” establishment claims, because they simply report study results, in a qualified manner with words such as “preliminary,” “promising,” “encouraging,” or “hopeful,” and are not reasonably interpreted as implying that the study results prove that the POM Products treat, prevent, or reduce the risk of disease. *See, e.g.*, RB at 75-82; RRB at 10-15. However, in the context of the Challenged Advertisements found to have made establishment claims, the foregoing language fails to materially alter the overall net impression that such advertisements were claiming clinical proof.

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<sup>8</sup> The nature of the POM Products as food, or food-derived, is relevant to, and is considered in connection with, the substantiation analysis in Section III.F.2, *infra*.

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*E.g.*, F. 300-301, 312, 333, 342, 349-350, 354; *see also* F. 519 (Dr. Stewart opining that the typical consumer would likely have little understanding of what “initial” or “pilot” means, particularly in the context of being referred to as having been published in a major journal).

Similarly, Respondents assert that advertising that a study on POM Juice showed “prolongation of PSA doubling times” does not convey the claim that POM Juice has been clinically proven to treat, prevent, or reduce the risk of “prostate cancer,” and that advertising a study that POM Juice consumption resulted in “significant reduction of . . . arterial plaque” or “improvement in blood flow” does not convey a claim of clinical proof of prevention, treatment, or reduction of the risk of “heart disease.” RRB at 10. However, as explained above, those of the Challenged Advertisements found to have made “clinically proven” claims expressly referred to “heart disease,” *e.g.*, F. 294, 301, 348, 374, 407, 414, “prostate cancer,” *e.g.*, F. 334, 352, 381, 403, and “erectile dysfunction,” F. 408, 413, or “erectile function” together with the phrase, “ED,” F. 324, 434, and drew a logical connection for the reader, including through associated explanatory text, between the study results and effectiveness for the referenced maladies. *E.g.*, F. 301-303, 323-325, 348-350, 353, 374, 379-380, 414. Thus, in the context of these advertisements, reasonable consumers would readily infer that the study results constituted clinical proof of effectiveness for the referenced maladies.

In addition, contrary to Respondents’ argument, the preponderance of the evidence does not support a finding that the use of qualified language, such as “may” or “can” necessarily prevents communication of a more definitive claim. To the extent Dr. Butters opined to this effect, *see* F. 497, that opinion is rejected as unsupported and inconsistent with common-sense. First, there is academic literature in the record indicating that qualifiers such as “can,” “could,” “might,” or “up to” can create the inference of a stronger claim. F. 589. Moreover, whether a consumer will interpret “may” or “can” to mean “will” depends on the context, and the totality of the advertisement. F. 527.

Finally, Respondents contend that interpreting any of the Challenged Advertisements to make the alleged claims ignores

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the role of humor, parody, or hyperbole present in Respondents' advertising. Notwithstanding Dr. Butters' opinion on this issue, F. 487-489, the preponderance of the evidence demonstrates that humor, parody, or hyperbole within an advertisement does not necessarily "block" communication of a serious message within that advertisement. Rather, as Dr. Butters acknowledged, parody and humor have the effect of capturing the attention of the advertisement viewer, to help the viewer connect with the message in the printed portion of the advertisement. F. 534. Humor can induce further processing of an advertisement and a search for further information. F. 535. While readers may discount puffery and hyperbole as an exaggeration, the fact that puffery and hyperbole are not to be taken literally does not mean that advertisements using such elements cannot convey a serious claim. F. 532-533. Thus, the fact that a number of the Challenged Advertisements found to have made the alleged claims made partial use of humor or hyperbole is insufficient, in the context of the other elements of those advertisements, to prevent conveying the challenged claims. *See, e.g.*, F. 300-301, 320, 327, 464, 476.<sup>9</sup>

## **F. Whether the Challenged Claims are False or Misleading**

### **1. Overview of applicable legal standards**

Having found that Respondents disseminated advertisements making the claims alleged in the Complaint, the next step is to

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<sup>9</sup> Respondents' contention that the evidence fails to show the date that certain advertisements were disseminated is moot, to the extent that, with one exception, such advertisements are not among those found to have made the challenged claims. *See* RFF 2252. As to that exception, CX0314, the evidence shows that this advertisement was disseminated in 2008. F. 307. Respondents' further contention that some advertisements found herein to have made the challenged claims are "outliers" that cannot support an injunctive order is addressed in Section III.H, *infra*, with respect to remedy. Finally, Respondents assert that certain advertisements should be eliminated from consideration because of an alleged admission by Complaint Counsel's rebuttal expert on marketing and market research, Dr. Michael Mazis, (F. 279-283) that such advertisements were not being challenged. Having fully reviewed the testimony and Dr. Mazis' report in this regard, that assertion is rejected as unsupported by the evidence.

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determine whether the claims are false or misleading. *Kraft*, 970 F.2d at 314; *Pantron I Corp.*, 33 F.3d at 1095; *Direct Marketing Concepts*, 569 F. Supp. 2d at 297. Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the “falsity” theory or (2) the “reasonable basis” theory. *Pantron I*, 33 F.3d at 1096; *Thompson Medical*, 1984 FTC LEXIS 6, at \*380-81. Complaint Counsel contends that Respondents’ claims are deceptive because they are both “false” and “unsubstantiated.” CCB at 36. Notwithstanding Complaint Counsel’s contention, as further explained below, the issue of whether Respondents’ claims were deceptive turns on the nature and quality of Respondents’ substantiation, and, therefore, “the falsity and reasonable basis theories collapse into the same inquiry: did [Respondents] possess adequate substantiation to make such a claim?” *QT, Inc.*, 448 F. Supp. 2d at 966.

The Complaint charges that Respondents have represented that clinical studies, research, and/or trials prove that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction, when in fact, studies, research and/or trials do not prove such claims, and, therefore, Respondents’ representations are false or misleading. Complaint ¶¶ 12-18. Complaint Counsel refers to these claims as “false establishment claims.” CCB at 20-24. The Complaint also charges that Respondents represented that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction without a reasonable basis to substantiate those representations. Complaint ¶¶ 19-21. Complaint Counsel refers to these charges as “unsubstantiated efficacy claims.” CCB at 25-26.

Establishment claims are those that contain representations regarding the amount and type of evidence the advertiser has for its product claims. *In re Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 259, at \*55 (Dec. 24, 2009); *Direct Marketing Concepts*, 569 F. Supp. 2d at 298 (citing FTC Policy Statement on Advertising Substantiation, appended to *Thompson Medical*, 104 F.T.C. at 839, 1984 FTC LEXIS 6, at \*434). The establishment claim theory “is based on the straightforward notion that when an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim

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false.” *Sterling Drug*, 1983 FTC LEXIS 66, at \*436. Common examples of establishment claims include statements such as “tests prove,” “doctors recommend,” or “studies show.” *Direct Marketing Concepts*, 569 F. Supp. 2d at 298-99 (citing Policy on Advertising Substantiation; *Thompson Medical*, 791 F.2d at 194) (other citations omitted). Complaint Counsel bears the burden of demonstrating that the level of support represented by Respondents was false, *i.e.*, that Respondents did not have the amount and type of substantiation they claimed to have had. See *Sterling Drug*, 1983 FTC LEXIS 66, at \*437; *Thompson Medical*, 791 F.2d at 194; *Bristol-Meyers*, 1983 FTC LEXIS 64, at \*252.

Non-establishment claims, or “efficacy claims,” are those about a product’s attributes, performance, or efficacy, without indicating any particular level of support for such claim. *Thompson Medical*, 1984 FTC LEXIS 6, at \*368; *Removatron* 884 F.2d at 1492 n.3 (“‘Non-establishment’ claims are statements to the effect that a product works.”). Under the reasonable basis theory of deception, because claims about a product’s attributes, performance, or efficacy carry with them the express or implied representation that the advertiser had a reasonable basis substantiating such claims, failure to have a reasonable basis for the claim is deceptive or misleading. *Pantron I*, 33 F.3d at 1096; *QT, Inc.*, 448 F. Supp. 2d at 959-60; *Direct Marketing Concepts*, 569 F. Supp. 2d at 298; *Thompson Medical*, 1984 FTC LEXIS 6, at \*367; *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*222 (Initial Decision). Under the reasonable basis theory, the government has the burden of proving by a preponderance of evidence that the Respondents did not have a reasonable basis for asserting that the challenged claims are true. *Pantron I*, 33 F.3d at 1096; *QT, Inc.*, 448 F. Supp. 2d at 959; *Thompson Medical*, 1984 FTC LEXIS 6, at \*379. Thus, as to both the alleged “false establishment claims” and the alleged “unsubstantiated efficacy claims,” proof of deception requires proof that Respondents’ substantiation failed to meet the level of substantiation required.

The district court in *FTC v. QT, Inc.* described the shifting burdens as follows:

[T]he Court must first determine what level of substantiation Defendants were required to have for their advertising claims, and this determination is a question of

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fact. Then, the Court must determine whether Defendants possessed that level of substantiation. . . . Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that Defendants' purported substantiation is inadequate, and the FTC need not conduct or present clinical studies showing that the product does not work as claimed.

448 F. Supp. 2d at 959 (citations omitted).

For efficacy claims, the Commission, in *Thompson Medical*, held that determining the appropriate level of substantiation requires weighing the following factors: (1) the product involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; (5) the consequences of a false claim; and (6) the amount of substantiation experts in the field would agree is reasonable. 1984 FTC LEXIS 6, at \*387 (citing *In re Pfizer, Inc.* No. 8819, 81 F.T.C. 23, 1972 FTC LEXIS 13, at \*91 (July 11, 1972)). Those factors, known as the “*Pfizer factors*,” have been applied to determine the appropriate level of substantiation for non-establishment claims in numerous cases since *Pfizer* was decided. *E.g.*, *Direct Marketing Concepts*, 569 F. Supp. 2d at 299 (citing *Removatron*, 884 F.2d at 1492 n.3); *QT, Inc.*, 448 F. Supp. 2d at 959 (citing Policy on Advertising Substantiation).

For establishment claims, the Commission does not require application of the *Pfizer* factors to determine the required level of substantiation, on the theory that the advertiser must be held to whatever level of substantiation is represented in the advertisement. *In re Removatron Intl Corp.*, No. 9200, 111 F.T.C. 206, 1985 FTC LEXIS 21, at \*190 (Sept. 30, 1985); *Thompson Medical*, 1984 FTC LEXIS 6, at \*387 n.59. If an advertisement represents that a particular claim has been scientifically established, the advertiser must possess a level of proof sufficient to satisfy the relevant scientific community of the claim's truth. *Removatron*, 1985 FTC LEXIS 21, at \*191 (citing *Thompson*, 104 F.T.C. at 821-22 n.59; *Bristol-Meyers*, 102 F.T.C. at 321, 331).

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Complaint Counsel charges that Respondents knew that their scientific studies were insufficient to support their efficacy and establishment claims. CCB at 3. *See also e.g.*, CCB at 41 (Complaint Counsel contending that Respondents “recognize[d] that they lack[ed] proof that the POM Products prevent or treat” heart disease). However, any opinions Respondents may have had regarding the adequacy of their substantiation do not constitute expert opinion on what “experts in the field would agree is reasonable” or on whether “the level of proof [relied upon is] sufficient to satisfy the relevant scientific community of the claim’s truth.” Accordingly, such evidence is not material or probative to the issue of whether Respondents possessed an adequate level of substantiation.

With these generally applicable principles in mind, to determine whether the challenged claims are false or misleading, it must first be determined what level of substantiation Respondents were required to have for their advertising claims. *QT, Inc.*, 448 F. Supp. 2d at 959. This determination is a question of fact to be determined based upon the evidence adduced at trial. *QT, Inc.*, 448 F. Supp. 2d at 959; *FTC v. Braswell*, CV 03-3700 DT, 2005 U.S. Dist. LEXIS 42976, at \* 35 (C.D. Cal. 2005). Next, it must be determined whether Respondents possessed that level of substantiation. *QT, Inc.*, 448 F. Supp. 2d at 959. Respondents have the burden of establishing what substantiation they relied on for their product claims. *Id.* Complaint Counsel has the burden of proving that Respondents’ purported substantiation is inadequate. *Id.*

## 2. Appropriate level of substantiation generally

A review of the briefs in this case reveals that there is no dispute that the appropriate level of substantiation is “competent and reliable scientific evidence,” both for Respondents’ establishment claims and for Respondents’ efficacy claims. The parties’ dispute centers upon what constitutes “competent and reliable scientific evidence.” *See, e.g.*, CCB at 2-3, 30, 40; CCRB at 18; RB at 32-38.

Complaint Counsel asserts that competent and reliable scientific evidence must include “RCTs,” which experts define as well-designed, well-conducted, randomized, double-blind,

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placebo-controlled human clinical trials, (F. 608) in order to provide adequate substantiation for both the alleged establishment claims and efficacy claims in this case. CCB at 32; CCRB at 18. Respondents dispute this notion, asserting that, in examining the totality of the evidence, basic science and “pilot” studies, not just RCTs, can be relied upon as competent and reliable evidence. RB at 32-38. “Basic science” refers to test-tube (*in vitro*) studies, *in vivo* animal studies, and pre-clinical research. F. 593.

As explained below, neither the FTC Act nor applicable case law imposes a requirement of RCTs to substantiate all “health-related efficacy claims,” as urged by Complaint Counsel. CCB at 32. Rather, and as Complaint Counsel’s cited cases make clear, the determination of the appropriate level of substantiation is a question of fact to be determined based upon the expert testimony adduced at trial. *QT, Inc.*, 448 F. Supp. 2d at 959; *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at \*35.

**a. RCTs are not a legal requirement**

In its Post-Trial Brief, Complaint Counsel asserts that “[c]ourts have consistently found or upheld that double-blind, randomized, placebo-controlled trials (“RCTs”) are required to provide adequate substantiation for the truthfulness of health-related claims.” CCB at 32. As a matter of law, “[n]othing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies.” *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008). Further, contrary to Complaint Counsel’s assertion, the cases upon which Complaint Counsel rely do not compel a conclusion that RCTs are required.

Complaint Counsel cites *FTC v. Direct Marketing Concepts, Inc.*, 569 F. Supp. 2d at 303, for the proposition that double-blind, placebo controlled studies are required to substantiate health-related efficacy claims. Although the district court in *Direct Marketing* stated, “it seems well-accepted that double-blind, placebo-controlled studies are necessary to substantiate health-related efficacy claims,” *id.* at 303, the First Circuit Court of Appeals, when reviewing the district court’s opinion, expressly noted that while the FTC had argued and produced expert testimony that the claims at issue should be substantiated by double-blind, placebo-controlled studies, “there may be other

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scientific evidence that could be sufficient, and we may assume for these purposes that a double-blind study is not necessarily required.” *FTC v. Direct Marketing Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010).

Complaint Counsel next cites *National Urological Group*, 645 F. Supp. 2d at 1202-03. However, in that case, which was before the court on the FTC’s motion for summary judgment, the court did not hold that claims for erectile dysfunction “required” double-blind placebo-controlled studies, as Complaint Counsel suggests. Instead, the court stated, “what constitutes competent and reliable scientific evidence in this case is a question of fact for expert interpretation.” *Id.* at 1190. In *National Urological Group*, the expert testimony was undisputed that the erectile dysfunction claims made in that case required well-designed, placebo-controlled, randomized, double-blind clinical trials for substantiation. Because the “defendants ha[d] not countered the testimonies of the FTC’s expert regarding what level of substantiation is required for the claims made,” the court concluded that there was no genuine dispute of fact on the requisite level of substantiation. *Id.* at 1202. In the instant case, by contrast, expert testimony on whether RCTs are required was clearly disputed and conflicting.

In *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, also cited by Complaint Counsel, defendants advertised the dietary supplements Lung Support Formula, AntiBetic Pancreas Tonic and Gero Vita GH3, one of which was advertised as a substitute for medical treatments. *Id.* at \*4, \*20-21 (AntiBetic). The court found that, by offering unrefuted evidence that the standard should be double-blind, placebo-controlled tests, the FTC had offered sufficient evidence to withstand summary judgment. *Id.* at \*35. The court further noted that the ultimate determination of the level of substantiation required would be determined by the court based upon the evidence at trial. *Id.*

Complaint Counsel also relies on *Removatron*, 884 F.2d 1489 (1st Cir. 1989), where the Court of Appeals upheld the Commission’s determination that a well-controlled scientific study was necessary to substantiate the respondent’s claims that a radio frequency energy hair removal device would permanently remove hair. *Id.* at 1498. The court explained the basis for its

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holding as follows: “The FTC’s expert, Dr. Van Scott, testified that, in this field, at least one well-controlled test would be needed to establish a permanency claim. He also testified that two tests would be better and three superb. The ALJ found that petitioners needed two well-controlled tests in order to establish their claims; the Commission decided one was sufficient. Thus, petitioners needed to present evidence that they possessed at least one well-controlled scientific study that supported their permanency claim.” *Id.* Since the only substantiation evidence in that trial was a single experiment which, according to the doctor who conducted it, did not actually demonstrate permanent hair removal, the respondent’s substantiation was found to be inadequate. *Id. Removatron*, therefore, is consistent with the requirement that the appropriate level of substantiation is determined by the evidence, and does not hold that RCTs are required as a general matter.

Additionally, in another case relied upon by Complaint Counsel, *Thompson Medical* 1984 FTC LEXIS 6, which involved an arthritis medication, Aspercreme, the Commission evaluated the efficacy of an over-the-counter analgesic drug, utilizing the six *Pfizer* factors, to conclude that the proper level of substantiation was two well-controlled clinical tests. 1984 FTC LEXIS 6 at \*291, 398. However, there the Commission also noted, “we do not preclude ourselves from also permitting advertisers to use other types of evidence to comply with our substantiation requirement.” *Id.* at \*399.

Finally, Complaint Counsel relies on *QT, Inc.*, 448 F. Supp. 2d at 961. In determining the appropriate level of substantiation in that case, the court stated at the outset: “The Court must first determine what level of substantiation Defendants were required to possess for [the claim that an ‘ionized’ bracelet was proven, by scientific tests, to provide immediate pain relief]. *This is a question of fact.*” *Id.* (emphasis added). The expert testimony in that case was that “at least one well-conducted, placebo-controlled, randomized, double-blind or sham-controlled clinical trial would be required by qualified experts in the field of pain due to rheumatic disease to support a claim that a product relieves or treats musculoskeletal pain,” and that “a placebo-controlled, randomized, double-blind trial is the gold standard in the

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scientific community and depending on the claims an advertiser wishes to make, such a gold-standard study should be attempted to support those claims.” *Id.* at 961-62. The court concluded that “with medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted.” *Id.* at 962. On appeal, the court expressly rejected the notion that RCTs are required as matter of law, stating: “Placebo-controlled, double-blind testing is not a legal requirement for consumer products.” *QT, Inc.*, 512 F.3d at 861. Thus, *QT* does not stand for the proposition that RCTs are necessarily required, but is consistent with the proposition that the appropriate level of substantiation is determined by what the evidence shows that experts in the relevant field would deem adequate.

**b. Summary of expert testimony on the appropriate level of substantiation**

Detailed findings of fact on the expert testimony adduced at trial on the appropriate level of substantiation are set forth in Section II.F, *supra*. In summary, Complaint Counsel’s experts in the fields of antioxidants and epidemiology (Dr. Meir Stampfer), heart disease (Dr. Frank Sacks), prostate cancer (Dr. James Eastham), and erectile dysfunction (Dr. Arnold Melman) each separately opined on the level of substantiation they would expect, as experts in their respective fields, to support claims that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, and claims that Respondents’ clinical research proves such benefits. These experts all testified that well-designed, well-conducted RCTs showing statistically and clinically significant improvements in valid endpoints are necessary to make claims that: (1) the Challenged Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction; or (2) studies show that the Challenged Products treat, prevent, or reduce the risk of heart disease, prostate cancer, and/or erectile dysfunction. F. 626, 638, 648, 654.

Respondents’ experts in the fields of the design of clinical research protocols (Dr. Denis Miller), nutrition (Dr. David Heber), cardiovascular health (Dr. Dean Ornish), urology and prostate health (Dr. Jean deKernion), and urology and sexual

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medicine (Dr. Arthur Burnett and Dr. Irwin Goldstein) offered rebuttal to Complaint Counsel's experts' testimony. Dr. Miller testified that Respondents do not need RCTs to substantiate POM's claims because the POM Products are absolutely safe, pure fruit products and Respondents have not suggested that the Challenged Products be used as substitutes for conventional medical treatment. F. 661; *see also* F. 662-670. Dr. Heber opined that experts in nutrition evaluate whether competent and reliable science supports health claims for safe, pure fruit products, such as pomegranate juice, based on the totality of evidence, which does not necessarily include RCTs. F. 671-673. Dr. Ornish testified that, in a nutritional context, *in vitro* and animal studies may be more effective in testing the efficacy of a nutrient and that the totality of Respondents' scientific evidence must be considered in evaluating cardiovascular health claims, which need not be substantiated by expensive RCTs. F. 674; *see also* F. 675-679. Dr. deKernion testified that in the case of a fruit juice, which has low or no toxicity, it is not necessary to use an RCT. F. 682. Dr. Burnett opined that a safe pure fruit juice, like pomegranate juice, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate health claims. F. 683. Dr. Goldstein testified that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health. F. 685-686.

**c. Overview as to the appropriate level of substantiation**

**i. Expert testimony does not establish that RCTs are required in this case**

The expert testimony in this case demonstrates that competent and reliable scientific evidence is required for claims about nutritional supplements when such products are advertised to treat diseases or medical conditions. *E.g.*, F. 662, 711, 964. *See also Daniel Chapter One*, 2009 FTC LEXIS 157, at \*233-35 (Initial Decision) (summarizing expert testimony and citing *Natural Solution*, 2007 U.S. Dist. LEXIS 60783, at \*11-12; *National Urological Group*, 645 F. Supp. 2d at 1190; *Direct Marketing Concepts*, 569 F. Supp. 2d at 300, 303). The greater weight of the persuasive expert testimony adduced at trial does not, however, support Complaint Counsel's position that, in order to have the

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required competent and reliable scientific evidence, Respondents must have had RCTs. F. 706, 707. Instead, the more persuasive expert testimony shows that RCTs are needed for a nutrient supplement if one makes a claim that the product causes the effect of treating, preventing, or reducing the risk of a disease and one offers the nutrient supplement as a replacement to medical care to treat, prevent, or reduce the risk of diseases. F. 706. The evidence further shows that RCTs are not required to convey information about a food or nutrient supplement where, as here, the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice. F. 707.

**ii. Expert testimony on the appropriate level of substantiation**

Having determined that RCTs are not required in this case, the next step is to determine what level of substantiation Respondents were required to have for their advertising claims. *QT, Inc.*, 448 F. Supp. 2d at 959. As stated above, for efficacy claims, the appropriate level is determined by weighing the six *Pfizer* factors, one of which is “the amount of substantiation experts in the field would agree is reasonable.” *Thompson Medical*, 1984 FTC LEXIS 6, at \*387. For establishment claims, the appropriate level of substantiation is determined by what would “satisfy the relevant scientific community that the claim[s are] true.” *Removatron*, 111 F.T.C. at \*246, 1985 FTC LEXIS 21 at \*195.

As asserted by Complaint Counsel, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31. Experts in the relevant scientific communities would require the same level of evidence to support claims that a product treats, prevents, or reduces the risk of a disease or dysfunction, as they would require to support claims that clinical studies, research, or trials prove the same claims. *E.g.*, F. 713. All four of Complaint Counsel’s experts in the relevant fields applied the same standards in evaluating Respondents’ level of substantiation without regard to whether the claims at issue were “clinically proven” establishment claims or whether the claims at issue were efficacy claims without reference to any studies. *E.g.*, F. 190, 199, 207, 214. As

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discussed below, the experts, including Complaint Counsel's experts, considered evidence relating to the nature of the product, the nature of the claim, and the feasibility of conducting RCTs. *See* F. 688-705. Thus, while application of the *Pfizer* factors is not necessarily required, because the experts considered essentially the same factors in determining the "proof sufficient to satisfy the relevant scientific community of the claim's truth" (*Removatron*, 1985 FTC LEXIS 21 at \*190), and because, with respect to Respondents' heart disease claims, Respondents did make non-establishment claims, a review of the *Pfizer* factors is appropriate.

Under *Pfizer*, "the amount of substantiation experts in the field would agree is reasonable," is one of six factors that must be evaluated to determine the appropriate level of substantiation for non-establishment claims. *Thompson Medical*, 1984 FTC LEXIS 6, at \*387. That evaluation is discussed in the three subsequent sections of the Initial Decision specific to what experts in each of the relevant fields believe to be reasonable substantiation for claims regarding heart disease, prostate cancer, and erectile dysfunction, respectively. The remaining five *Pfizer* factors are applicable in determining the required level of substantiation regardless of the relevant field, and are, therefore, addressed below as a preliminary matter, before the evaluation of the evidence on what experts in the fields of heart disease, prostate cancer, and erectile dysfunction would agree is reasonable substantiation. Those five *Pfizer* factors, analyzed below, are: (1) the products involved; (2) the type of claim; (3) the benefits of a truthful claim; (4) the ease of developing substantiation for the claim; and (5) the consequences of a false claim. *Thompson Medical*, 1984 FTC LEXIS 6, at \*387.

**(a) The products involved**

The POM Products are either food products or dietary supplements wholly derived from the pomegranate fruit. F. 57-58, 61, 67, 70-71. POM Juice is produced by pressing the whole fruit containing both arils (pomegranate berries) and the peel (husk) and internal membrane. F. 57-58. POMx is an extract from the pomegranate, made through a process by which POMx Liquid is first derived from the whole fruit, and then POMx is

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extracted from the POMx Liquid. F. 67, 70. POM Juice is sold in the refrigerated produce section of grocery stores. F. 65.

Pomegranate juice and its extract have a “high degree” of safety and are safe for human consumption. F. 78. Humans have consumed pomegranates for centuries as a safe and nutritious food. F. 77. The U.S. Food and Drug Administration (“FDA”) identifies pomegranate as being “generally recognized as safe” for human consumption. F. 82, 84; *see* 32 U.S.C. § 231(s). To establish such recognition, it must be shown that there is a consensus of expert opinion regarding the safety of the use of the substance. 21 C.F.R. § 170.30(a); *see* F. 83. Respondents’ expert, Dr. Heber, confirmed that pomegranate juice has no adverse side effects, in contrast to drugs. F. 85-88.

Complaint Counsel’s expert, Dr. Sacks, testified that the issue of the safety of the POM Products was not within the scope of his assignment in this case, that his expert report contains no opinions on the safety of the POM Products, and that he has “no opinion about whether [the POM Products are] safe or not.” F. 93. Complaint Counsel’s expert, Dr. Stampfer, admitted that there are no safety concerns with consuming pomegranate juice apart from “the usual harm that comes with fruit juice, sugary beverages . . . but that is not specific to pomegranate juice.” F. 94.

Scientific studies also confirm that POM Juice and POMx are safe for human consumption. F. 87, 88. Researchers validated the safety of POMx Pills in a clinical study where no adverse events or changes in blood count, serum chemistry or urinalysis were observed in the human subjects after consuming the extract for four weeks. F. 92. Researchers confirmed in a clinical study that the consumption of pomegranate juice had no drug interaction in the human volunteers. F. 91.

Complaint Counsel’s experts agreed that the level of scientific evidence required to support a claim considers the product being promoted. F. 695. The greater weight of the persuasive expert testimony is that RCTs are needed for pharmaceutical drugs to assess safety and efficacy because pharmaceutical drugs are unnatural, developed in laboratories, and have toxicities. F. 666, 675, 682, 686, 696. Pharmaceutical drugs, which are not known to be safe and always have toxicities and side effects, are held to a

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higher standard than a juice that is derived from a fruit that has been around for thousands of years. F. 666, 675, 682, 686, 697. Complaint Counsel's expert, Dr. Sacks, testified that you do not need RCT trials to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. F. 645. Complaint Counsel's expert, Dr. Stampfer, conceded that RCTs are not required (or better) for nutritional-based research and admitted that he has made public statements or recommendations that food and beverage products lower the risk of certain diseases in the absence of RCTs. F. 631, 632.

The standard applied to new drugs should not be applied to nutrients as long as the product is not claimed to be a substitute for conventional drug therapies or medical care and is shown to be safe. F. 666, 682, 697, 698. Thus, the facts that the POM Products are derived from a fruit and are known to be safe weigh in favor of a standard for substantiation that is less than that required for pharmaceutical drugs.

**(b) The type of claim**

The type of claim Respondents have been found to have made – that the POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction and that the POM Products are clinically proven to do so – weighs in favor of a high standard for substantiation. Where defendants make a “medical, health-related claim, . . . such a claim must be based on a heightened level of substantiation.” *QT*, 448 F. Supp. 2d at 962. In *QT*, where the expert testimony established that “a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted,” the court held that “Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim.” *QT*, 448 F. Supp. 2d at 962. In addition, where defendants claim that a product's efficacy has been “test-proven,” such a statement must be substantiated by “a reliable test” with “statistically significant results achieved.” *QT*, 512 F.3d at 862; *Removatron*, 884 F.2d at 1498 (“reasonable basis” for establishment claims meant well-controlled scientific studies).

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While Respondents here have been found to have made claims that the POM Products treat, prevent, or reduce the risk of diseases or dysfunction, it is significant to note that Respondents did not advertise or market the POM Products as an alternative to medical treatment. “The Complaint does not allege, and it is neither Complaint Counsel’s contention nor its burden, to demonstrate that Respondents are selling the POM Products as a substitute for conventional medical treatment.” CCRB at 40 n.36.

The greater weight of the persuasive expert testimony in this case confirms that the appropriate level of substantiation depends on the claims. If the claim does not suggest that an individual should forgo conventional medical care or treatment based on the consumption of a safe product and does not imply that a causal link between the product and the effect has been established, then evidence short of RCTs can be sufficient. F. 631, 707. Complaint Counsel’s expert, Dr. Stampfer, testified that if, for example, nuts are not being offered as a substitute to medical care, and the claim is that there is some evidence to suggest the possibility that nuts may reduce the risk of diabetes, then evidence short of RCTs can support that claim. F. 631. While claims of efficacy can be made only when a causal relationship with human disease is established by competent and reliable scientific evidence (F. 627; *see also* F. 629-631), based on the evidence and the law as applied to this case, competent and reliable scientific evidence does not mean RCTs.

**(c) The benefits of a truthful claim and the ease of developing substantiation for the claim**

“These two factors -- the benefits of a truthful claim and the ease of developing substantiation for the claim -- are typically considered together.” *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*232-33 (Initial Decision). “The consideration of these factors seeks to ensure that the level of substantiation required is not likely to deter product development or prevent disclosure of potentially valuable information about product characteristics to consumers.” *Id.* at \*233 (citing *Removatron*, 1985 FTC LEXIS 21, at \*212 n.20; *Thompson Medical*, 104 F.T.C. at 823-24, 1984 FTC LEXIS 6, at \*391).

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The fact that individuals could benefit from truthful claims about a product's ability to treat, prevent, or reduce the risk of diseases or medical conditions is obvious. Complaint Counsel's expert, Dr. Stampfer, conceded that he "believe[s] that it may be appropriate to use evidence short of an RCT for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." F. 631. Dr. Stampfer further testified that the failure to act, in the absence of conclusive RCT evidence, increases the risk of forgoing benefits to the public that might have been achieved with little risk and little cost and that one should "definitely" make that potential benefit available to the public rather than withhold it. F. 633. Although advertising is not a "public health recommendation," it does convey a message and provides "potentially valuable information" about products. *Thompson Medical*, 1984 FTC LEXIS 6, at \*391.

In a nutritional context, RCTs are prohibitively expensive and often not feasible because of the costs of conducting them. F. 632, 647, 673, 704. Complaint Counsel's expert, Dr. Eastham, testified that disease prevention studies should involve ten to thirty thousand participants which are "incredibly expensive" and in the range of \$600 million. F. 704. Foods, unlike pharmaceutical drugs, are not patentable, and manufacturers cannot recoup the costs of conducting RCTs through profits from exclusive intellectual property rights. F. 705.

Complaint Counsel's expert, Dr. Sacks, acknowledged that RCTs may also not be feasible because of logistical and ethical considerations. F. 641, 704. In studying a fruit or food, it is difficult to do double-blind, randomized, placebo-controlled trials because the subjects know what they are consuming. F. 641, 679, 703. Once a participant is assigned to the control group and they know what the intervention is, the participant can consume the food or juice anyway, whereas one would not be able to do so with an experimental drug. F. 703. Moreover, in a nutritional context, a hypothesis about disease causation can rarely, if ever, be directly tested in humans using the RCT design. F. 701.

The greater weight of the persuasive expert testimony in this case leads to the conclusion that where the product is absolutely

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safe, like the POM Products, and where the claim or advertisement does not suggest that the product be used as a substitute for conventional medical care or treatment, then it is appropriate to favor disclosure. See F. 633, 709; see also *Pearson*, 164 F.3d at 657 (under the First Amendment commercial speech doctrine, there is a “preference for disclosure over outright suppression”).

**(d) The consequences of a false claim**

The consequences of a false claim do not compel requiring a high level of substantiation. As analyzed above, there is no evidence to suggest, and Complaint Counsel does not argue, that Respondents urge individuals to consume the POM Products in place of conventional medical treatment. CCRB at 40 n.36. Compare *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*234, \*282 (Initial Decision) (finding that where representations in some instances suggested that individuals forego traditional cancer treatments in favor of purchasing and consuming the challenged products and evidence showed that foregoing a proven cancer treatment in favor of an ineffective treatment would be injurious to a patient’s health, the consequences of a false claim required a higher level of substantiation). Moreover, the evidence shows that the POM Products are safe. F. 77-78. See also F. 94.

In *Pearson v. Shalala*, 164 F.3d 650, 656 n.6 (D.C. Cir. 1999), the court of appeals explained that courts should distinguish between products (e.g., dietary supplements) that do not “in any fashion threaten consumer’s health and safety” and “drugs,” “wherein the potential harm presumably is much greater,” when evaluating restrictions on commercial speech. The court in *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002) further explained:

It is especially important to recognize that, in the present case, the potential harm to consumers from deception is severely limited . . . At worst any deception resulting from Plaintiffs’ health claim will result in consumers spending money on a product that they might not otherwise have purchased.

*Id.* at 16 (noting also that the economic injury is not insignificant).

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Spending money on an ineffective remedy is considered an economic injury for purposes of this *Pfizer* factor. *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*234 (Initial Decision) (citing *In re Schering Corp.*, No. 9232, 1991 FTC LEXIS 427, at \*134 (Sept. 16, 1991)); *Removatron*, 1985 FTC LEXIS 21, at \*212 n.20). In this case, for the 52 weeks ending July 20, 2008, the weighted average base price per unit for POM Juice was \$2.93 for an 8-ounce bottle or \$4.29 for a 16-ounce bottle. F. 97. A serving size of POM Juice is eight ounces and, thus, a one year supply costs at least \$780. *See* F. 64, 97. A one year supply of POMx costs approximately \$315. *See* F. 97. Although the cost of the POM Products may not be insignificant, when you take into account the fact, at least with respect to POM Juice, that consumers are buying what is considered to be a premium fruit juice (F. 95), the economic injury to consumers is not a material factor in determining the required level of substantiation.

**(e) The amount of substantiation experts in the field would agree is reasonable**

The last of the six *Pfizer* factors, the amount of substantiation experts in the field would agree is reasonable, must be examined in relation to each field being evaluated. In addition, for Respondents' claims that were establishment claims only, Respondents must "satisfy the relevant scientific community that the claim is true." *Removatron*, 1985 FTC LEXIS 21, at \*195. Accordingly, the amount of substantiation experts would agree is reasonable, the amount of evidence that would satisfy the relevant scientific community, and whether Respondents possessed that level of substantiation in regard to each of the three diseases or dysfunction, is evaluated in the following three sections of the Initial Decision.

**3. Substantiation for Respondents' heart disease claims**

**a. Overview**

As discussed in Section III.E.2.c, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease and, in many of these same

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advertisements, are clinically proven to do so, by lowering blood pressure, reducing arterial plaque and/or increasing blood flow to the heart. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of heart disease; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of heart disease. CCB at 37-44.

**i. Summary of expert opinions**

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. Meir Stampfer and Dr. Frank Sacks. Dr. Stampfer is a Professor of Epidemiology and Nutrition, Harvard School of Public Health; Faculty Member, Division of Biological Sciences, Harvard School of Public Health; Professor of Medicine, Harvard Medical School; and Faculty Member, Dana Farber Harvard Cancer Center. F. 182. Dr. Stampfer has been an investigator in several large studies focused on the relationship between nutrition and cardiovascular disease and has published more than 850 articles in medical journals. F. 183,184. Dr. Sacks is a Professor of Cardiovascular Disease Prevention, Department of Nutrition, Harvard School of Public Health, and Professor of Medicine, Harvard Medical School. F. 191. Dr. Sacks has researched cardiovascular disease ("CVD") and coronary heart disease ("CHD") and their risk factors, including lipid profiles, hypertension, obesity, and diabetes, and the effects of potential risk-modifying diets, foods, food components, and drugs. F. 192. Dr. Sacks has published more than 160 articles in peer-reviewed scientific journals relating to CVD, CHD, and the relationship between nutrition and these diseases. F. 193.

According to Dr. Stampfer, for products such as the POM Products, claims of efficacy can be made only when a causal relationship with human disease has been established and the RCT is the best study design that permits a strong causal inference concerning the relationship between an administered agent and any specific outcome. F. 631, 632. According to Dr. Sacks, to substantiate a claim that a product, including a conventional food or dietary supplement, can treat, prevent, or

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reduce the risk of heart disease, one must rely on appropriately analyzed results of well-designed, well-conducted RCTs. F. 638. Dr. Sacks further opined that the findings of the RCTs must be statistically significant (*i.e.*, have strong “*p*” values). F. 711. In addition, Dr. Sacks opined that the results of the RCTs must demonstrate significant changes in valid surrogate markers of cardiovascular health, such as blood pressure and LDL cholesterol (two surrogate markers recognized by the FDA) or C-reactive protein, HDL cholesterol, and triglycerides (three surrogate markers recognized by many experts in the field). F. 712, 761-763, 765-766.

In Dr. Sacks’ opinion, the same level of evidence is needed to show that clinical studies, research, or trials prove that a product treats, prevents, reduces the risk of heart disease, as is needed to substantiate a heart disease efficacy claim. F. 713.

Dr. Sacks acknowledged that there are common clinical recommendations today that have not been proven by RCTs, that in some instances, such as studies on foods, the blinding of patients is not possible, and that if a study becomes unblinded or does not have a placebo, the study can still have value. F. 641, 647. Moreover, Dr. Sacks testified that you do not need RCTs to test the benefit of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. F. 645. These positions weaken Dr. Sacks’ opinion in this case that Respondents must have had two RCTs to support their claims.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. David Heber and Dr. Dean Ornish. Dr. David Heber is a practicing physician, Professor of Medicine and Public Health at UCLA, and the founding Director of the UCLA Center for Human Nutrition, a center for clinical research, education, and public health endeavors. F. 221, 222. Dr. Heber has co-authored over 200 peer-reviewed publications in the field of nutrition and its relation to various diseases and written 25 chapters in other scientific texts. F. 224. Dr. Ornish is a well-known medical doctor and Clinical Professor of Medicine at the University of California at San Francisco. F. 227. Dr. Ornish is also the founder and

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President of the Preventative Medicine Research Institute (“PMRI”). F. 228. Dr. Ornish has directed clinical research on the relationship between diet and lifestyle and coronary heart disease for over 34 years and has written numerous books and articles for peer-reviewed journals. F. 229, 230.

Both Dr. Heber and Dr. Ornish opined that there is credible scientific evidence showing that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: (1) decreases in arterial plaque; (2) lowering of blood pressure; and (3) improvement in cardiac blood flow, based on the biological mechanism of prolonging the half-life of nitric oxide in the vasculature. F. 956, 960. Dr. Ornish opined that, taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. F. 959. Dr. Heber also opined that the body of research on pomegranate juice and extract provides support for potential heart benefits for heart disease. F. 954. Dr. Heber explained that although claims that pomegranate juice and extract have not been proven absolutely effective to treat, prevent, or reduce the risk of heart disease, the entire body of scientific evidence should be considered when evaluating nutritional science. F. 957.

Dr. Ornish disagreed that study results must be “statistically significant” with “strong ‘*p*’ values” (*i.e.*,  $p \leq 0.05$  or a 5 percent or less chance that the change is due to chance), testifying that: (1) in evaluating scientific research related to a whole food, it is not necessary to reach statistical significance, as opposed to a prescription drug with potential side effects; and (2) the convention that there be a five percent or less finding due to chance is an arbitrary number. F. 958. Respondents’ experts further dispute Dr. Sacks’ opinion that significant changes must be shown in valid surrogate markers and opine that myocardial perfusion (or blood flow to the heart) and carotid intima-media thickness are more closely related to, and predictive of, cardiovascular disease than blood pressure or LDL cholesterol. F. 764, 765, 771.

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**ii. Standard for substantiation**

Having considered the evidence on all the relevant factors, including the other five *Pfizer* factors analyzed in Section III.F.2, *supra*, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of heart disease and that they have been clinically proven to do so. F. 711, 713; *see also* F. 710, 712. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of heart disease, or have been clinically proven to do so, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of heart disease. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the POM Products treat, prevent, or reduce the risk of heart disease or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents' claims are false or misleading. *See QT*, 448 F. Supp. 2d at 959.

**b. Scientific evidence relied upon****i. Overview of cardiovascular heart disease**

Heart disease, including heart attacks or angina, occurs as the result of decades-long damage to blood vessels. F. 715, 716. The process begins with the oxidation of the protein known as low density lipoprotein ("LDL" or bad cholesterol) which circulates in the blood. F. 716. Once LDL becomes oxidized, the chemical nature of the protein changes, causing it to reside and accumulate in the blood vessel. F. 717. Macrophages, white blood cells that respond to inflammation by digesting cellular debris, begin to engulf and devour the oxidized cholesterol. F. 719. These macrophages continue to accumulate until they develop into "foam cells." F. 720. These foam cells become full of cholesterol and actually burst, bringing in more macrophages and more inflammation. F. 720. As this process progresses, plaque begins to form as yellow streaks in the coronary arteries. F. 721.

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Antioxidants play an important role in mitigating heart disease by, among other things, inhibiting oxidative stress, including reducing LDL oxidation (and its uptake) and inflammation. F. 726, 727. In addition, the presence of nitric oxide in the body also helps offer protection against atherosclerosis by regulating blood flow and contributing to smooth muscle relaxation. F. 723-725, 751. Nitric oxide helps maintain healthy blood vessels, which improves blood flow to almost every organ in the body, including the heart. F. 731. Several studies have indicated that pomegranate juice has antioxidant and anti-atherosclerotic properties due to the presence of multiple polyphenols such as tannins, flavonols, anthocyanins and ellagic acid. F. 725.

**ii. *In vitro* and *in vivo* studies**

Respondents sponsored several *in vitro* and *in vivo* animal studies to examine the effect of POM Juice and POMx Pills on cardiovascular health. *In vitro* studies are those where blood elements or cells are removed from the body and tested in a controlled laboratory environment, such as a test tube. F. 593. *In vivo* studies are those conducted within the living. Respondents acknowledge that their *in vitro* and *in vivo* studies are “basic science” or “pre-clinical.” RRCCFF 1083. Detailed findings on these studies are set forth in Section II.G.3, *supra*, and are summarized below.

Respondents have sponsored many published studies in cellular and animal models evaluating the effects of pomegranate juice and/or its extracts on cardiovascular function. F. 732. Beginning around 2000, and continuing to the present time, Dr. Michael Aviram began studies investigating pomegranate juice’s potential benefits to the cardiovascular system. F. 744. Dr. Aviram and his colleagues observed several beneficial effects of pomegranate juice and its extracts at the cellular and animal stage including, but not limited to: (1) reduction in oxidation of LDL cholesterol; (2) lessening the “uptake” of oxidized LDL by macrophage foam cells; (3) decrease in size of atherosclerotic lesions and foam cells; and (4) diminishing of platelet aggregation. F. 744.

Respondents have also sponsored research in the area of nitric oxide and understanding its role in cardiovascular health *in vitro*

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and in animals. F. 747. Dr. deNigris, Dr. Napoli, and, Dr. Ignarro conducted a number of studies in which they found that POM Juice and/or POMx Pills demonstrated: increasing and preserving levels of nitric oxide, decreasing expression of genes associated with stress, and progression of atherosclerosis; reducing LDL oxidation, size of atherosclerotic plaques, and formation of foam cells; reversing effects of shear stress, which can damage the endothelial cells or thin layer of cells that line the interior of blood vessels; decreasing cellular production and release of oxygen radicals in the vascular wall; inhibiting activation of oxidation-sensitive genes; and improving biological activity of nitric oxide. F. 751.

Complaint Counsel's expert, Dr. Sacks, acknowledges that some of Respondents' *in vitro* studies have shown pomegranate juice's favorable effects on the mechanisms involved in cardiovascular disease and that *in vitro* studies, like Dr. Aviram's, can be competent and reliable scientific evidence of an agent's effect on a particular mechanism. F. 745, 746. However, Dr. Sacks also opined regarding Respondents' basic research that *in vitro* and animal studies do not provide reliable scientific evidence of what effects a treatment will have inside the human body and, thus, do not provide reliable scientific evidence on whether an agent can treat, prevent or reduce the risk of cardiovascular disease in humans. F. 752. Respondents' expert, Dr. Ornish, testified that *in vitro* and animal studies are important in considering the totality of evidence in determining whether or not pomegranate juice in its various forms is beneficial, but that there are limitations to extrapolating from *in vitro* and animal studies to humans. F. 753.

Respondents' basic science indicates that pomegranate juice may be beneficial to cardiovascular health. F. 754. The basic research relied upon by Respondents is part of the totality of evidence that must be examined in evaluating the effects of the POM Products. F. 755. However, experts in the field agree that *in vitro* and animal studies need to be replicated in humans to show an effect on preventing or treating a disease. F. 755.

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**iii. Clinical trials; overview**

Complaint Counsel charges that Respondents did not have a reasonable basis and did not have clinical studies, research, or trials to prove that the POM Products prevent, reduce the risk of, or treat heart disease, by: (1) lowering blood pressure; (2) decreasing arterial plaque; and/or (3) improving blood flow to the heart. (Complaint ¶¶ 17-19). Respondents have sponsored approximately 10 published and several unpublished studies on humans, evaluating the effect of pomegranate juice and/or its extracts on cardiovascular health. F. 756. The results of the studies relied upon by Respondents and the conflicting expert opinions on these studies are found in Section II.G.5, *supra*, and discussed below.

**iv. Clinical trials; improving blood pressure**

In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by lowering blood pressure, in addition to the basic science discussed above, Respondents rely on the Aviram ACE/BP Study<sup>10</sup> and the Aviram CIMT/BP Study<sup>11</sup> of POM Juice. RRB at 106.

**(a) About the studies**

The Aviram ACE/BP Study was a study with ten elderly, hypertensive patients who drank 50 ml. of pomegranate concentrate daily, for two weeks. F. 774. The Aviram ACE/BP Study was unblinded and had no control group; instead, each patient's "before" measures were compared to his or her "after" measures. F. 776. The Aviram ACE/BP Study indicated that all

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10 The Aviram ACE/BP Study, conducted by Dr. Michael Aviram and his co-workers, was published as "*Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure,*" 158 *Atherosclerosis* 195-98 (2001). F. 774.

11 The Aviram CIMT/BP Study, conducted by Dr. Aviram and his co-workers, was published as, "*Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness (CIMT), blood pressure and LDL oxidation*" by Aviram M, Rosenblat M, Gaitini D, Nitecki S, Hoffman A, Dornfeld L, Volkova N, Presser D, Attias J, Liker H, and Hayek T, (*Clin Nutr.* 2004; 23:423-33). F. 789.

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ten patients experienced a statistically significant 5% reduction in systolic blood pressure from their baseline blood pressure measure. F. 778. The Aviram ACE/BP Study concluded that “pomegranate juice consumption can offer a wide protection against cardiovascular disease.” F. 779.

In the Aviram CIMT/BP Study, a group of ten patients with severe carotid artery stenosis consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. F. 790. A second group of nine patients who did not consume pomegranate juice acted as a control. F. 790. The Aviram CIMT/BP Study indicated that the pomegranate juice group members’ systolic blood pressure was significantly ( $p < 0.05$ ) reduced by 12% after one year of pomegranate juice consumption, compared to their baseline values. F. 794. In the group that did not consume pomegranate juice, blood pressure was unchanged. F. 794.

**(b) Expert opinions on the studies**

Complaint Counsel’s experts criticized the Aviram ACE/BP Study on the following grounds: the sample size of ten patients was too small to provide reliable evidence that the observed effects would be generally applicable to a larger population; the two-week period of the study was too short to provide reliable evidence that the indicated improvement in blood pressure would be enduring; and the Aviram ACE/BP Study did not have a control group, thus, it is not possible to conclude what caused the indicated improvements in the subjects’ blood pressure levels. F. 780. Complaint Counsel’s experts criticized the Aviram CIMT/BP Study for the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size; and the lack of any between-group statistical analysis. F. 798.

Respondents’ expert, Dr. Ornish, responded that there is a common misconception that a larger study is a better study, but the opposite can be argued; with a smaller number of patients, the treatment has to be more powerful and consistent in order to show a statistically significant effect. F. 783, 803; *see also* F. 785. Dr. Aviram testified that it is entirely appropriate for each patient to serve as his or her own control and that if a study is conducted

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without a placebo, that fact does not weaken its importance. F. 784.

Complaint Counsel's experts additionally opined that one cannot extrapolate the results of the two Aviram studies of POM Juice to the POMx products. *See* F. 948. Respondents counter this criticism by stating that, with respect to POMx Pills and POMx Liquid, Respondents detailed the findings of eight scientific studies that document the beneficial effects of POMx Pills and POMx Liquid on cardiovascular health. RRCCFF 965 (citing CX0053; PX0057; PX0056; PX0008; PX0017; PX0038; PX0139; PX0127; RFF 831-840, 924, 930-957, 1100). Furthermore, Dr. Heber, the only expert who opined on the bioavailability of pomegranate polyphenols, explained that because both the 100% Pomegranate Juice product and the POMx products contain ellagitannins that contribute to the antioxidant activity of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies. F. 953.

Lastly, Complaint Counsel charges that five subsequent RCTs sponsored by Respondents showed no benefit to blood pressure. These include the Ornish MP Study<sup>12</sup>; the Ornish CIMT Study<sup>13</sup>; the Davidson BART/FMD Study<sup>14</sup>; the Davidson CIMT Study<sup>15</sup>;

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12 The Ornish MP Study was conducted by Dr. Dean Ornish and colleagues and published as Sumner M, et al., *Effects of Pomegranate Juice Consumption on Myocardial Perfusion (MP) in Patients with Coronary Heart Disease*, 96 Am. J. Cardiology 810 (2005). F. 805. The Ornish MP Study was a randomized, placebo-controlled, double-blind study of 45 patients. F. 808. The Ornish MP Study indicated that there were no statistically significant differences between the two groups in blood pressure. F. 813.

13 The Ornish CIMT Study was an unpublished, randomized, double-blind, placebo-controlled 73-person study that measured carotid intima-media thickness (CIMT), blood pressure, and other related mechanisms for 12 months. F. 850. The Ornish CIMT Study indicated that there were no significant differences in the treatment group relative to the placebo group, over time, for any of the other heart-related measurements, including systolic and diastolic blood pressure. F. 859.

14 The Davidson BART/FMD Study, titled, *The Effects of Pomegranate Juice on Flow-Mediated Vasodilation*, is a published study. F. 871. Brachial artery reactivity testing ("BART") is a measurement of how much the brachial artery

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and the San Diego Study.<sup>16</sup> Complaint Counsel's expert, Dr. Sacks, opined that the Ornish CIMT Study's and the Davidson BART/FMD Study's findings of no statistically significant difference in blood pressure due to POM Juice consumption undermine the credibility of the results of the Aviram ACE/BP Study and Aviram CIMT/BP Study. F. 862, 909.

Respondents counter this criticism by stating that none of Respondents' subsequent studies examined blood pressure as a primary endpoint and, as a result, one cannot conclude that there was no effect of POM Juice or POMx on blood pressure. RRB at 94; F. 864, 866, 912. In any clinical study, it is routine to record blood pressure, pulse, body temperature, among other measurements, to make sure patients are healthy. F. 842. Although blood pressure is measured in many studies, a specific claim on blood pressure requires a very specific study involving special equipment and personnel. F. 842. Thus, Dr. Heber testified, where blood pressure was not the endpoint, any results for blood pressure cannot be relied upon as negative evidence. F. 841, 912. Complaint Counsel's expert, Dr. Sacks, concedes that

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dilates (enlarges) after a blood pressure cuff is inflated, and then released. F. 901. This is also called flow mediated dilation ("FMD") testing. F. 901. The Davidson BART/FMD Study took measurements of blood pressure, although blood pressure was not a primary or secondary endpoint of the study. F. 905. At the end of the Davidson BART/FMD Study, there were no significant differences between treatment and placebo groups in blood pressure. F. 906.

15 The Davidson CIMT Study, was published as Davidson MH., *et al.*, *Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease*, 104 Am. J. Cardiology 936 (2009). F. 871. In the Davidson CIMT Study, exploratory endpoints included changes in blood pressure, and the study indicated: "there were no differences between treatment groups for changes from baseline in traditional cardiovascular risk markers, including . . . blood pressures . . ." F. 877, 878.

16 The San Diego Study was published as Heber D. *et al.*, *Safety and Antioxidant Activity of a Pomegranate Ellagitannin-Enriched Polyphenol Dietary Supplement in Overweight Individuals with Increased Waist Size*, J. Agric Food Chem., Vol. 55, No. 24 (2007). F. 924. The San Diego Study measured blood pressure, but this was not a primary endpoint. F. 927. The study indicated: "[t]here were no apparent treatment related changes in weight, systolic blood pressure, diastolic blood pressure, pulse rate, respirations, or temperature." F. 928.

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in subsequent studies showing no statistically significant changes in blood pressure, the absence of such evidence is not proof that there is no effect. F. 867, 911.

**(c) Determination**

As discussed above, the expert testimony regarding the Aviram ACE/BP Study and Aviram CIMT/BP Study is conflicting. The greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring blood pressure demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through reducing blood pressure, or that clinical studies show the same.

**v. Clinical trials; reducing arterial plaque****(a) About the Aviram CIMT/BP Study**

In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by reducing arterial plaque, in addition to the basic science discussed above, Respondents rely on the Aviram CIMT/BP Study and the Davidson CIMT Study. RRB at 106.

Carotid intima media thickness (“CIMT”) testing measures the combination of the vessel muscle and atherosclerosis (arterial plaque). F. 767. Measures of CIMT are usually relevant to cardiovascular health, and if CIMT measures show consistent improvement, this would be an indicator that a treatment may be beneficial. F. 769. However, such measures alone are not conclusive evidence that an intervention treats existing heart disease. F. 769.

In the Aviram CIMT/BP Study, a group of ten patients with severe carotid artery stenosis (“CAS”) consumed 50 ml. of concentrated pomegranate juice daily for one year and five of them continued for up to three years. F. 790. A second group of nine patients who did not consume pomegranate juice acted as a control. F. 790. The results of the Aviram CIMT/BP Study showed that, in the control group that did not consume pomegranate juice, the patients’ CIMT increased by 9% during

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one year, whereas, pomegranate juice consumption resulted in a significant CIMT reduction, by up to 30%, after one year. F. 791. The Aviram CIMT/BP Study concluded that the “results of the present study . . . suggest that [pomegranate juice] consumption by patients with CAS decreases carotid IMT and systolic blood pressure and these effects could be related to the potent antioxidant characteristics of [pomegranate juice] polyphenols.” F. 797.

**(b) Expert opinions on the Aviram CIMT/BP Study**

Complaint Counsel’s expert, Dr. Sacks, testified that a qualified scientist would not be able to conclude with any credibility that the improvements in the treatment group indicated by the Aviram CIMT/BP Study were caused by the group’s consumption of pomegranate juice and not some other factor because of: the lack of a randomized, placebo-controlled group; the fact that the patients in the active and control groups received different treatment; the small sample size; and the lack of any between-group statistical analysis. F. 798.

Dr. Ornish testified that the findings in the Aviram CIMT/BP Study suggest that oxidative stress may have been reduced by pomegranate juice consumption in these patients. F. 793. Respondents assert that the fact that the Aviram CIMT/BP Study is considered “unblinded and uncontrolled” by Complaint Counsel does not invalidate the results. RRB at 95. However, Respondents’ expert, Dr. Ornish, agreed that the Aviram CIMT/BP Study was limited in scope and opined: “Thus, while not at all conclusive, the study suggests a benefit.” F. 802. He further testified that the Aviram CIMT/BP Study was “very provocative and interesting and laid the groundwork for even more conclusive studies.” F. 802.

**(c) About the Davidson CIMT Study**

The Davidson CIMT Study was an 18-month, 289-person randomized, double-blinded, placebo-controlled clinical trial conducted at two clinical research sites in accordance with good clinical practice guidelines and under a protocol approved by an institutional review board. F. 872. Participants in the Davidson

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CIMT Study drank eight ounces of pomegranate juice or placebo juice daily. F. 876. Adherence to product consumption was assessed at each visit by reviewing daily consumption diaries maintained by the subjects. F. 876. The protocol for the Davidson CIMT Study called for ultrasound testing of the carotid artery at baseline, at 12 months, and at 18 months. F. 877.

Among other findings, the Davidson CIMT Study indicated the following:

- Anterior and posterior wall CIMT values and progression rates did not differ significantly between treatment groups at any time point.
- The composite measurement of CIMT showed a significantly smaller value at 12 months in the pomegranate juice group compared to the control group . . . However, this difference was no longer significant at the end of the treatment period [18 months].
- Results of the present study showed no significant influence of 18 months of pomegranate juice consumption on CIMT progression in the overall study sample. However, results from *post hoc* exploratory analyses, which should be interpreted with caution, suggest that the rate of CIMT progression may have been slowed in subgroups characterized by more rapid CIMT progression, including those with increased levels of TG-rich lipoproteins, low levels of HDL cholesterol, and greater oxidative stress.
- Whether possible benefits of pomegranate juice consumption on CIMT progression in some subgroups relate to antioxidant activity is uncertain. A lack of significant improvements in most markers of oxidative stress argues against an important role for antioxidant activity. However, specific reactive oxygen/nitrogen species may be scavenged by pomegranate unique polyphenolic hydrolysable tannins. Indeed, a subgroup for whom there was an apparent benefit was the top tertile for baseline PD – AAPH, suggesting that

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antioxidant effects may have played a role in the protection against CIMT progression by pomegranate juice consumption.

F. 878.

**(d) Expert opinions on the Davidson CIMT Study**

Complaint Counsel charges that Respondents “cherry-picked observations from the Davidson CIMT Study” by, *inter alia*, (1) relying on the results at 12 months, rather than the results at 18 months; and (2) focusing on results of an exploratory sub-group analysis performed *post hoc*. CCB at 38. Respondents rejoin that: (1) the fact that differences in the composite measurement of CIMT were not statistically significant at 18 months does not change the fact that these differences were statistically significant at 12 months; and (2) findings related to subgroups cannot be ignored merely because they were formed in a *post hoc* analysis. RRB at 94-95.

Complaint Counsel’s expert, Dr. Sacks, testified that the Davidson CIMT Study is the largest of the heart studies conducted on pomegranate juice; was carefully designed, in that the protocol identified the endpoints to be measured, the procedures to be followed, inclusion and exclusion criteria, and the statistical analysis to be conducted; and that there was no evidence of critical problems in the conduct or analysis of the study (except its over-emphasis on the subgroup results). F. 884. Based on the findings of the Davidson CIMT Study (summarized above), particularly that, at the end of the study, there were no significant differences in CIMT progression rates between the subjects in the pomegranate juice and control groups, Dr. Sacks concluded that the Davidson CIMT Study is “competent and reliable evidence that consumption of pomegranate juice did not improve CIMT in subjects with one or more cardiovascular risk factors.” F. 884. Dr. Stampfer agreed and opined that that the main result from the Davidson CIMT Study provides substantial evidence *against* the hypothesis that pomegranate juice can reduce the progression of CIMT. F. 892.

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Respondents' experts opine that the Davidson CIMT Study constitutes competent and reliable scientific evidence that the consumption of POM Juice is beneficial to cardiovascular health by, among other things, reducing arterial plaque. F. 885. Dr. Ornish stated that the bottom line of the Davidson CIMT Study is that pomegranate juice *did* show a statistically significant improvement in CIMT after 12 months in the measure that was most clinically relevant; the fact that these differences in CIMT measurements were not statistically significant at 18 months does not change the fact that these differences were statistically significant after 12 months. F. 888.

Dr. Ornish explained that a potential reason for lack of a change in the CIMT progression rate at 18 months was that participants in the Davidson CIMT Study may have stopped drinking the juice after 12 months. F. 890. Dr. Ornish observed that it is not unusual for patients to be less than honest in describing their compliance, as patients often describe that it is embarrassing and even humiliating to report that they have not done what they were supposed to do. F. 890. However, Dr. Davidson, who evaluated compliance with the product consumption guidelines during the Davidson CIMT Study, testified that his review of compliance diaries showed high levels of compliance with the product consumption guidelines. F. 891.

Respondents' experts also opine that the Davidson CIMT Study provides supporting evidence that there were statistically significant lower CIMT progression rates for pomegranate versus control in the subgroup of persons with higher cardiovascular disease risk factors. F. 888. The Davidson CIMT Study described the subgroup analyses as "*post hoc* exploratory analyses, which should be interpreted with caution[.]" F. 878. Respondents' experts opined that in scientific research, *post hoc* analysis is routine. F. 896.

Complaint Counsel's expert, Dr. Sacks, opined that a *post hoc* analysis is one that is conceived after the researchers have seen the data and is, thus, generally a less valid approach than one planned for in the protocol, because it is more subject to bias. F. 895. Dr. Sacks further opined: because the subgroup data is hypothesis generating only, and has not been corrected for multiple comparisons, a qualified scientist could not rely on the

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*post hoc* analysis of the subgroup populations as reliable scientific evidence to support claims that POM Juice or POMx prevent, reduce the risk of, or treat heart disease in the subgroup populations identified. F. 899.

**(e) The Ornish CIMT Study**

Complaint Counsel further charges that Respondents, in making claims that the POM Products can treat or prevent heart disease by reducing arterial plaque, discount the outcome of the Ornish CIMT Study. CCB at 38. The Ornish CIMT Study was an unpublished, randomized, double-blind, placebo-controlled 73-person study, conducted by Dr. Ornish, one of Respondents' experts in this case. F. 850. The primary endpoint of the Ornish CIMT Study was to investigate the effects of pomegranate juice on CIMT in patients with at least one cardiovascular risk factor. F. 850. The treatment group drank eight ounces of pomegranate juice concentrate daily, and the control group drank eight ounces of placebo beverage daily, for one year. F. 850. According to the Ornish CIMT Study unpublished final report, there were no significant changes in the treatment group relative to the placebo for CIMT thickness or elastic properties. F. 858.

Dr. Sacks described the results of the Ornish CIMT Study as "convincingly null, showing that pomegranate juice treatment did not improve CIMT" and opined that the Ornish CIMT Study confirmed that the purportedly positive results of Dr. Aviram's unrandomized, uncontrolled 19-patient CIMT/BP Study lacked credibility. F. 861, 862. However, Dr. Sacks admitted that the lack of statistical significance for a positive result in the Ornish CIMT Study is not proof of a negative. F. 867.

Dr. Ornish testified that the Ornish CIMT Study was an indeterminate study that cannot be relied upon; "it neither proves or disproves." F. 864. Dr. Ornish explained that the protocol for the Ornish CIMT Study called for 200 patients, but ultimately, only 73 patients were recruited, 56 of whom completed one-year testing. F. 851. Dr. Ornish further stated: Even in this smaller group, we found improvements in right CIMT that approached statistical significance and that if these changes had been seen in a sample of 200 patients, then it would have been statistically significant. F. 857, 863. Dr. Heber observed that the Ornish

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CIMT Study “had inadequate power at that number of subjects,” so no conclusions could be drawn from the study. F. 865.

**(f) Determination**

As discussed above, the expert testimony regarding the studies measuring CIMT to support Respondents’ claims is conflicting. The greater weight of the persuasive expert testimony on the studies sponsored by Respondents measuring CIMT demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through reducing arterial plaque, or that clinical studies show the same.

**vi. Clinical trials; improving blood flow**

In support of claims that the POM Products treat, prevent, or reduce the risk of heart disease by improving blood flow (myocardial perfusion), in addition to the basic science discussed above, Respondents rely on the Ornish MP Study. RRB at 106.

**(a) About the Ornish MP Study**

In the Ornish MP Study, Dr. Ornish and his colleagues investigated whether the daily consumption of pomegranate juice for three months would affect myocardial perfusion (“MP”) in 45 patients who had coronary heart disease and myocardial ischemia (narrowing of the arteries) in a randomized, placebo-controlled, double-blind study, which was subsequently published. F. 805, 808. The Ornish MP Study indicated that after three months there was a significant ( $p = 0.05$ ) improvement of 17% in the summed differences score (“SDS”)<sup>17</sup> in the POM Juice group, as compared to an average worsening of 18% in the control group. F. 811. Thus, after three months, the comparative benefit in blood flow of the pomegranate juice group to the placebo group in the Ornish

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<sup>17</sup> The Ornish MP Study provides data on three imaging measures at baseline and three months for myocardial perfusion: the summed rest score, or “SRS” (imaging results before the pharmacologic or exercise challenge), the summed stress score, or “SSS” (imaging results after the pharmacologic or exercise challenge), and the summed difference score, “SDS” (calculated by subtracting the SRS from the SSS). F. 810.

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MP Study was about 35 percent. F. 811. The Ornish MP Study concluded: “Although the sample in this study was relatively small, the strength of the design and the clinically significant and statistically significant improvements in myocardial perfusion observed in the experimental group over a rather short period suggest that daily consumption of pomegranate juice may have important clinical benefits in this population.” F. 815.

**(b) Expert opinions on the Ornish MP Study**

Complaint Counsel criticizes the Ornish MP Study, *inter alia*, on the following grounds: (1) change in myocardial perfusion is not a recognized surrogate marker of therapeutic effects on coronary heart disease; (2) the Ornish MP Study indicates significant changes in only one of three measures of blood flow – in summed difference score (SDS), but not summed rest score (SRS) or summed stress score (SSS); (3) the study was designed to last 12 months, but was cut short at 3 months; (4) the study showed no improvement in other measures, such as blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress; and (5) there were problems in the design and conduct of the study. Respondents’ replies to each of these challenges to the adequacy of the Ornish MP Study to substantiate claims regarding improving blood flow are addressed, in order, below.

First, the Ornish MP Study measured improvements in myocardial perfusion. F. 808. Complaint Counsel’s experts opined that myocardial perfusion is a research tool, but is not recognized as a surrogate marker for heart disease and is not used as the primary outcome in studies of treatment efficacy for coronary heart disease. F. 825. Dr. Sacks further opined that even where blood flow is shown to have been improved, it will not necessarily result in improved cardiovascular health, such as reductions in heart attack and stroke. F. 825. However, Dr. Sacks conceded that proper blood flow from the coronary artery and to the heart is fundamental to lowering the risk of cardiovascular disease. F. 826.

Dr. Ornish, for Respondents, opined that blood flow is essential to life, an important measure of heart disease, and the “bottom line” in coronary heart disease (along with how well the heart is pumping blood) and, thus, when researchers measure

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myocardial perfusion, researchers are measuring what actually matters most. F. 827. As Dr. Ornish explained, blood carries oxygen and nutrients that feed the heart. F. 828. If the blood flow to the heart (perfusion) is reduced, then the heart is no longer receiving enough blood flow to maintain itself. F. 828. Coronary heart disease, which is the most common form of heart disease, occurs when the heart does not get enough blood to fuel itself and blood carries oxygen, which is the fuel for the heart. F. 828.

In addition, Respondents' experts opined that myocardial perfusion is more closely connected as a surrogate marker for cardiovascular disease than LDL cholesterol, which has been accepted by the FDA as a surrogate marker. F. 829. Dr. Ornish explained that when a person has a biomarker such as high LDL cholesterol, which increases his or her risk, that is far away from the actual event of a heart attack, which may be affected by many other factors, such as inflammation and oxidation. F. 829. There are a number of people who have low cholesterol levels, but get heart disease. F. 829. About 50 percent of the people who die from a heart attack actually have cholesterol in the normal range. F. 829. There are people who have high cholesterol levels who do not have heart disease, and the same is true for blood pressure. F. 829.

Second, the Ornish MP Study report indicates significant changes in only one of three measures of blood flow. F. 833. Complaint Counsel's experts testified that the .05 "*p*" value of the SDS improvement is not very persuasive where, as in the Ornish MP Study, there were three possible outcome measures (SSS, SRS, and SDS), and only one just met significance. F. 833.

Responding to these criticisms, Dr. Ornish explained that he did not ignore the SRS and SSS measures, but that those were not the objective of the Ornish MP Study because they measure infarcted or dead heart tissue. F. 832, 834. SDS is derived by subtracting SRS from SSS and the finding of statistically significant changes in SDS confirmed what the researchers were hoping to find -- an improvement in blood flow to the heart when compared to rest and stress. F. 832, 834.

Complaint Counsel's experts also opined that there was a large discrepancy between the pomegranate juice and the control

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groups in the baseline values of SRS and SSS, the two components of the SDS. F. 835. The control group's baseline values were worse than those of the pomegranate group, and, thus, it could be predicted that the control group, having worse coronary perfusion than the pomegranate group at baseline, would have a more accelerated form of the disease and show worsening on follow-up, according to Dr. Sacks. F. 836.

Dr. Ornish explained that there was a difference in SSS at baseline, but no statistically significant differences in SRS or SDS. F. 837. Dr. Ornish further testified that the Ornish MP Study employed an "analysis of variance," which took into account any baseline differences. F. 837.

Third, the Ornish MP study was originally designed to last 12 months, with measurements at baseline, 3 months, and 12 months. F. 843. Complaint Counsel charges that the study was cut short when the three-month data came in favorably and Dr. Ornish faced cost overruns. CCB at 39. Dr. Sacks opined that the shortened study period and failure to report the planned duration are inconsistent with widely-accepted standards for conduct of clinical trials and undermine any confidence in the findings. F. 843.

Dr. Ornish testified that the Ornish MP Study was terminated after three months only because the Resnicks did not provide the funding that they had previously committed to this study, not because the *p*-value was statistically significant at three months. F. 844. Dr. Ornish further opined that while he did not have 12 months of follow-up data, this does not reduce the confidence in the three-month findings of the Ornish MP Study. F. 844.

Fourth, Complaint Counsel's expert criticized the Ornish MP Study on the additional basis that blood pressure, cholesterol, inflammatory biomarkers, and oxidative stress were not improved. F. 838. Dr. Ornish himself concluded that "blood pressure . . . did not improve" in the Ornish MP Study. F. 839. However, Dr. Ornish explained, the fact that other factors such as blood pressure and cholesterol did not improve does not in any way provide evidence that pomegranate juice was not beneficial, as its effects may have been mediated via other pathways. F. 840.

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Fifth, Complaint Counsel's experts point out various other problems in the design and conduct of the study, including providing data on only 39 of the 41 patients and unblinding of 6 patients mid-way through the Ornish MP Study. F. 820, 824. In trial testimony and in his expert report, Dr. Ornish acknowledged that "some problems" occurred during the Ornish MP Study that were not "optimal," but opined that the difference in SDS remained statistically significant and, therefore, the conclusions of the study remain valid. F. 819, 821.

Complaint Counsel's expert, Dr. Sacks, concluded, "the interpretation of [the Ornish MP] study that is most consistent with the principles of clinical study design and conduct is that the treatment had no effect on any measure of cardiac health" and that experts in the field of cardiovascular disease would not consider the Ornish MP Study to support the proposition that pomegranate juice provides a heart disease benefit. F. 845.

Respondents' expert, Dr. Ornish, the author of the study, concluded that the Ornish MP Study constitutes credible and reliable science showing that pomegranate juice lessens the risk of cardiovascular problems; that in people who have already had heart disease, it improves blood flow and reverses the progression of heart disease; and if you can begin to reverse a disease, it would only make sense that pomegranate juice would work even better to help prevent heart disease in the first place. F. 847.

**(c) Determination**

As discussed above, the expert testimony regarding the Ornish MP Study is conflicting. The greater weight of the persuasive expert testimony on the Ornish MP Study demonstrates that the scientific evidence relied upon by Respondents is not adequate to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease through improving blood flow, or that clinical studies show the same.

**c. Conclusion**

Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic science and clinical trials, the greater weight of the persuasive expert

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testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that the POM Products treat, prevent, or reduce the risk of heart disease, by lowering blood pressure, reducing arterial plaque and/or increasing blood flow to the heart, or are clinically proven to do so. F. 962. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied heart disease claims found to have been made in this case, and that, therefore, such claims were false or misleading.

#### **4. Substantiation for Respondents' prostate cancer claims**

##### **a. Overview**

As discussed in Section III.E.2.d, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that the POM Products are clinically proven to treat, prevent, or reduce the risk of prostate cancer, by prolonging prostate-specific antigen ("PSA") doubling time. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of prostate cancer; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of prostate cancer. CCB at 44-50. With respect to claims made about prostate cancer, although Respondents have been found to have made establishment claims only, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31.

##### **i. Summary of expert opinions**

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. James Eastham and Dr. Stampfer. Dr. Eastham is Chief of Urology, Department of Surgery, and Director of Clinical Research, Urology Department at Memorial Sloan Kettering Cancer Center. F. 200. He is a board-certified urological surgeon who has treated more than

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2,000 patients with prostate cancer and has extensive experience, including as an investigator, in the design and conduct of clinical trials studying prostate cancer. F. 200, 201. Dr. Eastham is an expert in the fields of urology, including the prevention and treatment of prostate cancer, as well as clinical testing related to the prevention and treatment of prostate cancer. F. 204. Dr. Stampfer has participated in research investigating risk factors (including food intake and dietary factors) associated with prostate cancer. F. 183. An expert in nutrition, including its relation to the prevention and treatment of prostate cancer, and clinical testing related to the prevention of prostate cancer, Dr. Stampfer also reviewed Respondents' prostate cancer research and provided his independent opinion. F. 190.

Dr. Eastham and Dr. Stampfer state that to support claims that the POM Products prevent prostate cancer, or that they have been clinically proven to do so, experts in the field of prostate cancer would require at least one well-designed, randomized, double-blind, placebo-controlled clinical trial involving an appropriate sample population and endpoint. F. 626, 648. Dr. Eastham opined that the appropriate sample population for a cancer prevention trial "would involve more than 10,000 healthy men, ages 50 to 65, having no sign of prostate cancer." F. 1092. Dr. Eastham also testified that "[a] prostate cancer prevention study must be conducted over a long enough period of time to see an effect over time." F. 1093. Dr. Eastham states that "[t]he primary endpoint in a prostate cancer prevention trial for measuring whether a product has been effective is the prevalence or incidence of prostate cancer between the treatment and placebo groups at the conclusion of the study." F. 1089.

Dr. Eastham and Dr. Stampfer also state that to support claims that the POM Products treat prostate cancer, or that they have been clinically proven to do so, experts in the field of prostate cancer would require a randomized, placebo-controlled, double-blind clinical trial with an appropriate sample population and endpoint. F. 626, 648. Dr. Eastham and Dr. Stampfer further opine that PSA doubling time is not recognized by experts in the field as a surrogate endpoint in prostate cancer clinical trials. F. 1100.

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Complaint Counsel's experts concluded that evidence relied upon by Respondents does not constitute adequate substantiation for claims that the POM Products treat, prevent, or reduce the risk of prostate cancer or have been clinically proven to do so. F. 1019, 1086-1094, 1096-1099.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. David Heber and Dr. Jean deKernion. Dr. Heber is a practicing physician, Professor of Medicine and Public Health at UCLA, and the Director of the UCLA Center for Human Nutrition. F. 221, 222. Dr. Jean deKernion is the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs at the UCLA School of Medicine and served as the Dean of Urology at the UCLA School of Medicine for twenty-six years. F. 251. Dr. deKernion is also a practicing urologist certified by both the American Board of Surgery and the America Board of Urology. F. 250.

Dr. Heber reviewed Respondents' science in the area of prostate cancer and testified at trial that there is competent and reliable science showing that POM Juice and POMx Pills lengthen the PSA doubling time for men who have had prostate cancer and, thus, it is likely for those men to have a deferred recurrence or death from that disease; and that POM Juice and POMx Pills are likely to lower the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. F. 1120. Dr. Heber's expert report, however, was more limited than his trial testimony, opining: the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis [programmed cell death], as well as oxidative stress and inflammation, provides strong scientific rationale for the statement that pomegranate juice promotes prostate "health." F. 1121.

Dr. deKernion testified that the POM Products are beneficial to prostate health. F. 1124. Dr. deKernion opined that although there is not 100% proof that the POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies

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(discussed below) showed, with a “high degree of probability,” that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease. F. 1124. Dr. deKernion testified also that there is a high probability that the POM Products provide a special benefit to men with detectable PSA after radical prostatectomy. F. 1125.

**ii. Standard for substantiation**

Having fully considered and weighed the evidence adduced at trial, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or that they have been clinically proven to do so. *See* F. 963-966. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of prostate cancer, or that they are clinically proven to do so, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of prostate cancer. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents’ claims are false or misleading. *See QT*, 448 F. Supp. 2d at 959.

**b. Scientific evidence relied upon****i. *In vitro* and *in vivo* studies**

The mechanism by which pomegranates promote prostate health is through potent antioxidant and antiatherosclerotic properties<sup>18</sup> attributed to pomegranates’ high content of polyphenols, including ellagic acid and tannins. F. 725. Ellagic acid and tannins have been shown to exhibit *in vitro* and *in vivo* anticarcinogenic properties, such as induction of cell cycle arrest

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<sup>18</sup> Atherosclerosis is a buildup of plaque in arteries. F. 988.

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and apoptosis, as well as the inhibition of tumor formation and growth in animals. F. 990. *In vivo* research has demonstrated that pomegranate polyphenols reduce inflammation in prostate tumors. F. 995. *In vitro* and *in vivo* research has also demonstrated that in tumors treated with pomegranate extract, the nuclear factor-*kappa*B decreased (see below), thereby causing decrease of tumor growth. F. 1007.

Working from these foundations, Respondents sponsored several *in vitro* and animal studies to examine the effect of POM Juice and POMx Pills on prostate health. F. 1010. Detailed findings of fact on these studies are set forth in Section II.H.3, *supra*. In summary, in this pre-clinical research, which studied human prostate cancer cells in the lab and inside of mouse models, POM Juice was found to inhibit cancer cell growth, promote prostate cell death, and inhibit the inflammatory process, which is correlated with the growth of cancer. *See id.*

For example, in a study titled, “*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland,*” Dr. David Heber and colleagues evaluated the effects of pomegranate extract on prostate cancer growth in severe combined immunodeficient mice injected with human prostate cancer cells. F. 1014. The study showed that pomegranate extract significantly inhibited prostate cancer in the mice, as compared to the control. F. 1014. Researchers also found that ellagic acid and synthesized urolithins from the pomegranate extract were shown to inhibit the growth of human prostate cancer cells *in vitro*. F. 1014. The researchers concluded that the chemopreventive potential of pomegranate ellagitannins and localization of their bioactive metabolites in mouse prostate tissue *suggest* that the pomegranate *may play a role* in prostate cancer treatment and chemoprevention. F. 1014 (emphasis added). The researchers also stated that “[t]his warrants future human tissue bioavailability studies and further clinical studies in men with CaP [prostate cancer].” F. 1014.

Another study by Dr. Rettig and Dr. Heber, et al., titled, “*Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-kappaB-dependent mechanism,*” evaluated POMx Pills and POM Juice and found that their consumption was linked to reduction in cancer growth

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and decreased plasma PSA levels. F. 1016. The study found that one of the most well-established signaling pathways mediating inflammatory responses relevant to cancer is the nuclear factor-*kappa*B (“NF-*kB*”) pathway, which serves as a predictor for recurrence of prostate cancer after radical prostatectomy, and that POMx inhibited NF-*kB* and cancer cell viability in a dose response fashion *in vitro* and in a human LAPC4 prostate cancer xenograft mouse model. F. 1016. Based on the results, the researchers concluded “that pomegranate juice *could have potential* as a dietary agent to prevent the emergence of androgen-independence,” thus, potentially prolonging life expectancy of prostate cancer patients, and suggested “that this may be a high priority area for future clinical investigation.” F. 1016 (emphasis added).

As testified to by Dr. deKernion, Respondents’ *in vitro* and animal studies showed that pomegranate juice inhibited the growth of prostate cancer cells and actually killed cancer cells from humans that had been inserted into mice. F. 1020. However, as Dr. deKernion also testified, and Complaint Counsel’s experts concurred, one cannot always extrapolate from *in vitro* and animal results to what the results would be in humans. F. 1022. Experts in the field agree that even where the animal and *in vitro* evidence is strong and shows that an agent’s mechanism of action works, this evidence alone does not prove that an agent works in humans and, thus, does not show that the POM products treat, prevent, or reduce the risk of prostate cancer. F. 1024.

**ii. Clinical trials**

Respondents have sponsored one human clinical study, which is completed and published, and one human clinical study that is not yet published. F. 1025. The published study, titled, *Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer* by Pantuck, et. al, was published in the journal *Clinical Cancer Research* in 2006. (“Pantuck Study”). F. 1030. The ongoing human clinical study, by Dr. Michael A. Carducci, is completed, and an abstract summarizing the results has been published, but a final, peer-reviewed study report had not been published at the start of trial in this matter. The abstract is titled, *A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific*

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*Antigen Following Primary Therapy*, J Clin Oncol 29: 2011 (suppl 7; abstr 11) (“Carducci Study”). Detailed findings of fact on the Pantuck Study and the Carducci Study are set forth in Section II.H.4, *supra*, and summarized here.

**(a) The Pantuck Study**

The Pantuck Study was conducted by Dr. Allan Pantuck, an Associate Professor of Urology at UCLA Medical School who maintains a clinical practice at UCLA. F. 1026. Dr. Pantuck’s study was the first clinical trial of pomegranate juice in patients with prostate cancer. F. 1036. According to the published study report, the Pantuck Study was “an open-label, single-arm [one treatment group] clinical trial,” meaning it was not an RCT and did not have a placebo group. F. 1037. The Pantuck Study included 46 patients who had been diagnosed with prostate cancer. F. 1039. All 46 patients in the Pantuck Study drank eight ounces of pomegranate juice daily and had their blood drawn every three months to have their PSA determined. F. 1043. The presence of detectable PSA after radical prostatectomy or other radical treatment usually indicates cancer is present. F. 1041. PSA doubling time (“PSADT”) is a mathematical expression of the rapidity with which the prostate specific antigen is rising, and an expression of the rapidity of growth and number of prostate tumor cells. F. 1042.

Patients in the Pantuck Study who consumed POM Juice experienced a statistically significant increase in PSADT, when compared to their own baseline pre-treatment PSADT. F. 1044. In the Pantuck Study, the average pre-treatment PSADT before intervention was approximately 15 months, and after 33 months, the average post-treatment PSADT was approximately 54 months. F. 1054. Thus, mean PSADT significantly increased from a mean of 15 months at baseline to 54 months post-treatment. F. 1045. The Pantuck Study concluded that the statistically significant prolongation of PSA doubling time, coupled with corresponding laboratory effects on prostate cancer *in vitro* cell proliferation and apoptosis, as well as oxidative stress, warrant further testing in a placebo-controlled study. F. 1047.

In 2008, Dr. Pantuck presented a follow-up report and released the abstract titled, Pantuck, AJ, et al., “*Long term follow*

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*up of pomegranate juice for men with prostate cancer and rising PSA shows durable improvement in PSA doubling times,”* American Society of Clinical Oncology (“Pantuck Phase II Follow-Up Results”), which summarized follow-up results for the Pantuck Study. F. 1048. According to the published abstract, fifteen active patients (31%) remained on the study. F. 1049. All of the men who had dropped out of the Pantuck Study did so because their PSA had increased. F. 1049. The Pantuck Phase II Follow-Up Results stated that those who continued on pomegranate juice maintained a lengthening of their PSA doubling time compared to men who did not continue on pomegranate juice. F. 1050. The Pantuck Phase II Follow-Up Results found that long-term follow up of pomegranate juice consumption in men with prostate cancer and rising PSA following primary therapy demonstrates a durable increase in PSA doubling time and concluded that a multi-center, randomized phase III study is ongoing to further evaluate the benefits of pomegranate in a placebo-controlled manner. F. 1052.

When the Pantuck Study report was released in 2006, Dr. Pantuck was quoted in an American Association for Cancer Research press release, as stating: “[w]e don’t believe we are curing anyone from prostate cancer.” F. 1054. He pointed out that “although a third of patients experienced a decrease in PSA during the study, nobody’s PSA went to zero.” F. 1054. Dr. Pantuck further explained: “The PSA doubling time, however, was longer. For many men, this may extend the years after surgery or radiation that they remain recurrence free and their life expectancy is extended.” F. 1054.

**(b) The Carducci Study**

The Carducci Study was conducted by Dr. Michael Carducci, a Professor of Oncology and Urology at the Johns Hopkins University School of Medicine, in Baltimore, Maryland. F. 1065. Dr. Carducci has conducted 40 to 50 clinical trials relating to prostate cancer and has published approximately 80 articles related to prostate cancer. F. 1067.

In 2006, Dr. Carducci began working with Respondents to design the Carducci Study. F. 1068. Dr. Carducci submitted a proposed protocol for the Carducci Study to Respondents for a

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larger randomized three-arm (three groups) study, with two treatment arms and one placebo arm. F. 1068. Respondents conducted a cost and feasibility analysis and decided that the study proposed by Dr. Carducci was too costly, and, thus, the placebo arm was dropped from the study. F. 1069. The Carducci Study began in January 2008. F. 1070. In 2011, Dr. Carducci presented the abstract of his clinical research study titled, “*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-specific Antigen Following Primary Therapy*” at the disease specific meeting of the American Society of Clinical Oncology (“Carducci abstract”). F. 1072.

The Carducci Study was a multi-center, double blind Phase II randomized trial that studied the effect of two different doses of POMx Pills (one or three capsules) on PSADT in men who had received initial therapy for prostate cancer. F. 1070. One hundred and four (104) men were enrolled and treated for up to six months (92%), 12 months (70%), and 18 months (36%). F. 1075. PSA levels were obtained every three months. F. 1074.

The Carducci abstract stated: median PSADT lengthened from 11.9 months at baseline to 18.5 months after treatment, a within group measurement, which showed that POMx treatment significantly increased the PSA doubling time by over six months in both treatment arms. F. 1076. There was no significant treatment difference in PSADT between the group who took one capsule and the group who took three capsules of POMx. F. 1075. The Carducci abstract also stated that 13 patients (13%) had declining PSA levels during the study. F. 1077. The Carducci abstract concluded that POMx demonstrates “promising antitumor effects in prostate cancer.” F. 1078.

**(c) Expert Opinions of the Pantuck and Carducci Studies**

Complaint Counsel’s experts, Dr. Eastham and Dr. Stampfer, opined that the Pantuck Study and Carducci Study do not constitute adequate substantiation for Respondents’ claims that the POM Products treat, prevent or reduce the risk of prostate cancer, for a number of reasons, including: (1) the studies lacked a placebo-control group; (2) PSA doubling time is not a valid endpoint; (3) the studies do not assess whether the POM Products

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prevent prostate cancer; and (4) the results of the Pantuck Study on POM Juice cannot be used to support claims made about POMx Pills. Respondents' replies to each of these challenges to the adequacy of Respondents' substantiation are addressed, in order, below.

First, the Pantuck Study and Carducci Study did not have a placebo-control group. F. 1037, 1069, 1070. Complaint Counsel's experts opined that without a control group, it is not possible to conclude that the POM Products alone had an effect on the patients' PSA. F. 1087, 1088, 1096. Respondents' expert, Dr. deKernion testified that in both the Pantuck Study and the Carducci Study, the control was the previous PSA doubling time prior to treatment. F. 1115. The researchers measured the doubling time before patients took POM Juice or POMx and then measured doubling time afterwards, comparing one to the other. F. 1115. Dr. deKernion further testified that a control arm is often used to control for the placebo effect and that the use of a placebo group is more important when you have a subjective reporting (such as level of pain), as opposed to an objective reporting (such as PSADT). F. 1116, 1117. However, Dr. deKernion also acknowledged that without a placebo, one cannot be certain that the effect on PSA doubling time seen in the Carducci Study is attributable to POMx. F. 1118. Furthermore, Dr. Pantuck testified that the lack of a "blinded control" group was the "greatest limitation" of his study, and Dr. Carducci testified that without a placebo, he cannot be sure that the effect on PSADT observed in the Carducci Study is attributable to POMx.<sup>19</sup> F. 1060, 1083.

Second, the Pantuck Study and the Carducci Study used mean PSA doubling time as the primary endpoint. F. 1040, 1070. The expert testimony on the validity of PSA doubling time as a primary endpoint is conflicting. Complaint Counsel's experts, Dr. Stampfer and Dr. Eastham, both criticized this method, opining that it is unknown if PSADT predicts overall survival in prostate

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<sup>19</sup> In addition, the Carducci Study showed no difference between a one pill dose and a three pill dose. Complaint Counsel's expert, Dr. Stampfer, testified that the lack of a dose response, despite a three-fold difference in dosage, does not support a causal relationship between POMx and change in PSADT. F. 1075.

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cancer patients throughout its range, PSADT is not a surrogate for overall survival, and PSADT is not a relevant surrogate marker for prostate cancer prevention. F. 1089, 1097. However, Dr. Stampfer also testified that PSA doubling time is a “predictor of disease and mortality” and that, if the extension of PSA doubling time is true, it would substantially prolong lives. F. 1104. Dr. Eastham, too, offered a contradictory opinion to his opinion at trial in an article wherein he concluded, “PSADT is an important prognostic marker in men with biochemical failure after local therapy for prostate cancer, and it predicts the probable response to salvage radiotherapy, progression to metastatic disease and prostate cancer specific death.” F. 1102.

Respondents’ expert, Dr. Heber, testified that PSA doubling time is a “very important clinically utilized marker of clinical status.” F. 1112. *See also* F. 1113 (Dr. Heber testifying that there is a lot of support from the urological community to get the FDA to accept PSA doubling time as a surrogate endpoint). Dr. deKernion testified that given the understanding of PSA doubling time in predicting risk of clinical recurrence and to some extent survival, it is logical to use changes in PSADT as indicative of an intervention’s effectiveness regarding prostate tumor behavior. F. 1110. Dr. deKernion also acknowledged, however, that PSA doubling time is not accepted by experts in the field of prostate cancer as a surrogate endpoint for clinical benefit in chemotherapy trials. F. 1111.

As testified to by Dr. Pantuck, “[i]t remains controversial whether modulation of PSA levels represents an equally valid clinical end point.” F. 1059. On the one hand, Dr. Pantuck testified that “PSA has not been validated prospectively as a surrogate endpoint for a meaningful prostate cancer outcome.” F. 1059. On the other hand, Dr. Pantuck stated that “although PSA changes are thought to be prognostically important, it is based on level 2 evidence, and nobody has ever shown conclusively that changes in PSA kinetics arising from therapeutic intervention is meaningful.” F. 1059. Dr. Carducci’s testimony on this point also underscores this conflict. While Dr. Carducci testified that the use of PSA doubling time as a primary endpoint to determine if POMx has an effect on the disease state was a scientifically valid way to conduct the Carducci Study, he also acknowledged

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that PSA doubling time as a marker or surrogate has not been proven and that the endpoint of PSA doubling time is not a standard for regulatory approval of drugs at the FDA level. F. 1079, 1080.

There are no studies proving that changing the rate of PSA doubling time changes the natural history of prostate cancer by delaying the development of metastases or death from the disease. F. 1131. Experts in the field of prostate cancer agree that PSADT is not an accepted surrogate endpoint for survival or prostate cancer-specific mortality in prostate cancer treatment clinical trials. F. 1134. Although this Initial Decision does not require Respondents to meet FDA standards for clinical trials to substantiate claims about a food or food-derived product that is safe and not being sold as an alternative to medical treatment, because the use of PSA doubling time as a valid endpoint is controversial, this factors into evaluating the adequacy of Respondents' substantiation.

Third, Complaint Counsel's experts point out that the clinical studies examining the effect of the POM Products on prostate cancer have been conducted on men who either have prostate cancer, or have been treated for prostate cancer and have experienced a biochemical recurrence. F. 1039, 1070. Because the Pantuck Study and Carducci Study were designed as treatment studies, Dr. Eastham and Dr. Stampfer opine that there is no competent and reliable scientific evidence supporting a claim that the POM Products prevent prostate cancer. F. 1091, 1099.

Respondents' expert, Dr. deKernion, explained that in order to show an effect of POM Products on prostate cancer, the best way to do that research is on patients whose prostate had been removed, because the presence of PSA elevation is almost always an indication of remaining cancer. F. 1122. Dr. deKernion further opined that although there is not proof that POM Products reduce the risk of prostate cancer, the same mechanism shown in the *in vitro* and animal studies and in the Pantuck and Carducci human studies showed, with a "high degree of probability," that POM Juice and POMx would inhibit the clinical development of prostate cancer in men who have not been diagnosed with that disease and that POM Juice and POMx could possibly play a role

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in preventing them from getting prostate cancer. F. 1124; *see also* F. 1123.

Dr. Pantuck acknowledged that the Pantuck Study did not prove that pomegranate juice prevents or reduces the risk of prostate cancer because all the patients in the study already had prostate cancer and, thus, his study did not address anything related to causation. F. 1055. Dr. Carducci similarly testified that the Carducci Study was never designed to prove, and did not prove, that POMx prevents or reduces the risk of prostate cancer. F. 1084.

Fourth, Complaint Counsel's experts state that the Pantuck Study on POM Juice cannot provide reliable evidence to support claims about POMx Pills' benefit for prostate cancer. F. 1094. According to Dr. Eastham: POM Juice is not identical to POMx Pills and POMx Liquid; POM Juice has more than one active ingredient; processing may result in eliminating a needed ingredient; and even if the active ingredient is known and the alternate compound contains the same amount of active ingredient, the alternate compound may contain some other as yet unknown compound that might counter-act the benefit of the active agent. F. 1094. However, Dr. Eastham is not an expert in bioavailability and did not review the equivalency studies or articles on POM Juice, POMx Pills or POMx Liquid. F. 1095.

Dr. Heber, the only expert who opined on the bioavailability of pomegranate polyphenols, explained that because both the 100% Juice and POMx contain ellagitannins that contribute to the antioxidant activity of the products (and because both are bioavailable (absorbed) in humans), there is no difference in the antioxidant effect between POM Juice and POMx products in laboratory studies. F. 953, 1119. Dr. Heber testified that in laboratory studies he conducted, he found no difference in the antioxidant effect between POM Juice and POMx products and that animal studies indicate that the effects of pomegranate juice and POMx Pills on prostate cancer are equivalent. F. 1119. Moreover, the Carducci Study obtained a result similar to the Pantuck Study regarding the effect of POMx on PSADT. *Compare* F. 1076 *with* F. 1045.

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**c. Conclusion**

As discussed above, the expert testimony regarding the studies relied upon by Respondents is conflicting. The greater weight of the persuasive expert testimony demonstrates the following: The basic research, the Pantuck Study, and the Carducci Study, relied on by Respondents, support the conclusion that pomegranate juice has a beneficial effect on prostate health. F. 1142. Competent and reliable scientific evidence supports the conclusion that the consumption of pomegranate juice and pomegranate extract supports prostate health, including by prolonging PSA doubling time in men with rising PSA after primary treatment for prostate cancer. F. 1142. However, the greater weight of the persuasive expert testimony shows that the evidence relied upon by Respondents is not adequate to substantiate claims that the POM Products treat, prevent, or reduce the risk of prostate cancer or that they are clinically proven to do so. F. 1143. Indeed, the authors of the Pantuck Study and the Carducci Study each testified that their study did not conclude that POM Juice treats, prevents, or reduces the risk of prostate cancer. F. 1055, 1056, 1084, 1085. And, as Respondents' expert conceded, no clinical studies, research and/or trials show definitively that the POM Products treat, prevent, or reduce the risk of prostate cancer. F. 1135-1138.

Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic research and clinical trials, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate a claim that the POM Products treat, prevent, or reduce the risk of prostate cancer or that clinical studies, research, and/or trials prove that the POM Products treat, prevent, or reduce the risk of prostate cancer. F. 1143. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied prostate cancer claims found to have been made in this case, and that, therefore, such claims were false or misleading.

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**5. Substantiation for Respondents' erectile dysfunction claims****a. Overview**

As discussed in Section III.E.2.e, *supra*, the evidence demonstrates that Respondents disseminated advertisements that impliedly represented that drinking eight ounces of POM Juice daily, or taking one POMx Pill daily, is clinically proven to treat, prevent or reduce the risk of erectile dysfunction. Complaint Counsel contends that (1) Respondents did not possess and rely upon a reasonable basis to substantiate their efficacy claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction; and (2) clinical studies, research, and/or trials do not prove Respondents' establishment claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. CCB at 50-54. With respect to claims made about erectile dysfunction, although Respondents have been found to have made establishment claims only, by virtue of their very nature, the advertisements containing establishment claims also make the efficacy claims that are challenged as unsubstantiated in the Complaint. CCB at 31.

**i. Summary of expert opinions**

In support of its position, Complaint Counsel submitted the expert report and testimony of Dr. Arnold Melman, M.D., a Professor and Chairman of the Department of Urology at the Albert Einstein College/Montefiore Medical Center in New York. F. 208. Dr. Melman has extensive experience in designing and reviewing protocols for clinical trials. F. 209. Dr. Melman is an expert in the evaluation of whether a product treats, prevents, or reduces the risk of erectile dysfunction, and in the design and conduct of clinical trials involving erectile dysfunction. F. 211. Dr. Melman opined that to constitute a reasonable basis for the claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction, or have been clinically proven to do so, at least one well-designed, human RCT involving several investigatory sites is required. F. 654. Dr. Melman also opined that a well-designed, human RCT must use a validated tool for measuring treatment outcomes and that the clinical trial must have a total sample population large enough to produce clinically

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significant results and a statistical significance of  $p < 0.05$ . F. 655.

Dr. Melman's opinions are attenuated for several reasons. Although Dr. Melman testified that the Global Assessment Questionnaire ("GAQ") is not a validated measure for assessing erectile function, Dr. Melman had not heard of the term "GAQ" prior to forming his opinions in this case. F. 1196, 1233, 1234. Also, although Dr. Melman testified that Respondents are required to conduct RCTs before making erectile dysfunction claims about the POM Products, Dr. Melman has made claims about a gene transfer therapy for erectile dysfunction called "hMaxi-K," which he patented and hoped to market, based on an animal study and one study of 11 men. F. 659, 660, 1237. In addition, Dr. Melman testified that a study to support a treatment for erectile dysfunction must show that a man can complete intercourse to orgasm. F. 659.

In support of their position that they possessed and relied upon a reasonable basis to substantiate their claims, Respondents submitted the expert reports and testimony of Dr. Arthur Burnett and Dr. Irwin Goldstein. Dr. Burnett is an expert in the area of erectile health, a Professor of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital, and is well-known for his groundbreaking work on nitric oxide. F. 234, 238, 239. Dr. Burnett has treated between 10,000 and 15,000 patients for erectile dysfunction. F. 237. Dr. Burnett opined that Respondents' basic scientific and clinical evidence supports the conclusion that pomegranate juice's high antioxidant content improves erectile health and function by increasing the level and preservation of nitric oxide. F. 242. Dr. Burnett also concluded that a safe pure fruit juice, like pomegranate juice, which is not used as a substitute for proper medical treatment, does not require RCTs to substantiate erectile health claims. F. 683, 684.

Dr. Irwin Goldstein is an expert in sexual medicine who opined on the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. F. 243, 247. Dr. Goldstein is a board certified urologist and sexual medicine physician who has been involved in sexual medicine clinical practice, clinical research, and basic research since 1980. F. 243, 244. Dr. Goldstein testified that competent and reliable scientific

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evidence fully supports the conclusion that pomegranate juice produces a benefit to proper and effective erectile function. F. 249. Dr. Goldstein opined that RCT studies are not required to substantiate claims that pomegranate juice can aid in erectile health and that *in vitro* and animal studies demonstrated a likelihood that pomegranate juice improves erectile health. F. 686. Dr. Goldstein also opined that the consumption of pomegranate juice is a logical option for men who are not responsive to conventional drugs or who are unwilling to consider invasive or mechanical therapies for treatment of their erectile dysfunction. F. 1307, 1308.

**ii. Standard for substantiation**

Having fully considered and weighed the evidence adduced at trial, the evidence demonstrates that competent and reliable scientific evidence is required to support claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that they have been clinically proven to do so. *See* F. 1144-1148. Based on the greater weight of the persuasive evidence from the experts at trial, to support claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction, competent and reliable evidence must include clinical studies, although not necessarily RCTs, that show that the POM Products did treat, prevent, or reduce the risk of erectile dysfunction. *See id.* As analyzed below, Complaint Counsel has demonstrated that Respondents did not possess adequate competent and reliable scientific evidence to substantiate the implied claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that clinical tests show the same. Complaint Counsel has, therefore, met its burden of proving that Respondents' claims are false or misleading. *See QT*, 448 F. Supp. 2d at 959.

**b. Scientific evidence relied upon**

The mechanism by which pomegranates promote erectile health and function is through potent antioxidant components and the impact on nitric oxide, which is of "paramount importance" to good erectile health and function and is the key molecule that governs penile erections. *See* F. 1165-1184. Detailed findings of fact on Respondents' six *in vitro* and *in vivo* studies and one

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human clinical study are set forth in Section II.I.3, *supra*. Respondents' studies demonstrate the potential benefits of pomegranate juice on erectile health and function. F. 1310, 1312. These studies do not, however, show that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or show that clinical tests demonstrate that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. F. 1313, 1314.

**i. *In vitro* and *in vivo* studies**

Dr. Louis Ignarro is highly respected and won a Nobel prize for his discoveries concerning nitric oxide ("NO"). F. 1292, 1297. He conducted an *in vitro* study to evaluate pomegranate juice's capacity to protect NO against oxidative destruction. F. 1292. Based on his findings, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of NO against oxidative destruction, thereby resulting in augmentation of the biological actions of NO. F. 1293, 1294. Other studies show similar results. *See* Section II.I.3, *supra*. For example, using an animal model, Dr. Kazem Azadzoï and colleagues found that, due to high antioxidant capacity, long-term pomegranate juice intake increased intracavernosal blood flow in the penis, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. F. 1275-1279. In addition to these *in vitro* and *in vivo* studies, multiple other significant scientific studies exist that not only demonstrate the antioxidative powers of pomegranates in enhancing and preserving NO, but also support the general proposition that antioxidants positively influence erectile health. *See* Section II.I.3, *supra*.

Complaint Counsel's expert, Dr. Melman, opined that basic research studies about antioxidants' effects on NO levels may relate to the biochemical process for erectile function, but that basic research studies do not directly involve erectile function in humans and cannot alone prove that POM Juice treats, prevents, or reduces the risk of erectile dysfunction in humans. F. 1301. Respondents' experts reviewed the basic science relied upon Respondents and concluded: basic science alone supports the potential benefit at the human level to improve the physiology of erectile tissue preserving erect tissue health and, thus, suggests a

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probable benefit of pomegranate juice on erectile health. F. 1298-1300.

**ii. Clinical trial**

Respondents also sponsored a clinical study, performed by Dr. H. Padma-Nathan, and published in the *International Journal of Impotence Research* in 2007 (“Forest/Padma-Nathan Study”). F. 1206. The Forest/Padma-Nathan Study was an RCT of pomegranate juice versus placebo in men with erectile dysfunction. F. 1210. The Forest/Padma-Nathan Study engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week “washout.”<sup>20</sup> F. 1211.

Using a global assessment questionnaire (“GAQ”), Dr. Padma-Nathan found that participants rated pomegranate juice 50% more effective than a placebo at improving erections. F. 1212, 1224. The GAQ results achieved a probability value (“*p*-value”) of 0.058, meaning that the positive results of the study were 94.2% likely to be the result of something other than “chance.” F. 1225. Although the *p*-value was a few thousandths of a percentage point short of achieving statistical significance of 95%, the study has clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health. F. 1248, 1250.

Dr. Melman, Complaint Counsel’s expert, criticized the Forest/Padma Nathan Study on grounds that the GAQ is not a validated measure and does not provide clinically significant information; the study was not conducted over a sufficient duration to show a sustained clinically significant effect on erectile function; and the study results did not achieve statistical significance. F. 1233, 1235-1236. Respondents’ experts reviewed the clinical evidence that Respondents relied upon and

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<sup>20</sup> The Forest/Padma-Nathan Study used a crossover design, and the 53 participants who completed the study received a different beverage during the two 28-day treatment periods. Participants in cohort one consumed POM Juice in period one and then switched to the placebo beverage in period two. Participants in cohort two consumed the placebo beverage in period one and POM Juice in period two. F. 1211.

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concluded that even though statistical significance was not reached, the Forest/Padma-Nathan Study “provides very valuable information” regarding erectile health and function and is “clinically significant” because “it supports the conclusion that the positive results in the basic science are borne out in human function.” F. 1238, 1239, 1245. *See also* F. 1240-1245.

**c. Conclusion**

The greater weight of the persuasive expert testimony demonstrates the following: The basic research relied upon by Respondents and the Forest/Padma-Nathan Study support the conclusion that pomegranate juice has a beneficial effect on erectile tissue physiology, health, and function. F. 1310, 1312. The evidence relied upon by Respondents also supports the conclusion that pomegranate juice is a *potential* treatment for erectile dysfunction. F. 1147, 1243, 1252. The evidence relied upon by Respondents is not, however, adequate to substantiate a claim that clinical studies show that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that clinical studies show the same. F. 1253, 1313, 1314. Indeed, the authors of the Forest/Padma-Nathan Study each testified that the study did not conclude that POM Juice treats, prevents, or reduces the risk of erectile dysfunction. F. 1230.

Respondents’ defense on this issue is that they did not make any claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. As such, Respondents’ experts did not provide expert opinion on whether Respondents’ science was adequate to support a claim that the POM Products treat, prevent, or reduce the risk of erectile dysfunction. Rather, the expert report of Dr. Goldstein states: “The available body of scientific literature – including *in vitro*, *in vivo*, and preliminary clinical trials – strongly suggests that consuming pomegranate juice promotes erectile health.” F. 249. The expert report of Dr. Burnstein concludes that the basic scientific and clinical evidence is sufficient to support the use of pomegranate juice as a potential benefit for vascular blood flow and the vascular health of the penis. F. 242, 1184. Thus, Respondents have failed to provide expert opinion on the central issue of whether Respondents’ science was adequate to support an implied claim that the POM Products treat, prevent, or reduce the risk of erectile dysfunction,

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or that they are clinically proven to do so. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at \*243 (Initial Decision).

Based on the more persuasive expert testimony at trial, competent and reliable scientific evidence demonstrates that pomegranate juice in its various forms provides a positive benefit to erectile health and erectile function. F. 1312. However, as testified to by Respondents' expert, the use of pomegranate juice to promote erectile *health* is a separate and distinct concept from the use of this nutraceutical as a safe and effective treatment for the medical condition of erectile *dysfunction* such as with a PDE5 inhibitor. F. 249, 1311 (emphasis in original).

Having fully considered and weighed all the evidence and the conflicting expert testimony on Respondents' basic science and clinical trial, the greater weight of the persuasive expert testimony demonstrates that there is insufficient competent and reliable scientific evidence to substantiate claims that the POM Products treat, prevent, or reduce the risk of erectile dysfunction or that they are clinically proven to do so. F. 1313, 1314. Accordingly, Complaint Counsel has met its burden of proving that Respondents' substantiation was inadequate to make the implied erectile dysfunction claims found to have been made in this case, and that, therefore, such claims were false or misleading.

## 6. Summary

To summarize, in finding that Respondents' substantiation was not adequate, the facts that the POM Products are derived from a fruit, are safe, and are not advocated as an alternative to medicine were all considered. In addition, the cost and feasibility of conducting RCTs and the benefits of truthful claims were also considered. Ultimately, however, the determination as to what "amount of substantiation experts in the field would agree is reasonable" and "the level of proof sufficient to satisfy the relevant scientific community of the claim's truth" must, in accordance with applicable law, turn on the nature of the claims made by Respondents.

In this case, as found in Section III.E.2., *supra*, Respondents disseminated advertisements that impliedly represented that the POM Products treat, prevent, or reduce the risk of heart disease,

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prostate cancer, and/or erectile dysfunction, and/or that “clinical studies, research, and/or trials prove” that the POM Products treat, prevent, or reduce the risk of the same. As to these advertisements, whether or not Respondents’ substantiation was adequate to support general and highly qualified health claims is not the material issue. Having crossed the line from making general and highly qualified health claims to making implied disease claims, “the level of proof sufficient to satisfy the relevant scientific community of the claim’s truth” and “the amount of substantiation experts in the field would agree is reasonable” were necessarily heightened. *QT*, 448 F. Supp. 2d at 962 (where defendants make a “medical, health-related claim,” . . . such a claim must be based on a heightened level of substantiation”). With respect to both the establishment and efficacy claims that Respondents have been found to have made, Respondents’ substantiation failed to meet the level of substantiation required. Because Complaint Counsel met its burden of proving that Respondents’ substantiation was inadequate, the advertisements compiled in the Appendix to this Initial Decision are false and misleading.

**G. Whether Respondents’ Claims are Material****1. Overview**

Having found that Respondents disseminated advertisements conveying the claims alleged in the Complaint and that those claims were false or misleading, the next step is to determine whether those claims are material to prospective consumers. *Kraft*, 970 F.2d at 314. “The basic question” on the issue of materiality “is whether the act or practice is likely to affect the consumer’s conduct or decision with regard to a product or service. If so, the practice is material, and consumer injury is likely, because consumers are likely to have chosen differently but for the deception.” *Deception Statement*, 1984 FTC LEXIS 71, at \*171; *see also* Joint Stipulations of Law and Facts, Stipulations of Law ¶ 4 (stipulating that “[a] ‘material’ misrepresentation or practice is one which is likely to affect a consumer’s choice of or conduct regarding a product”). In other words, information is material if it is “important to consumers.” *Deception Statement*, 1984 FTC LEXIS 71, at \*188.

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Materiality is a test of the likely effect of the claim on the conduct of a consumer. *Novartis Corp.*, 127 F.T.C. at 691. “Materiality turns upon whether those consumers who have drawn the claim from the advertisement and been misled by it are also likely to have their conduct affected by the misrepresentation.” *Id.* To be material, “a claim does not have to be the *only* factor or the *most* important factor likely to affect a consumer’s purchase decision, it simply has to be *an* important factor.” *Id.* at 683 (emphasis in original).

Complaint Counsel contends that the challenged claims are presumed to be material because, among other reasons, the claims are “health-related efficacy claims.” CCB at 26-27. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at \*245 (Initial Decision). Moreover, Complaint Counsel asserts, there is evidence, including Respondents’ own marketing surveys, demonstrating that the challenged claims are material. CCB at 28-29. Respondents contend that regardless of whether a presumption of materiality applies in this case, Respondents have rebutted the presumption, with survey evidence and expert opinion that the claims are not material to consumers’ purchase decisions, and that Complaint Counsel has failed to adduce evidence that the challenged claims are, in fact, material. Therefore, Respondents argue, Complaint Counsel has failed to meet its burden of proof on materiality. RB at 82-92.

The presumption of materiality simply reflects the “general judgment that substantive claims in advertisements (in other words, claims other than “puffery” or window-dressing) would not have been made except to affect a consumer’s choice of or conduct regarding a product. Thus, the very existence of the claim ordinarily is sufficient evidence for the Commission to conclude it is material. “However, respondent is always free to counter this evidence either with arguments pertaining to the content of the ad itself or with extrinsic evidence.” *Thompson Medical*, 1984 FTC LEXIS 6, at \*374 n.45.

In *Novartis*, the Commission explained the operation of the presumption of materiality as follows:

Certain categories of information are presumptively material, including, but not limited to, express claims,

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claims significantly involving health or safety, and claims pertaining to the central characteristic of the product. *Deception Statement*, 103 F.T.C. at 182. Similarly, the Commission will infer materiality where the record shows that respondent intended to make an implied claim.

*Id.* . . .

“To establish a ‘presumption’ is to say that a finding of the predicate fact, here, any of the factors listed above, produces a required conclusion in the absence of explanation,” here, materiality. *St. Mary’s Honor Ctr. v. Hicks*, 509 U.S. 502, 506 (1993) (internal quotation marks omitted). In order to rebut the presumption, respondent must come forward with sufficient evidence to support a finding that the claim at issue is not material. Respondent can present evidence that tends to disprove the predicate fact from which the presumption springs (*e.g.*, that the claim did *not* involve a health issue) or evidence directly contradicting the initial presumption of materiality. This is not a high hurdle. Unless the rebuttal evidence is so strong that the fact finder could not reasonably find materiality, the fact finder next proceeds to weigh all of the evidence presented by the parties on the issue. *See id.* at 516 (noting that after the presumption drops out, “the inquiry . . . turns from the few generalized factors that establish [the presumption] to the specific proofs and rebuttals . . . the parties have introduced”). While the presumption itself is negated by sufficient rebuttal evidence, as previously noted, the predicate facts that gave rise to the presumption are not. These facts remain evidence from which materiality can be inferred. *See Boise Cascade*, 113 F.T.C. at 975 (1990). However, this evidence is simply part of the entire body of evidence considered. *See also 21 Charles Alan Wright and Kenneth W. Graham, Jr., Federal Practice and Procedure: Evidence* §§ 5122 *et seq.* (1977 and 1998 Supp.) (discussing the history and application of presumptions).

*Novartis*, 127 F.T.C. at 686-87.

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Applying the principles of *Novartis* to the evidence in this case, it is unnecessary to rely on any presumption because, as further discussed below, the preponderance of the evidence shows that the challenged claims are material. Even if a presumption arises, and even if Respondents' evidence sufficiently rebuts the presumption, a "weigh[ing] of all of the evidence presented by the parties on the issue" shows that the challenged claims would be important to consumers, and likely to affect consumers' conduct or decisions. *Novartis*, 127 F.T.C. at 686. Accordingly, because the evidence is sufficient to prove materiality in the instant case, irrespective of any legal presumption, logic dictates that this Initial Decision need not, and it does not, analyze the effect of a presumption of materiality in this case.

## 2. Evidence of materiality

The evidence shows, and Respondents have failed to effectively rebut, the "predicate fact" that the advertising claims at issue involve health-related matters; specifically, efficacy for disease or dysfunction, and clinical proof of such efficacy. F. 580-583; *see Novartis*, 127 F.T.C. at 686-87. Common sense and experience readily support the conclusion that Respondents' claims in this regard would be important to consumers considering a purchase and likely affected consumers' decisions. Such a conclusion requires "no great leap." *Novartis*, 127 F.T.C. at 687.

Moreover, the evidence shows that advertising the results of studies related to heart disease, prostate cancer, and erectile dysfunction resulted in sales and that Respondents were aware of this fact. F. 1317, 1321, 1323-1324, 1326. *See Kraft*, 114 F.T.C. 40, 1991 FTC LEXIS 38, at \*46 (finding that materiality was shown by evidence that the challenged advertisement copy led to increased sales). For example, in evaluating how copy-dense or "medically oriented" to make a planned POMx Pill advertisement, Diane Kuyoomjian, Senior Vice President of Marketing for POM from 2008 to 2009, reminded Mrs. Resnick in a January 2009 e-mail: "[y]ou'll recall that a previous ad test with less copy did not generate as many orders. That would suggest we keep the research info in the new ad, which would make it information dense as well." F. 1323. In addition, Ms. Leow, a creative director for Roll, stated that scientific information in advertising

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and marketing material helps sell the products, because the scientific information provided the consumer with a “reason to believe.” F. 1326. *See also* F. 1321. (September 2006 press article, stating “every time a new study [was] released touting” a health benefit of pomegranate juice, there was a “spike in sales. The study . . . linking the consumption of pomegranate juice to a reduction in prostate cancer was especially helpful.”). Further, Mr. Resnick testified that POM communicates to consumers the “[company’s] belief that pomegranate juice is beneficial in treating some causes of impotence, for the purpose of promoting sales of its product,” F. 1316, and he further acknowledged that the kinds of benefits revealed by POM’s research results are the primary reason people buy pomegranate juice. F. 1317; *see also* F. 1319 (draft creative brief describing concept behind advertising dollars spent on research as, “We don’t just say our product is great, we have clinical studies that prove its efficacy”). Mr. Resnick also acknowledged that consumers buy pomegranate juice “because they believe and in fact it does postpone the onset of prostate cancer, which postpones the onset of death.” F. 1317-1318.

In addition, in the ordinary course of business, POM conducted consumer research to understand the characteristics, attitudes and usage habits of POM customers and to identify barriers and opportunities for increasing consumption, particularly in relation to other brands of pomegranate juice. F. 1330. These studies also support a conclusion that the challenged claims are material to consumers. *See Kraft*, 1991 FTC LEXIS 38, at \*40 (relying on consumer survey evidence to finding of materiality). The 2009 OTX Attitudes and Usage Study (“OTX A&U Study”) (F. 1331) found that, of the survey respondents that identified “health” as a reason for drinking pomegranate juice, 47% of the POM Juice drinkers chose the further response, “helps protect against prostate cancer.” F. 1332-1335. Similarly, in August 2007, Respondents commissioned a Zoomerang online survey of the general public, “[t]o better understand pomegranate and non-pomegranate juice consumers,” with respect to, among other things, “[i]mportance of certain health benefits.” F. 1342. Six health benefits were listed and these survey respondents were asked to rank which was the most important to them personally. F. 1342. For heavy pomegranate juice drinkers, the number one

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response, for both males and females was “cardiovascular,” and the number two choice for men was “prostate.” F. 1342. For members of the general public responding to the Zoomerang question regarding ranking of health benefits, 60% ranked cardiovascular health as the first or second most important benefit, 40% of males ranked prostate health as the first or second most important benefit, and approximately 18% of males did so for erectile dysfunction. F. 1343. While Respondents’ marketing expert, Dr. David Reibstein, criticized the methodology of using closed-ended questions, such as were used in the OTX A&U Study, because they can “cue” the survey respondent to certain answers and inflate results, F. 1340, closed-ended questions tend to be used when studying purchase motivations and have the advantage of allowing the researcher to obtain specificity in the responses. F. 1341. The materiality survey relied on in *Kraft* also made use of similar closed-ended questions. 1991 FTC LEXIS 38, at \*40 (relying on survey asking respondents to rate the importance of a claim that cheese was “a source of calcium”).

Additional evidence of the materiality of Respondents’ advertising claims is demonstrated by Respondents’ “creative briefs,” which served to direct the content of their advertising. F. 145-151. For example, a creative brief for the POM Wonderful website, from approximately June 2008, shows that the purpose of the “Health Benefits” section of the POM Wonderful website was to communicate the “heart health,” “prostate health,” and “E.D.” “health benefits,” including by explaining how such benefits are provided. F. 1325. Further, in order to engage website viewers, the “Health Benefits” section was to provide “expert” information on heart and prostate matters, as well as a database of studies and results, searchable by subject matter, including heart and prostate. F. 1325; *see also* F. 1327-1328 (creative briefs describing main creative focus for advertising assignments as “prostate cancer”). Respondents’ arguments that creative briefs cannot be relied upon because they reflect the opinions of low level employees, is unsupported by the evidence, *see e.g.*, F. 154, 181, and is unpersuasive.

Finally, in over a decade, POM sponsored over 100 studies at 44 different institutions, and over \$35 million has been invested in POM’s research program. F. 128, 131. POM uses the results of

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studies it has sponsored for marketing purposes, as part of POM's "unique selling proposition." F. 113. Considering these circumstances, particularly that POM was aware that among those purchasing the POM Products were "people that have heart disease or prostate cancer in their family, or have a fear of having it themselves," F. 1320, it defies credulity to suggest that Respondents would advertise study results related to these conditions if such advertising did not affect consumer behavior. In fact, Respondents' marketing expert, Dr. Reibstein, stated that it was indeed possible, and he would expect that, to consumers who were concerned about heart disease, prostate cancer, or erectile dysfunction, a claim that drinking a bottle of POM Juice a day was effective for these conditions would be important to their purchasing decisions. F. 1329.

### 3. Respondents' evidence of immateriality

Respondents rely on the results of the Reibstein Survey, which showed, among other things, that a very small number of survey respondents (12 out of 750), when asked to identify their reasons for purchasing, repurchasing, or recommending pomegranate juice, including POM Juice, identified a specific disease, and of those who did, fewer still mentioned "heart disease" or "cancer." F. 1344, 1351-1365. Based on these study results, Dr. Reibstein expressed the opinion that there is a very small percentage of people that bought, would buy again, or would recommend POM Juice to a friend because they believe that it cures or prevents a specific disease. F. 1372. The Reibstein Survey obtained these results by asking a series of open-ended questions, such as: "Why did you purchase POM Wonderful 100% Pomegranate Juice?" and asking survey respondents to provide "*specific details.*" F. 1354. In this regard, the Reibstein Survey was flawed because it only assessed consumer motivations generally; it did not actually assess whether any of the challenged claims in the Complaint would be important to the survey respondent's decision to purchase the products. F. 1373. Moreover, the survey did not ask any follow-up questions, including of the 35.2% of POM Juice purchasers who stated that they bought or would repurchase POM Juice because it was "healthy." F. 1354, 1361, 1375. The failure to probe further as to what these survey respondents meant by "healthy" and whether there were specific reasons or benefits that underlay their "healthy" responses, constitutes methodological

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flaws that render the Reibstein Survey insufficiently probative to outweigh the substantial, probative evidence, summarized above, showing that disease claims are likely to be important to, and to influence, consumer decision making. *See Kraft*, 1991 FTC LEXIS 38, at \*47 (rejecting materiality survey as insufficiently probative because limited response options offered to survey participants failed to adequately elicit all of the ways in which consumer conduct with respect to the product might be affected by the implied claims at issue). A more probative survey on materiality would have provided survey respondents with a statement about what the claim was, and inquired how important they think that claim would be to their potential purchase decision, F. 1374, as did the survey in *Kraft*, 1991 FTC LEXIS 38, at \*40. Also affecting the relative weight of the Reibstein Survey is the fact that it was commissioned and designed for use in litigation, F. 1344, while the OTX A&U Study and the Zoomerang online survey were conducted in the ordinary course of business. F. 1330, 1331, 1342.

#### **4. Conclusion**

The evidence of materiality in the record outweighs Respondents' evidence of immateriality and, therefore, Complaint Counsel has met its burden of proof on the third element of its deceptive advertising claim. Accordingly, because Complaint Counsel has met its burden as to all three elements of a deceptive advertising claim, liability has been established. The Initial Decision next addresses the appropriate remedy.

#### **H. Remedy**

##### **1. General legal principles**

Having concluded that Respondents violated the FTC Act, that Act authorizes an order requiring respondents to cease and desist from such acts or practices. 15 U.S.C. § 45(b); *FTC v. Nat'l Lead Co.*, 352 U.S. 419, 428 (1957). "As the Court has said many times before, the Commission may exercise only the powers granted it by the Act. The relevant sections empower the Commission to prevent the use of unfair methods of competition and authorize it, after finding an unfair method present, to enter an order requiring the offender 'to cease and desist' from using

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such unfair method.” *Nat’l Lead Co.*, 352 U.S. at 428 (1957) (internal citation omitted).

The purpose of a cease and desist order is to prevent the violations from being repeated, including by “creating stringent monetary incentives (in the form of civil penalties) for its observance.” *In re Litton Indus., Inc.*, No. 9123, 97 F.T.C. 1, 1981 FTC LEXIS 94, at \*147 (Jan. 5, 1981); accord *Thompson Medical*, 1984 FTC LEXIS 6, at \*405-06 (describing order as appropriate “to prohibit and prevent [the respondent] from engaging in deceptive acts or practices”). Thus, “[t]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past.” *FTC v. Colgate-Palmolive Co.*, 380 U.S. 374, 395 (1965) (quoting *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952)). The FTC is permitted “to frame its order broadly enough to prevent respondents from engaging in similarly illegal practices in future advertisements.” *Colgate-Palmolive Co.*, 380 U.S. at 395. “Having been caught violating the Act, respondents ‘must expect some fencing in.’” *Id.* (quoting *Nat’l Lead*, 352 U.S. at 431). The cease and desist order must be sufficiently clear so that it is comprehensible to the violator, and must be reasonably related to the violations found to exist. *Colgate-Palmolive*, 380 U.S. at 392, 395.

Applying the foregoing principles, and after consideration of all the arguments of the parties and the entire record of the case, the attached order, to be entered herewith (hereafter, “Order”), will serve to prohibit and prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise. The scope and terms of the Order are substantially the same as was entered by the Commission, and upheld on appeal to the United States Court of Appeals, to redress unsubstantiated disease claims in *Daniel Chapter One*, No. 9329, 2010 FTC LEXIS 11 (Jan. 25, 2010), review denied, *Daniel Chapter One v. FTC*, No. 10-1064, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010), cert. denied, 131 S. Ct. 2917 (2011).

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**2. Respondents' preliminary arguments**

Respondents argue on various grounds that no cease and desist order should issue in this case, despite violations having been found. These arguments are addressed below

**a. Outliers**

Respondents assert that no cease and desist order may issue in this case based on eight of the Challenged Advertisements, which Respondents assert should be considered “outliers.” Respondents define these “outliers” as advertisements run in the 2003-2006 timeframe, and not thereafter, in which the images and the language regarding the health benefits of POM Juice were “more aggressive than was typical of Respondents.” RB at 67-68. According to Respondents, no relief can be based upon these “outliers” because such advertisements have stopped and Complaint Counsel has failed to demonstrate that such conduct will be repeated. RB at 68-69, citing *FTC v. Evans Products Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985) (stating that past wrongs are not enough for the grant of an injunction, and that an injunction will issue only if the wrongs are ongoing or likely to recur).

Respondents' argument is unconvincing. Of the eight asserted “outliers,” only four are among the Challenged Advertisements found to have made the implied claims alleged in the Complaint: (1) CX0036 (“Cheat Death” print advertisement); (2) CX0016 (“Drink and be healthy” print advertisement); (3) CX0314 (magazine wrap advertisements); and (4) CX0034 (“Amaze your cardiologist” print advertisement). *See* F. 580-583. In addition, even if the exact same advertisements have not been repeated, this does not mean that Respondents' violations will not be repeated, particularly in light of the fact that numerous advertisements disseminated after 2006 were found to have made implied disease claims, without adequate substantiation. F. 307-308, 321, 328, 344, 365, 432, 580-583, 962, 1143, 1313-1314. That the form of the advertisements communicating these implied claims may have changed is not persuasive evidence that Respondents' past wrongs are not likely to reoccur. Furthermore, even if the “outliers” were not considered violations for purposes of injunctive relief, there would be sufficient violations based upon other advertisements to justify injunctive relief in this case. *Bristol-Meyers*, 1983 FTC

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LEXIS 64, at \*250-51 (finding adequate number of deceptive advertisements to support the order, even though the number was fewer than the number found by the ALJ); *In re Fedders Corp.*, No. 8932, 85 F.T.C. 38, 71-72 (Jan. 14, 1975) (holding that one or two advertisements can be sufficient number of violations to support order).

Accordingly, Respondents' "outlier" defense is rejected.

**b. Liability of Roll**

Complaint Counsel argues that both POM and Roll are liable for the violations in this case and should both be subject to a cease and desist order, based upon two alternative theories: the "common enterprise" theory, based on the interrelated nature of the two corporate Respondents; and the "active participant" theory, based on Roll's direct activities with regard to POM's advertising, including through Roll's internal advertising agency, allegedly with knowledge of the deceptive nature of the POM advertisements. CCB at 54-56. Respondents contend that no cease and desist order should issue against Roll. RRB at 169-171.

It is well established that "[w]here one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others." *FTC v. Bay Area Bus. Council, Inc.*, No. 02-C-5762, 2004 U.S. Dist. LEXIS 6192, at \*33-34 (N.D. Ill. Apr. 8, 2004) (finding a common enterprise where the corporate defendants were owned by the same person, were operated by the same people, often shared offices, did business under each other's names, accessed the same customer databases, shared and transferred proceeds as needed, and were considered a collaborative effort by the owner), *aff'd*, 423 F.3d 627 (7th Cir 2005); *Telebrands Corp.*, 140 F.T.C. at 451 (Initial Decision) ("Corporate respondents acting in concert to further a common enterprise are each liable for the acts and practices of the others in furtherance of the enterprise."). To determine whether a common enterprise exists, courts will consider a variety of factors including: "common control; the sharing of office space and officers; whether business is transacted through a maze of interrelated companies; the commingling of corporate funds and failure to maintain separation of companies; unified advertising; and evidence that reveals that

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no real distinction exists between the corporate defendants.” *Nat’l Urological Group*, 645 F. Supp. 2d at 1182. Courts look for vertical or horizontal commonality. *FTC v. Network Servs. Depot, Inc.*, 617 F.3d 1127, 1142-43 (9th Cir. 2010) (noting evidence showing that the companies pooled resources, staff, and funds; shared common owners and managers; and participated to some extent in a common venture).

Applying the foregoing principles, the evidence demonstrates that POM and Roll are a “common enterprise.” F. 12, 19-21, 27-28, 1380, 1382, 1384, 1386-1390. Among other things, Respondents Stewart and Lynda Resnick are the sole owners of Roll and its affiliated companies, including POM Wonderful. F. 12. Mr. Resnick is Chairman and President, and Mrs. Resnick is a director and Vice Chairman of Roll. F. 19. Mr. Resnick is also Chairman and Chief Executive Officer of POM. F. 20-21. POM is headquartered in the same building as Roll, in many cases with employees of both companies occupying the same floor. F. 1380. Roll provides risk management, human resources, consulting, and travel services to POM without any reimbursement, and advertising and marketing services have been provided by Roll to POM without necessarily receiving reimbursement. F. 1385. In addition, for accounting purposes, Roll and its affiliated companies, including POM, were represented as being under common control or ownership and have been included together on consolidated financial and tax statements. F. 1387. Moreover, the Resnicks have had ultimate say over all business functions of both Roll and POM, including setting policy and supervising the senior executives of both companies, disregarding corporate formalities. F. 1386.

Respondents fail to make any discernable argument that POM and Roll are not a common enterprise, focusing their argument instead on whether Roll was an “active participant” in POM’s advertising and/or had actual or constructive knowledge of any deception. RRB at 169-171. Considering the facts clearly supporting liability of Roll based on the common enterprise theory, Roll is jointly liable with POM and will be held to the provisions of the attached Order. It is, therefore, unnecessary to determine whether or not Roll is also liable under the “active

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participant” theory. Thus, this Initial Decision need not, and does not, include any conclusions or analysis regarding that issue.

### 3. Liability of Individual Respondents

#### a. Applicable legal principles

“To obtain injunctive relief against an individual for a business entity’s acts or practices, the FTC first must prove the entity violated § 5. See *Federal Trade Comm’n v. Think Achievement Corp.*, 144 F. Supp. 2d 993, 1009-11 (N.D. Ind. 2000), *aff’d*, 312 F.3d 259 (7th Cir. 2002). The FTC must further show the individual participated directly in the business entity’s deceptive acts or practices, or had the authority to control them. See *Federal Trade Comm’n v. Publishing Clearing House, Inc.*, 104 F.3d 1168, 1170 (9th Cir. 1997).” *FTC v. Freecom Communs., Inc.*, 401 F.3d 1192, 1202-03 (10th Cir. 2005); *FTC v. Amy Travel Serv., Inc.*, 875 F.2d 564, 573 (7th Cir. 1989). An individual’s authority to control the corporation’s deceptive acts may be “evidenced by active involvement in business affairs and the making of corporate policy, including assuming the duties of a corporate officer.” *Amy Travel Serv.*, 875 F.2d at 573.

#### b. Stewart and Lynda Resnick

While Respondents assert generally that no liability should attach to any of the individual respondents, Respondents specifically address their argument only to the liability of Respondent Matthew Tupper, which is discussed below. Applying the well-established principles of individual liability, summarized above, the evidence amply supports the conclusion that both Respondents Lynda Resnick and Stewart Resnick actively participated in the acts and practices found to have violated the FTC Act and/or had the authority over them. The Resnicks are the sole owners of POM and Roll. F. 12. Mr. Resnick is the Chairman of both corporate entities, and the Chief Executive Officer of POM with overall responsibility and control over the business, including setting the budgets for marketing, advertising and medical research. F. 19-20, 22-23, 1393. He considers himself ultimately responsible for whether advertising should or should not go out, although he delegated day-to-day responsibility to Mr. Tupper. F. 25. In addition, Mr. Resnick has

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been involved at a high level with POM's advertising and marketing campaigns, including on occasion seeing headlines before advertisements were disseminated, when Mrs. Resnick has chosen to involve him, and has been intimately involved in POM's scientific research program. F. 23, 26, 1392-1395. The facts support Mr. Resnick being subject to a cease and desist order in this case.

Mrs. Resnick is a director and Vice Chairman of Roll. F. 27-28. According to Mrs. Resnick, when it comes to marketing and creative issues, everyone has a "dotted line" to her. F. 35. Although Mrs. Resnick was not an officer of POM, Mrs. Resnick participated in POM's business on almost a daily basis in the company's early years, and on a weekly or biweekly basis thereafter and through 2010. F. 30. As of 2011, Mrs. Resnick was still the chief marketing person at POM. F. 31. Mrs. Resnick has had a principal role in approving advertising content since POM's inception. F. 143, 160-161, 166-168, 1399. For example, Mrs. Resnick requested that copies of all advertising campaigns be submitted to her for final approval including headlines used in POM's advertisements. F. 1399. Mrs. Resnick held regular creative meetings with the senior in-house representatives of POM and Roll, including representatives of POM's marketing department, Roll's public relations department and Roll's advertising agency, Fire Station, to review and approve advertising concepts. F. 33, 141-143. If there were disputes or issues to resolve regarding advertising decisions, the final authority was either Mr. or Mrs. Resnick; however, as the overseer of all branding and marketing, Mrs. Resnick had the "final word" on advertising content and concepts. F. 1397, 1400. *See also* F. 33-34. Moreover, Mrs. Resnick was involved in several of the specific advertisements found herein to have violated the FTC Act. Mrs. Resnick was "very involved" in developing the POMx brochure, identified as CX1426, Exhibit I "Antioxidant Superpill" package insert, when it was first produced; Mrs. Resnick was involved in the approval of the print advertisement identified as CX0029 ("10 OUT OF 10 PEOPLE DON'T WANT TO DIE"); Mrs. Resnick approved the headline for the POMx print advertisement headlined "The Only Antioxidant Supplement Rated X"; and Mrs. Resnick approved the print advertisement identified as CX0031 ("Floss your

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arteries” print advertisement). F. 1401-1404. The evidence is more than sufficient for Mrs. Resnick to be subject to a cease and desist order.

As the Commission stated in *Telebrands Corp.*, “it is not only appropriate but sometimes preferable to make the principal of a corporation subject to fencing-in so that the individual cannot circumvent the order by establishing a new company with a different name.” 140 F.T.C. 278, 344 n.62. Accordingly, based on the Resnicks’ participation in and control over the acts and practices in this case, it is appropriate for them to be subject to a cease and desist order individually, along with the corporate Respondents. Indeed, as to Mr. and Mrs. Resnick, Respondents fail to articulate any factual or legal basis for a contrary result.

**c. Matthew Tupper****i. “Control” as a mandatory prerequisite to finding individual liability of corporate officer**

Mr. Tupper has been an officer of POM since 2003, first with the title of Chief Operating Officer and then with the title of President. F. 37-38. Mr. Tupper acknowledges that he was involved in POM’s operations, science research, and marketing. However, according to Mr. Tupper, none of these aspects of POM’s business were under his ultimate control, but rather were under the ultimate control of Mr. and/or Mrs. Resnick. RTB at 2, 6-8. Mr. Tupper acknowledges, as he must, that the applicable test for individual liability is met by evidence of *either* participation in the deceptive practices at issue *or* authority to control them. RTB at 3-5. *See, e.g., Freecom Communs.*, 401 F.3d at 1203; *Amy Travel Serv.*, 875 F.2d at 573. Mr. Tupper contends, however, that despite being stated in the alternative, “in practice,” authority to control is the key factor for liability, not participation. RTB at 3. To the contrary, “[e]ither participation or control suffices.” *QT*, 512 F.3d at 864. In *Direct Marketing Concepts*, a case upon which Mr. Tupper relies, the court reaffirmed the “either/or” nature of the individual liability test by rejecting the argument by the defendant co-owner of the corporation “that he did not edit the content of advertising.” Relying on *Freecom Communications*, the court held it sufficient

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that the co-owner controlled the corporations, and, therefore, “could have nipped the offending infomercials in the bud . . . .” 624 F.3d at 13. Similarly, in *Freecom Communications*, upon which Mr. Tupper also relies, the court held that the lower court’s “finding that [the individual defendant] never personally [made the misrepresentations at issue] is beside the point because the law did not require the FTC to make such a showing. To justify the imposition of injunctive relief against the individual, the FTC is required to show the individual participated directly in the business entity’s deceptive acts or practices, or had the authority to control such acts or practices.” 401 F.3d at 1204.<sup>21</sup>

Mr. Tupper further maintains that, despite the well-established rule that evidence of either participation or control can support imposing individual liability, he is “unaware of any case” in which individual liability of a corporate officer was based on participation alone, and cites cases in which the corporate officer was found liable based on evidence of *both* participation by the corporate officer *and* authority to control the corporation. RTB at 4-5. *E.g.*, *In re Universal Electronics Corp.*, No. 8815, 78 F.T.C 265, 1971 FTC LEXIS 55, at \*65-66 (Jan. 28, 1971) (Initial Decision) (finding that evidence demonstrated that officer formulated, directed, and controlled the acts and practices of the corporate respondent; and that he was responsible for, familiar with, and personally participated in, the specific acts and practices at issue); *FTC v. Neovi, Inc.*, 598 F. Supp. 2d 1104, 1117 (S.D. Cal 2008) (stating that “the Court agrees with the FTC that [the

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<sup>21</sup> Mr. Tupper also relies on an initial decision in an FTC case from 1974, *In re Auslander Decorator Furniture, Inc.*, 83 F.T.C. 1542, 1974 WL 175916 (April 23, 1974), in which the hearing examiner declined to find individual liability on the part of two nominal officers because “the record [was] devoid of evidence of actual control or responsibility by [the two individuals] . . . over the affairs of ADF, and . . . their participation in the unlawful acts and practices of ADF was that of employees working under the direction and supervision of” the owner of the company. That case pre-dates by many years the long line of federal appellate court cases, from *Amy Travel* to *QT*, cited above, which make clear that participation is one of two grounds that justify individual liability. *Auslander* is contrary to such cases. Under these circumstances, *Auslander* cannot reasonably be deemed controlling authority. In any event, unlike *Auslander*, both participation and control have been demonstrated in this case, as more fully discussed below, and for that reason as well, *Auslander* is not dispositive.

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individual defendants] had the authority to control the corporate Defendants' unfair practices, [and] that they participated in those activities . . . ."); *FTC v. Transnet Wireless Corp.*, 506 F. Supp. 2d 1247, 1271-1272 (S.D. Fla. 2007) (concluding, based on evidence, that individual defendants had "authority to control the corporation" and directly participated in the practices at issue); *Amy Travel Serv.*, 875 F.2d at 574 (affirming individual liability of principal officers and shareholders where it was found they controlled the corporations and where it was also "clear that [the individual defendants] were the ones behind the vacation passport scheme," including writing telemarketing scripts); *FTC v. Publ'g Clearing House, Inc.*, 104 F.3d 1168, 1171 (9th Cir. 1997) (noting that individual defendant's activities as corporate officer "included obtaining and signing PCH's business license and signing the fund-raising agreement between PCH and [a fraudulent charity whose] application to conduct charitable solicitation identified [her] as the person in 'direct charge of conducting the solicitation'"). *See generally* cases cited at RTB 4-5. Mr. Tupper's cited cases do not support interpreting the rule that "[e]ither participation or control suffices," *QT, Inc.*, 512 F.3d at 864, to mean that only "authority to control" will suffice. Furthermore, consistent with the above-cited cases, individual liability is warranted in this case because, as further discussed below, Mr. Tupper both participated in the deceptive advertising practices at issue and had the authority to control POM's practices in this regard. *See also* *FTC v. Consumer Alliance, Inc.*, No. 02C2429, 2003 U.S. Dist. LEXIS 17423, at \*20-22 (N.D. Ill. Sept. 29, 2003) (finding individual liability where the defendants reviewed, approved, and drafted telemarketing scripts used to deceive consumers and had authority to supervise and discipline employees).

**ii. Mr. Tupper's participation in and control over the practices at issue in this case**

On the issue of participation, the evidence shows that Mr. Tupper's responsibilities within POM included implementing POM's direction with regard to health benefit advertising and the use of science in connection with the advertising. F. 51. With respect to this advertising, Mr. Tupper was the "connecting piece" between the marketing vision and the communication of the science. F. 51-52, 1409, 1411. Mr. Tupper participated in

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meetings in which Fire Station and POM personnel presented and reviewed advertising concepts and advertising. F. 156, 1419. Mr. Tupper has reviewed and given direction to POM's marketing staff on parts or elements of creative briefs. F. 1417. Mr. Tupper reviewed advertising copy (including headlines), made changes to copy, and, depending on the project, had final say over POM advertising content and which advertisements should or should not run. F. 160, 162, 1420. Mr. Tupper led meetings to review advertising copy from a scientific perspective prior to dissemination of the advertising. F. 1410, 1416. Sometimes, Mr. Tupper would provide the specific words to use when presenting medical research facts, and in other instances, POM Marketing or Fire Station employees would "take a stab at writing [this information] and send it to [Mr. Tupper] to approve." F. 1421. Mr. Tupper participated in drafting the *Time* magazine cover wraps found herein to have made the claims alleged in the Complaint. F. 306-310, 581, 1431. Mr. Tupper also reviewed press releases prior to issuance. F. 1430. In addition, as POM's President, Mr. Tupper attended most of the marketing meetings with Mrs. Resnick, which included discussions of POM's scientific research. F. 142, 144, 1412. In fact, Mr. Tupper had a significant degree of involvement in the research aspects of POM's business, and his responsibilities included discussing which research areas are appropriate for funding, participating in the internal decision-making as to what research to fund, and overseeing for POM the clinical trials on POM's products that were conducted by research institutions. F. 53, 1424-1429; *see also* F. 119 (finding and contacting scientific experts to conduct research). POM's former Senior Vice President of Marketing, Ms. Kuyoomjian, relied on her conversations with Mr. Tupper to understand content in POM's advertising regarding the relationship between POM advertisements and the scientific support for these advertisements. She also relied on Mr. Tupper to be the "arbiter" of whether people felt POM's advertising was accurate. F. 1414, 1418, 1421. Accordingly, Mr. Tupper's level of participation is more than adequate to support individual liability for POM's deceptive advertisements. *See Amy Travel Serv.*, 875 F.2d at 573 (affirming finding proof of participation based on individual defendants' writing telemarketing script used in deception); *Publ'g Clearing House*, 104 F.3d at 1171 (affirming lower court's finding of proof of participation based on

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individual defendant's signing a contract used in a fraudulent scheme); *Consumer Alliance*, 2003 U.S. Dist. LEXIS 17423, at \*20-22 (finding individual liability where the defendant reviewed, approved, and drafted telemarketing scripts used to deceive); *In re Griffin Sys., Inc.*, No. 9249, 117 F.T.C. 515, 1994 FTC LEXIS 76, at \*25 (April 29, 1994) (finding participation based upon individual respondents' preparing solicitation materials that contained misrepresentations, including making changes in the content of those materials).<sup>22</sup>

The evidence also demonstrates that Mr. Tupper had authority to control the practices of POM. Mr. Tupper was an officer of POM and, in his capacity as an officer, Mr. Tupper, together with others, formulated, directed, or controlled the policies, acts, or practices of POM. F. 37-38, 42. Mrs. Resnick considered Mr. Tupper her partner at POM since 2003 and relied on him to oversee POM's marketing when she reduced her day-to-day involvement beginning in 2007. F. 39, 1407. Mr. Resnick delegated the authority to decide which advertisements should run to Mr. Tupper. F. 1406. Mr. Tupper was responsible for managing the day-to-day affairs of POM, including management of the day-to-day operations of the POM marketing team. F. 25, 44. Mr. Tupper oversaw and administered POM's budget for all departments, and had authority to sign checks and contracts on behalf of the company. F. 45. Mr. Tupper had numerous POM employees reporting to him directly, including the vice presidents for marketing, corporate communications, clinical development, and operations. F. 47-50. Mr. Tupper had the authority to hire

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<sup>22</sup> Mr. Tupper also argues that he was less involved in POM's advertising during the period 2003 to 2006, and for this reason, he cannot be deemed to have "participated" in any deceptive advertisements from this period. RTB at 10. However, the evidence shows that Mr. Tupper was, in fact, engaged in the medical research aspect of POM's business from the time he first joined POM full time in 2003, although beginning in late 2006 or 2007, he became more engaged, as the "connecting piece" between research and marketing. F. 37, 1411. In any event, as explained above in connection with Respondents' "outlier" argument, even if advertisements from 2003 to 2006 are not considered, the violations would be sufficient to justify a cease and desist order against Mr. Tupper. See *Bristol-Meyers*, 1983 FTC LEXIS 64, at \*250-51; *Fedders Corp.*, 85 F.T.C. at 71-72. Thus, whether or not Mr. Tupper was less involved in these earlier advertisements is not determinative as to whether a cease and desist order may issue against him.

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and fire POM employees, including the head of POM's marketing department, on his own, or, depending on the situation, in consultation with either Mr. or Mrs. Resnick. F. 46. Thus, the evidence is sufficient to show authority to control. *Benrus Watch Co. v. FTC*, 352 F.2d 313, 325 (8th Cir. 1965) (affirming individual liability against officers who "formulated, directed, and controlled" the policies and practices of the corporate respondents); *accord In re Universal Electronics Corporation*, 1971 FTC LEXIS 55, at \*65-66 (Initial Decision); *FTC v. World Media Brokers*, 415 F.3d 758, 764-65 (7th Cir. 2005) (finding that individual defendants' assumption of duties of corporate officers, such as corporate signing authority, "establishe[d] a level of corporate involvement sufficient to demonstrate" authority to control); *FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 636-38 (same); *Consumer Alliance*, 2003 U.S. Dist. LEXIS 17423, at \*20-21 (finding liability where individual had authority to control based upon hiring, supervision, and disciplinary authority over employees). *Compare QT, Inc.*, 448 F. Supp. 2d at 973-74 (finding FTC failed to meet burden under test for individual liability where corporate secretary "did not participate directly in the deceptive acts and practices carried out by the corporate Defendants" or "possess 'a level of corporate involvement sufficient to demonstrate the requisite authority to control the corporate defendants.'" (citation omitted)).

Mr. Tupper's contention that he did not have "sole" or "ultimate" control of POM, RTB at 2, 7, even if true, is not determinative. A similar argument was made and rejected in *Griffin Systems, Inc.*, 1994 FTC LEXIS 76. In that case, the evidence showed that the corporate officer, Mr. Giordano, like Mr. Tupper in this case, administered the day-to-day affairs of the office, and, like Mr. Tupper, had duties including, among other things, hiring and supervising employees, and advising employees about the challenged solicitation materials. 1994 FTC LEXIS 76, at \*4; *see* F. 25, 44, 46-50, 1414, 1418, 1421. The Commission found these facts sufficient to support individual liability, despite evidence showing that the officer shared his authority with the other individual respondents in that case. *Id.* at \*23. The Commission explained:

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In support of their argument that it is inappropriate to hold Mr. Giordano individually liable for the actions of Griffin, the respondents emphasize that Mr. Giordano was not in sole control of Griffin. We are not aware of any authority indicating that sole control of a company is necessary to establish individual liability. Indeed, there have been a number of cases in which more than one individual has been held to formulate, direct, and control the practices of a single corporation.

*Id.* at \*24. In the instant case, the evidence, summarized above, amply demonstrates that Mr. Tupper had sufficient authority, particularly with regard to the content of advertisements, to control the practices at issue. Moreover, Mr. Tupper does not cite to any evidence that he ever expressed concerns about, or objections to, the POM advertisements at issue to Mr. or Mrs. Resnick or that any such concerns or objections were overruled by either of them. As in *Griffin Systems*, the evidence is clear that Mr. Tupper “was part of the inner circle that formulated, controlled, and directed” POM and “therefore it is appropriate to place him under order.” *Id.*

**iii. Breadth of cease and desist order**

Mr. Tupper contends that it is unnecessary and unreasonable to bind him to a cease and desist order in addition to the other Respondents. He asserts that extending the proscriptions in the order to any food, drug, or dietary supplement would “potentially attach to any company he is associated with for the next twenty years” and, thereby, “effectively ensure that no company, with interests in foods, drugs or supplements would ever employ” Mr. Tupper. RTB at 9-10. This argument is unpersuasive. The Order binds Mr. Tupper personally, and his successors or assigns. Order, Definitions para. 2. The cease and desist Order does not, by its terms, bind Mr. Tupper’s future employers.<sup>23</sup>

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<sup>23</sup> Of course, Mr. Tupper’s future employers would be bound, as would any business, to compliance with the FTC Act. As noted above, the “competent and reliable evidence” substantiation standard for disease or efficacy claims only obliges advertisers “to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception.” *Daniel Chapter One*, 2009 FTC LEXIS 259, at \*70.

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In addition, Mr. Tupper contends that the proposed order is unreasonable and overbroad as applied to him, based upon his asserted limited control over and participation in the challenged practices, when considering the seriousness of the conduct, the deliberateness of the conduct and its transferability to other products. RTB at 10-12; *see Telebrands*, 457 F.3d at 358. As noted above, Mr. Tupper's participation in and control over the deceptive practices at issue in this case is more than sufficient to justify a cease and desist order against him. The *Telebrands* factors are analyzed below in Section III.H.4.a.

#### **4. Provisions of the Order**

Having determined that a cease and desist order is required against POM, Roll, Mr. and Mrs. Resnick, and Mr. Tupper, this section of the Initial Decision addresses the specific provisions of the Order. The provisions of the Order are substantially the same as Complaint Counsel's proposed order, which is the Notice Order that was attached to the Complaint issued in this case (hereafter, "proposed order"), except that the Order does not include Complaint Counsel's proposed part I, as further explained in Section III.H.4.b.

##### **a. Multi-product coverage (Order, Definitions para. 5)**

The FTC's authority includes power to issue orders "encompassing all products or all products in a broad category, based on violations involving only a single product or group of products." *ITT Continental Baking Co. v. FTC*, 532 F.2d 207, 223 (2d Cir. 1976).

Coverage of all products in a broad category is a means of "fencing-in" one who has violated the statute. Fencing-in provisions serve to "close all roads to the prohibited goal, so that (the FTC's) order may not be by-passed with impunity." *FTC v. Ruberoid Co.*, 343 U.S. 470, 473, 72 S. Ct. 800, 803, 96 L. Ed. 1081 (1952) (footnote omitted). Fencing-in provisions must bear a "reasonable relation to the unlawful practices found to exist." *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95, 85 S. Ct. at 1047-1048 (footnote omitted). *Litton Indus., Inc. v. FTC*, 676 F.2d 364, 370 (9th Cir. 1982).

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In determining whether a fencing-in order bears a “reasonable relationship” to a violation of the FTC Act, courts and the Commission consider: (1) the degree of transferability of the violation to other products; (2) the deliberateness and seriousness of the violation; and (3) any history of prior violations. *Telebrands*, 457 F.3d at 358; *Kraft*, 970 F.2d at 326. “The reasonable relationship analysis operates on a sliding scale -- any one factor’s importance varies depending on the extent to which the others are found. In other words, the more serious a violation, the less important transferability and prior history become. . . . All three factors need not be present for a reasonable relationship to exist.” *Telebrands Corp.*, 457 F.3d at 358-59 (citation omitted). “[T]he more egregious the facts with respect to a particular element, the less important it is that another negative factor be present. In the final analysis, [courts] look to the circumstances as a whole and not to the presence or absence of any single factor.” *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 392 (9th Cir. 1982); *see also Kraft*, 970 F.2d at 327.

Applying the foregoing principles to the facts of this case, and as discussed below, the Order’s provisions will apply to the POM Products as well as to any other food, drug or dietary supplement products sold by POM and the other Roll entities. *See* Order, Definitions para. 5.

**i. Transferability**

As the Commission stated in *Litton Industries*,

The rationale for entry of a multi-product order based upon violations in the advertising of only one or a few products is that many kinds of deceptive advertising are readily transferrable to a variety of products, and it would serve the public poorly to halt the use of a deceptive tactic in the advertising of one product if the respondent remained free to repeat the deceptive practice in another guise, with no threat of sanction save for another order to cease and desist. *FTC v. Colgate-Palmolive Co.*, 380 U.S. at 394-95 (1965).

*Litton Indus., Inc.*, 1981 FTC LEXIS 94, at \*147. Indeed, the “prevention of ‘transfers’ of unfair trade practices is a

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fundamental goal of the Commission’s remedial work.” *Sears, Roebuck*, 676 F.2d at 394. Where a violation has been demonstrated, “the Commission need not wait until a ‘transfer’ occurs” to other products. *Id.* at 395.

A violation is considered transferable when other products could be sold utilizing similar techniques. *Colgate-Palmolive*, 380 U.S. at 394-95; *Sears, Roebuck*, 676 F.2d at 392. For example, “misrepresenting that doctors prefer a product, or that tests prove the product’s superiority, is a form of deception that could readily be employed for any non-prescription drug product.” *American Home Prods. v. FTC*, 695 F.2d 681, 708 (3rd Cir. 1982). In the instant case, this transferability factor weighs strongly in favor of a multi-product order. As in *Daniel Chapter One*, Respondents’ advertising techniques “could readily be employed” for any food, drug or dietary supplement. *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*284 (Initial Decision).

Respondents argue that the POM Products are only a small portion of the products Respondents sell. RRB at 204-205. Such assertion, even if true, is not material to whether the advertising claims made for the POM Products are nevertheless transferable to the other categories of products that are covered by the Order and that are sold by POM and/or the affiliated Roll entities, such as other pomegranate-based products (sold by POM); citrus fruits (sold by Paramount Citrus), nuts (sold by Paramount Farms); bottled water (sold by FIJI Water); and wine (sold by Justin Vineyards). *F. 56*, 1378. *Standard Oil v. FTC*, 577 F.2d 653 (9th Cir. 1978), upon which Respondents rely, is readily distinguishable because in that case, as the court stated, “[t]he over-breadth of the order results from its coverage of “any . . . product in commerce” which is advertised by Standard . . . .” *Id.* at 661. In the instant case, the Order is limited to Respondents’ advertising of food, drugs and dietary supplements. Order, Definitions para. 5.

Respondents further contend that their other products that do not involve pomegranates, such as citrus fruits, water, nuts and wine, are so “dramatically different” from the POM Products that Respondents would not use POM research to understand any components of such products. RRB at 205-206. Even if true, this contention is beside the point because the advertising technique,

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*i.e.*, sponsoring research of a product's health benefits and using the results to make disease claims, is readily transferable to advertising any food, drug or dietary supplement. In this regard, Respondents admit that they have sponsored "research exploring the health benefits of Wonderful Pistachios and Fiji Water" but assert that they have a "history" of "not advertising those benefits until the science is sufficiently developed." RRB at 207. This case demonstrates, however, that Respondents' judgment as to what constitutes advertising "health benefits" as opposed to what constitutes advertising a scientifically proven effect for disease, has not always been exercised appropriately.

Finally, Respondents assert that the deceptive claims found to have been made in this case are "peripheral" to their advertising strategy, and that their central advertising and marketing strategy has evolved away from health advertising and more toward "history" and "sexuality." RRB at 208. However, Respondents' asserted change of strategy does not make their past advertising themes and techniques any less transferable. As previously noted, such themes and the techniques used to communicate them are fully transferable – whether Respondents may opt to engage in other strategies in the future is not determinative.

Thus, the ease of transferability strongly supports the provisions in the Order making the Order applicable to any food, drug, or dietary supplement products.

**ii. Seriousness and deliberateness**

The seriousness of the Respondents' conduct is evidenced by the fact that the deceptive advertising claims found to have been made in this case pertained to serious diseases and dysfunction of the body, including cancer. *See Daniel Chapter One*, 2009 FTC LEXIS 157, at \*282 (Initial Decision); *see also Stouffer*, 1994 FTC LEXIS 196, at \*39 (holding that deceptive low sodium health claim was serious because of overall health ramifications). The seriousness of Respondents' conduct is further demonstrated by the inability of consumers to evaluate whether Respondents' implied disease claims are true or actually supported by cited studies. *Id.*; *Thompson Medical*, 1984 FTC LEXIS 6, at \*417. Thus, Respondents' claims concerning product effectiveness and clinical proof are "ones to which consumers were particularly

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susceptible.” *Id.*; see also *Litton Indus. Inc.*, 1981 FTC LEXIS 94, at \*150 (holding that use of survey results to support claim of product superiority has considerable potential to deceive, and, therefore, misuse of surveys in this regard is a serious violation). Respondents’ assertion that consumers can access the identified studies themselves, RRB at 181, even if true, is not persuasive evidence that consumers can accurately assess the significance of the studies, much less in relation to Respondents’ advertising claims.

The deliberateness of Respondents’ conduct is also shown by the consistency of Respondents’ advertising themes over the years, which supports a conclusion that the advertisements found herein to have violated the FTC Act did not constitute accident or an “isolated instance.” *Thompson Medical*, 1984 FTC LEXIS 6 at \*417. Respondents’ contention that representations in certain advertisements were the result of mistake, RRB at 182; see RB at 67-68, even if assumed to be true, is insufficient to support a conclusion that Respondents’ violations on the whole were accidental or inadvertent. Moreover, while it is arguable that the language used to make their advertising claims became less “aggressive” over the years, as Respondents contend, RB at 67-68; RRB at 182, there is little doubt that a central, and persistent, theme of Respondents’ advertising was the POM Products’ purported ability to affect diseases and dysfunction, and the scientific studies purportedly showing such effects. See, e.g., Appendix to Initial Decision; F. 145-151. In addition, the advertising appeared in a wide variety of national and local media, for multiple years. F. 169-170, 291, 297, 307-308, 321, 328, 344, 365, 416, 421, 428, 432, 440, 449, 456, 469, 580-583. See *Sears, Roebuck*, 676 F.2d at 394 (in upholding multi-product order, noting that advertising campaign cost \$8 million, ran for four years, and appeared in magazines, newspapers and on television throughout the country); *Daniel Chapter One*, 2009 FTC LEXIS 157, at \*281 (Initial Decision) (noting that respondents made numerous deceptive representations over the Internet, in their publications, and through the DCO radio program, over the course of several years).

Respondents contend that POM’s internal procedures for evaluating its advertisements and science should also be

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considered. Specifically, Respondents point to testimony that since 2007, POM has implemented a more formalized vetting process for advertisements relating to the health benefits of its products, which requires multiple stages of review that ultimately culminate in approval by the legal department before any advertisement is run. (Tupper, Tr. 2977-78). The evidence shows, however, that a number of the advertisements found to have violated the FTC Act were disseminated after 2007, when Respondents' review process was purportedly implemented. F. 307-308, 321, 365, 580-583, 962, 1143, 1313-1314. Therefore, it cannot be concluded, as Respondents urge, that their internal processes will ensure that only accurate information will be presented to the public in the future.<sup>24</sup>

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24 Complaint Counsel argues that deliberateness is also demonstrated by what Complaint Counsel asserts is evidence that “[d]espite concerns expressed by the New York State Attorney General’s Office, the Council for Better Business Bureaus’ National Advertising Division (“NAD”), NBC television, Dr. Pantuck, several IRBs [Institutional Review Boards], the FTC, and the FDA that POM’s advertising claims misled consumers, POM continued to make the same or similar claims.” CCB 59-60. Complaint Counsel further contends that “Respondents’ own internal assessments recognized that their research was not sufficient to substantiate POM’s claims,” citing evidence regarding Respondents’ evaluation of their research in relation to FDA approval standards. CCB at 60. *See, e.g.*, F. 1133 (internal document stating, “it is unclear whether PSADT is acceptable as a registrational endpoint for a drug designed to prolong the time to disease progression after initial therapy for prostate cancer”). Respondents strongly dispute the evidence upon which Complaint Counsel relies to make these charges, and/or the inferences Complaint Counsel draws from the cited evidence. RRB at 183-201. However, this Initial Decision need not, and does not, decide whether or not these additional potential grounds for finding deliberateness have been demonstrated because the evidence already demonstrating seriousness and deliberateness, and particularly transferability, more than adequately supports the multi-product Order entered in this case. Moreover, whether or not Respondents knew their studies were inadequate to obtain FDA drug approval for the POM Products, as Complaint Counsel contends, is not material since, as this Initial Decision has determined, Respondents were not required to substantiate their claims with the type of clinical trials that might be deemed necessary for drugs. *E.g.*, F. 693, 694-710, 963, 1147-1148; Analysis Section III.F.2-5, *supra*.

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**iii. Prior violations**

There is no evidence of prior violations of the FTC Act by Respondents. However, as noted above, all of the three relevant elements need not be present to warrant a multi-product order. *Telebrands Corp.*, 457 F.3d at 358-59. Courts look to the circumstances as a whole “and not to the presence or absence of any single factor.” *Sears, Roebuck*, 676 F.2d at 392. In *Telebrands*, the Court of Appeals upheld the Commission’s conclusion that the strength of the evidence as to the first two factors sufficiently established that there was a reasonable relationship between the remedy and the violation, and it was not necessary to also consider any prior consent orders. *Telebrands Corp.*, 457 F.3d at 362. Thus, while here there is no history of violations in this case, that factor is less important, taking into account the strength of the other relevant factors, particularly the ease of transferability to other products.

**b. Part I of the Order**

Part I of the Order prohibits Respondents from making representations that any Covered Product, as defined in the Order, “is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of” heart disease, prostate cancer, or erectile dysfunction, “unless, at the time it is made, the representation is non-misleading and, Respondents possessed and relied upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.” Order, Part I. “Competent and reliable scientific evidence” is defined in the Order to mean “tests, analyses, research, or studies, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” Definitions, para. 4. Commission orders requiring respondents to have competent and reliable scientific evidence, as defined in this Order, that is based on the expertise of professionals in the relevant area and that has been conducted and evaluated by persons qualified to do so, are typical

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and have been consistently upheld by the appellate courts. *E.g.*, *Daniel Chapter One*, 2010 FTC LEXIS 11, *review denied*, 2010 U.S. App. LEXIS 25496 (D.C. Cir. 2010); *Telebrands Corp.*, 140 F.T.C. at 347, *aff'd*, 457 F.3d 354 (4th Cir. 2006); *In re Kraft*, 1991 FTC LEXIS 38, at \*59-60, *aff'd*, 970 F.2d 311 (7th Cir. 1992). Such a requirement in this case serves the purpose of preventing future violations, is reasonably related to the violations found to exist, is sufficiently clear and precise, and is amply supported by legal precedent and the facts of this case.

**c. Part I of the proposed order (FDA pre-approval substantiation requirement)**

**i. Overview**

Part I of the Order entered herewith differs from Part I of Complaint Counsel's proposed order. Part I of the proposed order would prohibit Respondents from making any representation that any POM Product "is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of" heart disease, prostate cancer, or erectile dysfunction, unless, at the time it is made, the representation is non-misleading and:

- A. the product is subject to a final over-the-counter ("OTC") drug monograph promulgated by the Food and Drug Administration ("FDA") for such use, and conforms to the conditions of such use;
- B. the product remains covered by a tentative final OTC drug monograph for such use and adopts the conditions of such use;
- C. the product is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use; or
- D. the representation is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 ["NLEA"].

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As Complaint Counsel explains, part I of the proposed order:

provides that the necessary substantiation for future claims that any POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease – including heart disease, prostate cancer, or erectile dysfunction – is FDA approval, which may be provided in the form of a tentative final or final over-the-counter (“OTC”) drug monograph, a new drug application, or labeling approval under regulations promulgated pursuant to the Nutrition Labeling and Education Act of 1990 (“NLEA”). For example, a claim that POM Juice reduces the risk of heart disease would need to be supported by an FDA regulation authorizing such a claim in labeling.

CCB at 62-63. Complaint Counsel refers to these provisions as the “requirement of FDA pre-approval.” CCB at 64-65. (hereafter, “FDA pre-approval requirement”).

Complaint Counsel further explains that, under the proposed order, if Respondents “make a *qualified* claim, one that characterizes the limited scientific evidence supporting a relationship between a POM product and reductions in disease risk in a careful manner that eliminates any misimpression that a POM product actually reduces risk,” then the substantiation they must possess is “competent and reliable scientific evidence,” as provided under part III of Complaint Counsel’s proposed order. CCRB at 50-51 (emphasis in original). However, “[i]f Respondents make [an] *unqualified* disease claim” in the future that any POM Product “*is effective* in the diagnosis, cure, mitigation, treatment, or prevention of any disease,” then the “substantiation [Respondents] must possess for their claims would be FDA pre-approval.” CCRB at 50 (emphasis in original). Thus, pursuant to part I of the proposed order, the FTC would determine (and ultimately have to prove at a contempt proceeding in court) whether Respondents made an “unqualified” disease claim, as opposed to a “qualified” “limited” and “careful” claim, and unless the FDA has already determined, applying FDA regulations, that Respondents’ substantiation was adequate for that claim, then Respondents would be in violation of the FTC order. March 6, 2012 Tr. 67 (closing arguments).

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As more fully discussed below, Complaint Counsel argues that its proposed FDA pre-approval framework is a form of fencing-in that is reasonably related to the violations in this case, is clear and concise, and provides a necessary “bright-line” rule for future claims. *Id.* at 66-67; CCB at 62-65. Respondents oppose the FDA pre-approval requirement on a variety of grounds, including that the requirement is unlawful because it exceeds the authority granted the FTC under the FTC Act and would violate Respondents’ First Amendment freedom to engage in commercial speech. RB at 98-99; RRB at 210-218. Complaint Counsel has failed to demonstrate that the proposed FDA pre-approval requirement is necessary or appropriate for this case, as further explained below.

No previous decision by the Commission or any court has required FDA pre-approval as the required level of substantiation, including for purposes of a cease and desist order. Most recently, in *Daniel Chapter One*, in which the respondents were found to have made unsubstantiated disease claims in violation of Sections 5 and 12 of the FTC Act, the Commission entered an order prohibiting them from making such claims in the future “unless the representation is true, non-misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.” 2010 FTC LEXIS 11, at \*3. This is also the standard adopted in the Order entered herewith. *See* Order Parts I and III. “Competent and reliable scientific evidence” was defined in the order entered in *Daniel Chapter One*, as in the instant Order, as “tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” 2010 FTC LEXIS 11, at \*1.<sup>25</sup> *See* Order, Definitions para. 5. *Daniel Chapter One* is clear authority for entering an order in this case requiring competent and reliable

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<sup>25</sup> Complaint Counsel’s proposed order would apply the competent and reliable evidence standard, as set forth above, to representations “about the health benefits, performance, or efficacy of any Covered Product” under part III. Thus, Complaint Counsel acknowledges that this standard is sufficient for those claims, but nevertheless contends that FDA pre-approval should be the required substantiation for disease claims.

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scientific evidence to substantiate disease claims. Indeed, the competent and reliable scientific evidence standard was deemed sufficient to redress the conduct in *Daniel Chapter One*, which was arguably more egregious than that presented by the instant case. The implied claims in *Daniel Chapter One*, unlike the instant case, were found to have been “so strongly implied as to be virtually express.” 2009 FTC LEXIS 157, at \*53, 55 (Initial Decision). In addition, unlike the instant case, the respondents in *Daniel Chapter One* conducted *no* testing on the effects of the challenged products, much less clinical testing, and the scientific substantiation relied upon by those respondents consisted of nothing more than compilations of citations to literature, mostly non-peer-reviewed papers, on the use of herbal medicines for a number of different diseases. *Id.* at \*237-39; compare F. 732, 756, 1010, 1185. Moreover, in *Daniel Chapter One*, unlike the instant case, the respondents urged their customers to forgo medical treatment and instead use their products to treat cancer as an alternative to pursuing established medical treatments. *Id.* at \*282-83.

Complaint Counsel’s arguments in support of deviating from the order entered and upheld in *Daniel Chapter One* are addressed below.<sup>26</sup>

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<sup>26</sup> Relying, *inter alia*, on *Jacob Siegel Co. v. FTC*, 327 U.S. 608 (1946), Complaint Counsel appears to argue that the Commission is empowered to include virtually any provision in a cease and desist order, so long as it is “reasonably related” to the violations in the case and is sufficiently clear and precise. CCB at 57-58. It is, of course, well established that Congress, through the FTC Act, has granted the Commission “wide discretion in its choice of a remedy deemed adequate to cope with . . . unlawful practices” and that “the courts will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist.” *Jacob Siegel Co.*, 327 U.S. at 611-613. However, this should not be seen as a directive that any and all “reasonably related” remedies are to be ordered. The “reasonable relation” test is an outside limit on the permissible exercise of the FTC’s discretion, rather than a standard for determining what remedy will serve the purpose of prohibiting and preventing the recurrence of deceptive trade practices. *See In re Litton Indus., Inc.*, 1981 FTC LEXIS 94, at \*147 (“The purpose of a cease and desist order is to prevent the violations from being repeated, including by creating stringent monetary incentives (in the form of civil penalties) for its observance.”).

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**ii. Complaint Counsel’s “reasonably related” justification for FDA pre-approval requirement**

Complaint Counsel contends that requiring FDA pre-approval for disease claims is “reasonably related” to the violations in this case because (1) the FDA’s standard for labeling approval for a food-disease relationship claim under NLEA (“significant scientific agreement” by experts that the claim is supported) is “cited” in the FTC *Enforcement Policy Statement on Food Advertising*; and (2) the FDA standard for drug approval under the Food, Drug and Cosmetic Act (“adequate and well-controlled” clinical investigations by experts demonstrating effectiveness), is “similar” to the “competent and reliable scientific evidence” standard applied in *Daniel Chapter One*, and referred to in the FTC publication, *Dietary Supplements: An Advertising Guide for Industry*. However, the foregoing FTC publications do not constitute regulatory law, which is made either by adjudication, 15 U.S.C. §45(b); 5 U.S.C. § 556, or by promulgated regulation, 15 U.S.C. §57b-3; 5 U.S.C. §553.<sup>27</sup> See *Ford Motor Co. v. FTC*, 673 F.2d 1008, 1009 (9th Cir. 1981) (noting that an administrative agency such as the FTC may announce principles through adjudication or rulemaking (citing *NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 294 (1974))). The standard for substantiation for disease claims that has been reflected in adjudication is the “competent and reliable scientific evidence” standard, based on

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27 Complaint Counsel also notes that the Commission has entered into consent orders with other respondents requiring similar FDA pre-approval requirements. CCB at 64. Consent orders do not constitute legal precedent. “The circumstances surrounding . . . negotiated [consent decrees] are so different that they cannot be persuasively cited in a litigation context.” *United States v. E. I. du Pont de Nemours & Co.*, 366 U.S. 316, 331 n.12 (1961). Rather, as confirmed by the express terms of the consent orders cited by Complaint Counsel, a consent order “is for settlement purposes only and does not constitute an admission by the respondent that the law has been violated.” *In re Dannon Co.*, 151 F.T.C. 62, 91 (2011); *In re Nestle Healthcare Nutrition, Inc.*, 151 F.T.C. 1, 10 (2011); see also *In re Iovate Health Sciences U.S.A., Inc.*, No. 10-CV-587 (W.D.N.Y. July 29, 2010) (stating that Commission and Defendants “stipulate and agree to entry of this Order” but “do not admit or deny any of the allegations . . . .”) (available at <http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf>).

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the opinions of experts in the relevant fields, as applied in this case and as affirmed most recently in *Daniel Chapter One*.

Moreover, as explained in Section III.F.2 of this Initial Decision, applicable case law clearly establishes that the required level of substantiation is a question of fact, based upon evidence on numerous factors, including the nature of the product, the safety of the product, the overall context in which the transaction occurs, and what experts in the relevant field would consider sufficient to support the claim at issue. *E.g.*, *QT, Inc.*, 448 F. Supp. 2d at 959; *FTC v. Braswell*, 2005 U.S. Dist. LEXIS 42976, at \*35; *Thompson Medical*, 1984 FTC LEXIS 6, at \*387. In the instant case, after conducting the trial, and thoroughly reviewing the evidence and the voluminous transcript and record, it has been determined that the required level of substantiation for Respondents' implied disease claims is "competent and reliable scientific evidence," as defined by experts in the respective fields, and that such evidence does not require RCTs, such as those that would be required under FDA standards, because such claims were made for a safe food product that was not being urged as a substitute for medical treatment or advice. *See* F. 693, 694-710, 963, 1147-1148. This Initial Decision has not determined that FDA standards are the required level of substantiation for the implied disease claims found to have been made in this case, nor have Respondents been held liable herein for failing to meet FDA standards. Rather, it has been determined that, applying the competent and reliable scientific evidence standard, as defined by the experts in the respective fields, Respondents' substantiation was inadequate to support the implied disease claims found to have been made in this case and, therefore, Respondents violated the FTC Act. To the extent that part I of the proposed order seeks to impose a different and/or higher level of substantiation for future implied disease claims, which it effectively would do, part I of the proposed order is not reasonably related to the violations found to exist. *See Daniel Chapter One*, 2009 FTC LEXIS 259, at \*70 (stating that order's requirement that "Respondents possess and rely upon competent and reliable scientific evidence that substantiates" their claims "only obliged [them] to do that which

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the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception”).<sup>28</sup>

Similarly, Complaint Counsel asserts that it is proper to defer to FDA standards and evaluation of scientific evidence because such deference “is consistent with prior Commission practice.” CCB at 63-64. Complaint Counsel cites *Thompson Medical*, in which the Commission noted that it was “additionally persuaded” that two well-controlled clinical tests was the correct level of substantiation for drug efficacy claims because “this is the standard currently being required . . . by the FDA” and advertisers of drug products will benefit from “greater regulatory certainty.” *Thompson Medical*, 104 F.T.C. at 826, 1984 FTC LEXIS 6, at \*398. In the instant case, however, as noted above, the evidence failed to show that RCTs were required to substantiate Respondents’ implied claims because, among other reasons, the POM Products are food, or food-derived products, and were not being urged as an alternative to medical care or advice. F. 693, 694-710, 963, 1147-1148. Thus, *Thompson Medical* does not support imposing the proposed FDA pre-approval requirement in the Order in this case.<sup>29</sup>

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28 In support of its argument that FDA drug approval standards are “similar” to FTC requirements, Complaint Counsel cites to the portion of the *Daniel Chapter One* Initial Decision that found as a fact, based on the weight of the expert testimony presented in that case, that “competent and reliable scientific evidence” to support the respondents’ cancer effectiveness claims required “well-designed, controlled, clinical trials . . . .” 2009 FTC LEXIS 157, at \*109-11. Consistent with that evidence, the order in *Daniel Chapter One*, like the Order in this case, defined competent and reliable scientific evidence as “tests, analyses, research, [or] studies, . . . conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.” Thus, *Daniel Chapter One* is not authority for requiring Respondents in this case to substantiate claims in accordance with FDA approval standards.

29 However, were Respondents to advertise a “drug” in the future, *Thompson Medical* clearly shows how application of the competent and reliable scientific evidence standard, as defined in the Order, could well result in a required level of substantiation that is consistent with FDA standards for drug approval.

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**iii. Complaint Counsel’s “bright-line rule” justification for FDA pre-approval requirement**

Complaint Counsel further argues that the FDA pre-approval requirement is justified because it is “clear and precise,” as required under *Colgate-Palmolive*. According to Complaint Counsel, FDA pre-approval is a “bright-line rule” that will “significantly increase . . . enforceability,” “eliminate any confusion or ambiguities over the appropriate standard that Respondents must have to make disease claims” and prevent litigation. CCB at 64-65, 67. However, neither FDA pre-approval, nor FDA standards for obtaining such approval, constitutes the required level of substantiation under the FTC Act or applicable case law. Nor have FDA standards been found to constitute the required level of substantiation based on the evidence in the instant case. Thus, the “bright-line” proposed by Complaint Counsel would be imprudently drawn in this case. Moreover, “the complexity of the scientific issues, the unquestioned expertise of the FDA to evaluate scientific evidence relating to disease claims, and the Commission’s interest in harmonizing with the FDA,” CCB at 67, do not constitute sufficient reasons to create a new level of substantiation, through a cease and desist order against Respondents, *a fortiori*, considering the level of substantiation found to be required in this case. Indeed, the Second Circuit Court of Appeals has indicated that a “bright-line” of FDA approval for FTC cease and desist orders is “unnecessary, if not undesirable.” *Bristol-Meyers Co. v. FTC*, 738 F.2d 554, 560 (2d Cir. 1984). In that case, the court rejected Bristol-Meyers’ request to modify the FTC’s cease and desist order to permit it to rely on demonstrating FDA approval of claims for its over-the-counter analgesics, stating: “FDA determinations are usually complex and subject to varying interpretations. To allow [respondents] to rely on its evaluation of these determinations could conceivably lead to more deceptive advertisements and to more disputes with the FTC.” *Id.* The reasoning in *Bristol-Meyers* is equally applicable in the instant case, where Complaint Counsel seeks to replace the governing

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“competent and reliable scientific evidence” standard with FDA approval standards.<sup>30</sup>

In addition, Complaint Counsel misconstrues the purpose of the requirement that FTC orders be “clear and precise.” The Court in *Colgate-Palmolive* explained that “an order’s prohibitions ‘should be clear and precise in order *that they may be understood by those against whom they are directed . . .*’” 380 U.S. at 392 (emphasis added) (citation omitted). This language does not indicate that the “clarity and precision” requirement is designed for the benefit of the FTC in litigating potential future enforcement actions. Moreover, some level of uncertainty is contemplated by the FTC Act, as noted by the Supreme Court in *Colgate-Palmolive*: “If, however, a situation arises in which respondents are sincerely unable to determine whether a proposed course of action would violate the present order, they can, by complying with the Commission’s rules, oblige the Commission to give them definitive advice as to whether their proposed action, if pursued, would constitute compliance with the order.” 380 U.S. at 394; *Kraft*, 970 F.2d at 326 (citing the ability to seek an advisory opinion under 16 C.F.R. § 2.41(d) as a method of reducing advertiser uncertainty).<sup>31</sup> Moreover, whatever bright-line rule might be applied to substantiation will not necessarily reduce the risk of future litigation over whether Respondents made disease claims in the first place. As this case demonstrates, there is ample room for disagreement over whether or not advertisements make “unqualified” disease claims, as opposed to “qualified” “health benefit” claims, and the task of interpreting advertisements clearly does not lend itself to a bright-line rule.

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30 It must also be noted that there is no evidence in the record of any coordination with, or acceptance by, the FDA with respect to requiring the FDA to pre-approve advertising claims challenged under the FTC Act.

31 Rule 2.41 states in pertinent part: “(d) Any respondent subject to a Commission order may request advice from the Commission as to whether a proposed course of action, if pursued by it, will constitute compliance with such order. The request for advice should be submitted in writing to the Secretary of the Commission and should include full and complete information regarding the proposed course of action. On the basis of the facts submitted, as well as other information available to the Commission, the Commission will inform the respondent whether or not the proposed course of action, if pursued, would constitute compliance with its order.” 16 C.F.R. § 2.41(d).

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In any event, Complaint Counsel cites no authority supporting a conclusion that the competent and reliable evidence standard, as provided in the Order upheld in *Daniel Chapter One*, is insufficiently clear or precise. In *Colgate-Palmolive*, the Supreme Court upheld the FTC order's requirement of a "test, experiment or demonstration" to substantiate future claims, and rejected the lower court's finding that such provision was invalid as too difficult to interpret. 380 U.S. at 393-94. The Court stated: "We believe that respondents will have no difficulty applying the Commission's order to the vast majority of their contemplated future commercials." *Id.* at 394. *See also Bristol-Meyers Co.*, 738 F.2d at 560 (rejecting argument that order's requirement of "reasonable basis" substantiation "to consist of 'competent and reliable scientific evidence'" was unduly vague). Indeed, Complaint Counsel's proposed order expressly relies on the competent and reliable evidence standard, albeit for claims other than disease claims, pursuant to proposed part III, and this standard has been incorporated into the Order for all claims governed by the Order. For all the foregoing reasons, there is no basis for concluding that the competent and reliable evidence standard is insufficiently clear or precise for purposes of enforcement.

Complaint Counsel further argues that a "bright-line" rule is necessary because, according to Complaint Counsel, Respondents have shown a willingness to "flout the law," including, among other allegations, that Respondents failed to make any specific changes to their advertising in response to an FTC warning letter sent to Respondents in January 2008 and an FDA warning letter sent in January 2010. CCB at 65-66. The evidence upon which Complaint Counsel relies, even if true, indicates a disagreement between the Respondents and regulatory authorities regarding whether Respondents' advertising made disease claims and if so, whether those claims were adequately substantiated. *See id.* The disagreement with the FTC culminated in this litigation, in which neither side's position, as to the claims made or the adequacy of the substantiation, has been totally vindicated. Under these circumstances, Respondents' choice not to "heed warnings" and instead to litigate is not fairly interpreted as a willingness to "flout the law" but could be interpreted as an allowable choice made within the system as it exists.

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**iv. Summary**

Considering the entire record in this case, implementing Complaint Counsel's proposed FDA pre-approval requirement would constitute unnecessary overreaching. The competent and reliable evidence standard is established precedent, is reasonably related to the violations found to exist, and is sufficiently clear and precise to guide Respondents' future advertising practices. Precedent does not support implementing an FDA pre-approval requirement as a "bright-line" rule in this case. If Respondents choose to go "perilously close to an area of proscribed conduct," then they will "take the risk that [they] may cross the line." *Colgate-Palmolive*, 380 U.S. at 393.<sup>32</sup>

**d. Part II of the Order**

Part II of the Order, consistent with the proposed order, prohibits Respondents from misrepresenting "the existence, contents, validity, results, conclusions, or interpretations of any

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32 Because Complaint Counsel has failed to adequately justify departing from established precedent to provide for the proposed FDA pre-approval requirement, that requirement is not included in the Order. Thus, this Initial Decision need not, and does not, address whether or not the proposed FDA pre-approval requirement should also be rejected because it exceeds the Commission's authority under the FTC Act and/or violates Respondents' First Amendment rights. It should be noted, however, that Respondents' generalized assertion that none of its commercial speech should be "barred" is without merit. RRB at 177. Requiring adequate substantiation for advertising claims does not "bar" commercial speech, but serves to prevent dissemination of misleading claims. *E.g., Bristol-Meyers*, 738 F.2d at 562 ("Even in the absence of a finding of actual deception, agencies may properly regulate speech that is merely potentially deceptive."); *Sears, Roebuck*, 676 F.2d at 399 ("[T]he Commission may require prior reasonable substantiation of product performance claims after finding violations of the Act, without offending the [F]irst [A]mendment."); *Jay Norris, Inc. v. FTC*, 598 F.2d 1244, 1252 (2d Cir. 1979) ("[B]ecause the FTC here imposes the requirement of prior substantiation as a reasonable remedy for past violations of the Act, there is no unconstitutional prior restraint of petitioners' protected speech."). *See also Zauderer v. Office of Disciplinary Council*, 471 U.S. 626, 638 (1985) (holding that "[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading"); *In re R. M. J.*, 455 U.S. 191, 207 (1982) (stating that "the States retain the authority to regulate advertising that is inherently misleading or that has proved to be misleading in practice").

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test, study, or research.” One of the violations alleged and proved in this case is that Respondents impliedly represented they had clinical proof of the effectiveness of the POM Products, when such clinical proof was not, in fact, adequate to substantiate this implied claim. Requiring Respondents to ensure that any advertised research results are fully accurate and non-misleading is reasonably related to this violation. In their Post-Hearing Briefs, Respondents do not articulate any argument for concluding that the provision is not reasonably related to the violations found in this case.

**e. Part III of the Order**

Part III of the Order, consistent with the proposed order, prohibits Respondents from making any representation about the “health benefits, performance, or efficacy of any Covered Product” unless the claim is not misleading, and supported by “competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.” This provision is reasonable and appropriate, and obliges Respondents only “to do that which the case law under Sections 5 and 12 of the FTC Act has defined as necessary to avoid deception.” *Daniel Chapter One*, 2009 FTC LEXIS 259, at \*70. Respondents, in their Post-Hearing Briefs, do not articulate any argument against applying this standard to future advertising claims within the scope of Part III.

**f. Miscellaneous provisions**

Part IV of the Order, consistent with the proposed order, provides that nothing in the Order prohibits Respondents from making claims that are specifically permitted in labeling, pursuant to FDA standards and regulations. In contrast to Complaint Counsel’s proposed and rejected FDA pre-approval requirement, which made FDA standards the minimum substantiation for disease claims, this provision properly gives Respondents a “safe harbor” against any future FTC challenge to Respondents’ advertising representations, by enabling Respondents to demonstrate FDA approval. Substantially the same provisions

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were entered in the Order in *Daniel Chapter One*, 2010 FTC LEXIS 11, at \*4-5 (Part IV) and are also appropriate in this case.

Parts V-IX of the Order, consistent with the proposed order, impose certain record-keeping, notification, and reporting requirements, and properly serve to facilitate administration of the Order. Finally, part X of the Order, consistent with the proposed order, provides for the termination of the Order in twenty (20) years. Respondents assert that a twenty-year period is “unconscionable” given that a portion of the advertising at issue occurred, and according to Respondents ceased, more than five years ago. However, as indicated in subsection 2.a., above, numerous advertisements disseminated after 2006 were found to have made implied disease claims, without adequate substantiation. F. 307-308, 321, 328,344, 365, 432, 580-583, 962, 1143, 1313-1314. Accordingly, a twenty-year duration is not unconscionable for the reason asserted by Respondents. *See also Daniel Chapter One*, 2010 FTC LEXIS 11, at \*9-10 (Part XI) (providing for termination of order in twenty years).

## 5. Conclusion

The Order entered herewith will serve to prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

## IV. SUMMARY OF CONCLUSIONS OF LAW

1. Complaint Counsel bears the burden of proving jurisdiction and liability by a preponderance of evidence.
2. Respondents POM Wonderful (“POM”) and Roll Global (“Roll”) are corporations within the meaning of Sections 4 and 5 of the Federal Trade Commission Act (“FTC Act”).
3. Respondents Stewart Resnick (“Mr. Resnick”), Lynda Resnick (“Mrs. Resnick”) and Matthew Tupper (“Mr. Tupper”), are “persons” within the meaning of Section 5 of the FTC Act.

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4. Respondents' sales of POM Wonderful 100% pomegranate juice ("POM Juice"), and pomegranate extract products known as POMx Pills and POMx Liquid ("POMx") (collectively, the "POM Products"), are in or affecting commerce, as required by the FTC Act, 15 U.S.C. § 45(a)(1).
5. The Commission has jurisdiction over Respondents, and the conduct challenged in the Complaint, under Sections 4 and 5 of the FTC Act. 15 U.S.C. § 44, 45.
6. Under the Commission's precedent regarding the statutory term "advertisement," the media appearances and interviews by Respondents, challenged in this case as
7. advertisements, do not constitute "advertisements" within the scope of the FTC Act because they were not paid for or sponsored by Respondents. 15 U.S.C. § 45, 52. Respondents do not dispute that the remaining advertisements and promotional materials disseminated by Respondents and challenged in this case (the "Challenged Advertisements") constitute "advertisements" within the meaning of the FTC Act.
8. The POM Products constitute "food" or "drugs," under Section 12 of the FTC Act. 15 U.S.C. § 55.
9. An advertisement is deceptive under the FTC Act if it is likely to mislead consumers, acting reasonably under the circumstances, in a material respect. The determination of whether Respondents disseminated false advertisements in violation of the FTC Act requires a three-part inquiry: (1) whether Respondents disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers.
10. An advertisement is deemed to convey a claim if a significant minority of reasonable consumers would interpret the advertisement to contain that message.

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Whether an advertisement conveys a claim is a question of fact.

11. To determine whether an advertisement conveys an alleged claim, the first step is to examine the advertisement itself (a “facial analysis”). A proper facial analysis requires an evaluation of such factors as the entire document, the juxtaposition of various phrases in the document, the nature of the claim, and the nature of the transaction.
12. If, after viewing the advertisement as a whole, examining the interaction of all the different elements in the advertisement, it can be concluded with confidence that an advertisement can reasonably be read to contain a particular claim, a facial analysis is sufficient basis to conclude that the advertisement conveys the claim. However, an implied claim must be reasonably clear or conspicuous from the face of the advertisement.
13. If, after a facial analysis, it cannot be concluded with confidence that a particular advertisement can reasonably be read to contain a particular implied message, the advertisement will not be deemed to have made the alleged claim unless extrinsic evidence allows the conclusion that such a reading of the advertisement is reasonable.
14. “Target audiences,” for purposes of interpreting advertising, refer to special audiences who as a group have a greater or lesser capability to recognize deceptive advertising than ordinary members of the adult population or have a distinctive reaction to particular advertising claims. Complaint Counsel has failed to prove that its asserted “target audience” of educated, affluent, health-conscious consumers would be more likely to interpret, or in fact did interpret, the Challenged Advertisements differently than ordinary consumers, or in what manner that group would do so.
15. The evidence demonstrates that Respondents disseminated advertisements that a significant minority of reasonable

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consumers would interpret to contain an implied claim that drinking eight ounces of POM Juice daily, taking one POMx Pill daily, and/or taking one teaspoon of POMx Liquid daily, treats, prevents, or reduces the risk of heart disease, prostate cancer and/or erectile dysfunction, and/or is clinically proven to do so, as alleged in the Complaint. It is not necessary to demonstrate that every Challenged Advertisement conveyed one or more of the alleged claims. Accordingly, even though the evidence failed to demonstrate that all of the Challenged Advertisements made the alleged claims, Complaint Counsel met its burden of proving the first element of a false advertising claim.

16. Two theories have been used to prove that an advertisement is deceptive or misleading: (1) the “falsity” theory or (2) the “reasonable basis” theory. As to both the alleged “false establishment claims” and the alleged “unsubstantiated efficacy claims,” proof of deception requires proof that Respondents’ substantiation failed to meet the level of substantiation required. Because whether Respondents’ claims were deceptive turns on the nature and quality of Respondents’ substantiation, the falsity and reasonable basis theories collapse into the same inquiry: did Respondents possess adequate substantiation to support their claims?
17. To determine whether the challenged claims are false or misleading, it must first be determined what level of substantiation Respondents were required to have for their advertising claims. This determination is a question of fact to be determined based upon the evidence adduced at trial. Next, it must be determined whether Respondents possessed that level of substantiation. Respondents have the burden of establishing what substantiation they relied on for their product claims. Complaint Counsel has the burden of proving that Respondents’ purported substantiation is inadequate.
18. Neither the FTC Act nor applicable case law requires well-designed, well-conducted, randomized, double-blind,

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placebo-controlled human clinical trials (“RCTs”) to substantiate all health-related efficacy claims.

19. The evidence shows that the appropriate level of substantiation for the implied claims in this case that a product can treat, prevent, or reduce the risk of a disease is competent and reliable scientific evidence. Where such claims are made in connection with a food, or food-derived product, that is safe, and that is not being offered as a substitute for medical treatment, well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials, such as those required by the Food and Drug Administration are not required. However, for claims that a food or food-derived product treats, prevents, or reduces the risk of a disease, experts in the field would agree that competent and reliable scientific evidence must include clinical studies, although not necessarily double-blind, randomized, placebo-controlled clinical trials, adequate to show that the product did treat, prevent, or reduce the risk of disease.
20. The weight of the persuasive expert testimony demonstrates that there was insufficient competent and reliable scientific evidence to support the implied claims, made in advertisements disseminated by Respondents, that the POM Products treat, prevent or reduce the risk of heart disease, prostate cancer, or erectile dysfunction, or are clinically proven to do so. Therefore, such claims were false or misleading within the meaning of Section 12 of the FTC Act, and Complaint Counsel met its burden of proving the second element of a false advertising claim.
21. An act or practice is material if it is likely to affect the consumer’s conduct or decision with regard to a product or service. Information is material if it is important to consumers.
22. To be material, a claim does not have to be the only factor or the most important factor likely to affect a consumer’s purchase decision; it need only be an important factor.

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23. The implied claims found to have been made in this case are material because they are health-related and resulted in increased product sales for Respondents. In addition, consumer research of the attitudes and usage habits of POM customers, conducted in the ordinary course of POM's business, shows that such claims are material to consumers. Accordingly, Complaint Counsel has met its burden of proving the third element of a false advertising claim.
24. Because Complaint Counsel has met its burden as to all three elements of a false advertising claim (see Conclusion No. 8, above), liability has been established.
25. Having concluded that Respondents violated the FTC Act, that Act authorizes an order requiring Respondents to cease and desist from such acts or practices.
26. Where one or more corporate entities operate in a common enterprise, each may be held liable for the deceptive acts and practices of the others. POM and Roll are liable as a "common enterprise" and, accordingly, both are held liable herein.
27. Injunctive relief may be obtained against an individual for a business entity's deceptive acts or practices if the individual either participated directly in the business entity's deceptive acts or practices, or had the authority to control them. The evidence demonstrates that Mr. Resnick, Mrs. Resnick, and Mr. Tupper each participated directly in the business entity's deceptive acts or practices, and/or had the authority to control them, and, therefore, each individual is held liable herein, along with POM and Roll.
28. Sole or ultimate control of a company is not necessary to establish individual liability. To establish liability on the basis of authority to control, it is sufficient that Mr. Tupper was part of the inner circle that formulated, controlled, and directed POM.

## Initial Decision

29. The purpose of a cease and desist order is to prohibit and prevent liable parties from engaging in deceptive acts or practices in the future. The cease and desist order must be sufficiently clear that it is comprehensible to the violator, and must be reasonably related to the violations found to exist.
30. The Commission's authority includes power to issue cease and desist orders encompassing all products or all products in a broad category, based on violations involving only a single product or group of products. Coverage of all products in a broad category is a means of "fencing-in" one who has violated the statute.
31. In determining whether a fencing-in order bears a "reasonable relationship" to a violation of the FTC Act, courts and the Commission consider: (1) the deliberateness and seriousness of the violation; (2) the degree of transferability of the violation to other products; and (3) any history of prior violations. All three factors need not be present for a reasonable relationship to exist. The more egregious the facts with respect to a particular factor, the less important it is that another negative factor be present.
32. A violation of the FTC Act is considered transferable where other products could be sold utilizing similar techniques. In the instant case, this transferability factor weighs strongly in favor of a multi-product order covering any food, drug or dietary supplement, not just the POM Products. Respondents' advertising techniques could readily be employed for any food, drug or dietary supplement.
33. The seriousness of Respondents' violations is shown by the fact that the claims pertained to serious diseases and dysfunction of the body, including cancer, and the inability of consumers to evaluate whether Respondents' implied disease claims were true or actually supported by cited studies. The deliberateness of Respondents' conduct is shown by the consistency of Respondents' advertising themes over the years and by the fact that Respondents'

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advertising appeared in a wide variety of national and local media, for multiple years, which facts support the conclusion that the advertisements found herein to have violated the FTC Act did not constitute accident or an “isolated instance.”

34. Although Respondents have no prior violations, the strength of the other relevant fencing-in factors, particularly transferability, is sufficient to establish a reasonable relation between the multi-product remedy and Respondents’ violations found in this case.
35. The provision in the Notice Order prohibiting Respondents from making any disease claims in the future, unless such claim has been first approved by the Food and Drug Administration (“FDA”) (the “FDA pre-approval requirement”) is rejected as unsupported by governing precedent and the facts of this case, and is not reasonably related to the violations of the FTC Act found herein.
36. No previous decision by the Commission or any court has required FDA pre-approval as the required level of substantiation for disease claims, including for purposes of a cease and desist order.
37. The required level of substantiation is a question of fact, and the evidence in this case demonstrates that Respondents’ implied disease claims require “competent and reliable scientific evidence,” which does not necessarily require well-designed, well-conducted, randomized, double-blind, placebo-controlled human clinical trials, such as those required by the FDA.
38. The requirement in the order that respondents possess “competent and reliable scientific evidence” was deemed sufficient to redress unsubstantiated disease claims in *Daniel Chapter One*, No. 9329, 2010 FTC LEXIS 11 (Jan. 25, 2010), *review denied*, *Daniel Chapter One v. FTC*, No. 10-1064, 2010 U.S. App. LEXIS 25496 (D.C. Cir. Dec. 10, 2010), in which the violations were arguably more egregious than in the instant case.

## Initial Decision

39. The requirement in the Order in this case that Respondents possess competent and reliable evidence, as defined in the Order, to substantiate their claims is consistent with established precedent, is reasonably related to the violations found to exist in this case, is sufficiently clear and precise to guide Respondents' future advertising practices, and is adequate to prohibit and prevent Respondents from engaging in the same or similar violations in the future.
40. The Order attached herewith will serve to prohibit and prevent Respondents from engaging in deceptive advertising practices in the future, is reasonably related to the unlawful acts or practices found to exist, and is sufficiently clear and precise.

**ORDER****DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

- A. Unless otherwise specified, "individual respondents" shall mean Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of POM Wonderful LLC ("POM Wonderful") and Roll Global ("Roll").
- B. Unless otherwise specified, "Respondents" shall mean POM Wonderful and Roll, their officers, agents, successors and assigns; and the individual respondents and each of their successors, assigns, agents, and representatives.
- C. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- D. "Competent and reliable scientific evidence" shall mean tests, analyses, research, or studies, conducted and evaluated in an objective manner by persons

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qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

- E. “Covered Product” shall mean any food, drug, or dietary supplement, including, but not limited to, the POM Products.
- F. “Food” and “drug” shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- G. “Endorsement” shall mean as defined in 16 C.F.R. § 255.0.
- H. “POM Product” shall mean any food, drug, or dietary supplement containing pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.
- I. The term “including” in this Order shall mean “without limitation.”
- J. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

**I.**

**IT IS ORDERED** that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque,

## Initial Decision

lowering blood pressure, or improving blood flow to the heart; treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); or treat, prevent, or reduce the risk of erectile dysfunction; unless, at the time it is made, the representation is non-misleading and, Respondents possessed and relied upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

**II.**

**IT IS FURTHER ORDERED** that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

**III.**

**IT IS FURTHER ORDERED** that Respondents, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, Respondents rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire

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body of relevant and reliable scientific evidence, to substantiate that the representation is true.

**IV.**

**IT IS FURTHER ORDERED** that:

- A. Nothing in this Order shall prohibit Respondents from making any representation for any product that is specifically permitted in labeling for such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990; and
- B. Nothing in this Order shall prohibit Respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

**V.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging, and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other

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communications with consumers or with governmental or consumer protection organizations; and

- D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

**VI.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

**VII.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and individual respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. *Provided, however,* that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and individual respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and individual

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respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

**VIII.**

**IT IS FURTHER ORDERED** that each individual respondent, for a period of ten (10) years after the date of issuance of this Order, shall notify the Commission of the discontinuance of any current business or employment, or of an affiliation with any new business or employment. The notice shall include the individual respondent's new business address and telephone number and a description of the nature of the business or employment and all duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful*. *Provided, however,* that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

**IX.**

**IT IS FURTHER ORDERED** that POM Wonderful, Roll, and their successors and assigns, and individual respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. In addition, within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

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**X.**

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; *provided, however*, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years;
- B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and
- C. This Order, if such complaint is filed after the Order has terminated pursuant to this Part.

*Provided, further*, that if such complaint is dismissed or a federal court rules that Respondents did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

## Complaint

## IN THE MATTER OF

**FRESENIUS MEDICAL CARE AG & CO. KGAA**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4348; File No. 111 0170  
Complaint, February 28, 2012 – Decision, May 23, 2012*

This consent order addresses the \$2.1 billion acquisition by Fresenius Medical Care AG & Co. KGaA of certain assets of Liberty Dialysis Holdings, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the Federal Trade Commission Act by substantially lessening competition in 43 markets for the provision of outpatient dialysis services. The consent order requires Fresenius to divest 60 dialysis clinics and terminate one management contract in 43 geographic markets across the United States.

*Participants*

For the *Commission*: Jordan Andrew, Lisa D. DeMarchi Sleigh, Amy S. Posner, and Mark Silvia, and Aylin M. Skroejer.

For the *Respondent*: Brian Burke and Katherine Funk, Baker & McKenzie LLP; and Robert Leibenluft and Mary Anne Mason, Hogan Lovells US LLP.

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission (“Commission”), having reason to believe that the Respondent Fresenius Medical Care AG & Co. KGaA (“Fresenius”), a company subject to the jurisdiction of the Commission, has entered into an agreement to acquire Liberty Dialysis Holdings, Inc. (“Liberty”), a company subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission Act (“FTC Act”), as amended, 15 U.S.C. § 45, that such acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof

## Complaint

would be in the public interest, hereby issues its Complaint, stating its charges as follows:

**I. DEFINITIONS**

1. “Dialysis” means filtering a person’s blood, inside or outside of the body, to replicate the functions of the kidney.
2. “ESRD” means end stage renal disease, a chronic disease characterized by a near total loss of function of the kidneys, which in healthy people remove toxins and excess fluid from the blood.
3. “Outpatient dialysis services” means all procedures and services related to administering chronic dialysis treatment.

**II. RESPONDENT**

4. Fresenius Medical Care AG & Co. KGaA (“Fresenius”) is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its offices and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America with its office and principal place of business located at 920 Winter St., Waltham, MA 02451-1457. Respondent Fresenius, among other things, is engaged in the provision and sale of outpatient dialysis services.

5. Respondent Fresenius is, and at all times herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**III. THE ACQUIRED COMPANY**

6. Liberty is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 7650 SE 27<sup>th</sup> St., Suite 200, Mercer Island, WA. Liberty, among other

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things, is engaged in the provision and sale of outpatient dialysis services.

7. Liberty is, and at all times herein has been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. §12, and is a corporation whose business is in or affects commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

### **IV. THE PROPOSED ACQUISITION**

8. On August 1, 2011, Fresenius entered into an agreement (“Purchase Agreement”) to acquire Liberty for approximately \$2.1 billion in cash and the assumption of Liberty debt (the “Acquisition”).

### **V. THE RELEVANT MARKET**

9. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the provision of chronic outpatient dialysis services. Most ESRD patients receive dialysis treatments three times per week in sessions lasting between three and five hours. ESRD is fatal if not treated with dialysis. The only alternative to outpatient dialysis treatments for patients suffering from ESRD is a kidney transplant. However, the wait-time for donor kidneys – during which ESRD patients must receive dialysis treatments – can exceed five years. Additionally, many ESRD patients are not viable transplant candidates. As a result, few ESRD patients receive transplants, and most have no alternative to ongoing outpatient dialysis treatment.

10. The relevant geographic market for the provision of dialysis services is defined by the distance ESRD patients are willing or able to travel to receive outpatient dialysis treatments, and is thus local in nature. Because ESRD patients often suffer from multiple health problems and may require assistance traveling to and from the dialysis clinic, these patients are unwilling and/or unable to travel long distances to receive dialysis treatment. As a general rule, ESRD patients do not travel more than 30 miles or 30 minutes to receive dialysis treatment,

## Complaint

although travel times and distances vary depending on geographic barriers, travel patterns, and whether an area is urban, suburban, or rural.

11. For the purposes of this Complaint, the geographic markets within which to assess the competitive effects of the proposed Acquisition are 43 areas comprised of or within the following metropolitan areas: (1) Anchorage, AK CBSA; (2) Flagstaff, AZ; (3) San Francisco–Oakland–Fremont, CA CBSA; (4) San Diego–Carlsbad–San Marcos, CA CBSA; (5) Pueblo, CO CBSA; (6) New Haven–Milford, CT CBSA; (7) Seaford, DE CBSA; (8) Philadelphia–Camden–Wilmington, PA-NJ-DE-MD CBSA; (9) Sarasota–Bradenton–Venice, FL CBSA; (10) Palm Bay–Melbourne–Titusville, FL CBSA; (11) Macon, GA CBSA; (12) Milledgeville, GA CBSA; (13) Savannah, GA CBSA; (14) Honolulu, HI CBSA; (15) a 70-mile radius surrounding Sandpoint, ID; (16) Coeur d’Alene, ID CBSA; (17) Muncie, IN CBSA; (18) Chicago–Naperville–Joliet, IL-IN-WI CBSA; (19) Kokomo, IN CBSA; (20) Lafayette, IN CBSA; (21) Michigan City–La Porte, IN CBSA; (22) Washington–Arlington–Alexandria, DC-VA-MD-WV CBSA; (23) Grand Rapids–Wyoming, MI CBSA; (24) Jackson, MI CBSA; (25) Niles–Benton Harbor, MI CBSA; (26) Charlotte–Gastonia–Concord, NC-SC CBSA; (27) Poughkeepsie–Newburgh–Middletown, NY CBSA; (28) Atlantic City, NJ CBSA; (29) Lawton, OK CBSA; (30) Pittsburgh, PA CBSA; (31) McMinnville, TN CBSA; (32) Memphis, TN-MS-AR CBSA; (33) Nashville–Davidson–Murfreesboro–Franklin, TN CBSA; (34) Tullahoma, TN CBSA; (35) College Station–Bryan, TX CBSA; (36) Laredo, TX CBSA; (37) Dallas–Fort Worth–Arlington, TX CBSA.

**VI. THE STRUCTURE OF THE MARKET**

12. The market for the provision of outpatient dialysis services is highly concentrated in each of the local areas identified in Paragraph 11, as measured by the Herfindahl-Hirschman Index (“HHI”) concentration ratios. The proposed acquisition represents a merger to monopoly in 18 markets and would cause the number of providers to drop from three to two in 23 markets identified in paragraph 11 while significantly increasing concentration in two markets that would have more than two remaining competitors.

### Complaint

13. Fresenius and Liberty are actual and substantial competitors in each of the relevant markets, or will be following a planned entry by one of the two parties.

## **VII. ENTRY CONDITIONS**

14. Entry or expansion into the relevant markets is difficult, most significantly because of the need to locate and contract with a nephrologist with an established referral base to serve as medical director. By law, each dialysis clinic must have a nephrologist medical director. In addition to supervising patient care, the medical director serves as the principal source of patient referrals to the clinic. Most geographic markets have a limited number of nephrology groups, many of which are under exclusive contracts with the major dialysis services chains. The lack of available nephrologists with an established referral stream is a significant barrier to entry in each of the relevant geographic markets identified in Paragraph 11. Additionally, an area must have certain attributes, such as a growing ESRD population, low penetration of other dialysis chains, and a high ratio of commercial to medicare patients, to attract entry. The absence of these attributes is an additional barrier to entry in many of the relevant geographic markets.

15. New entry into the relevant markets sufficient to deter or counteract the anticompetitive effects described in Paragraph 16 is unlikely to occur, and would not occur in a timely manner.

## **VIII. EFFECTS OF THE ACQUISITION**

16. The effects of the Acquisition, if consummated, may be substantially to lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

- a. eliminating actual, direct, and substantial competition between Fresenius and Liberty in the relevant markets;

## Order to Hold Separate

- b. increasing the ability of the merged entity unilaterally to raise prices for outpatient dialysis services in the relevant markets; and
- c. reducing incentives to improve service in the relevant markets.

**IX. VIOLATIONS CHARGED**

17. The Purchase Agreement described in Paragraph 8 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 8, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED,** the Federal Trade Commission on this the twenty-eighth day of February, 2012, issues its Complaint against said Respondent.

By the Commission.

**ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS**  
**[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Fresenius Medical Care AG & Co. KGaA of Liberty Dialysis Holdings, Inc. (“Liberty”), and Fresenius Medical Care AG & Co. KGaA (hereafter referred to as “Respondent Fresenius”) having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Fresenius with violations of Section 7 of the

## Order to Hold Separate

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent Fresenius, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent Fresenius of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent Fresenius that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission, having thereafter considered the matter and having determined that it had reason to believe that Respondent Fresenius has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues the following Order to Hold Separate and Maintain Assets (“Hold Separate Order”):

1. Respondent Fresenius Medical Care AG & Co. KGaA is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius Medical Care AG & Co. KGaA is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America (“FMCNA”) with its office and principal place of business located at 920 Winter St., Waltham, MA 02451-1457.

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2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent Fresenius, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that all capitalized terms used in this Hold Separate Order, but not defined herein, shall have the meanings attributed to such terms in the Decision and Order contained in the Consent Agreement. In addition to the definitions in Paragraph I of the Decision and Order attached to the Agreement Containing Consent Orders, the following definitions shall apply:

- A. “Fresenius Clinics” means the Fresenius-owned Clinics listed in Appendix A to the Decision and Order and the Fresenius Clinics in Non-Public Appendix F to the Decision and Order.
- B. “Decision and Order” means:
  1. the Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance of a final Decision and Order by the Commission; and
  2. the Final Decision and Order issued and served by the Commission.
- C. “Divestiture Date” means the earliest date on which all of the divestitures of the Appendix A Clinic Assets, except for the Secondary Divestiture Assets, as required by the Decision and Order have been completed.
- D. “Hold Separate Period” means the time from the Effective Date until one day after the Divestiture Date, or the divestiture of the Dallas Joint Venture Equity Interests, whichever is later.
- E. “Hold Separate Trustee” means the person appointed pursuant to Paragraph III of this Hold Separate Order.

## Order to Hold Separate

- F. “Monitor” means any monitor appointed pursuant to Paragraph VII of this Hold Separate Order.
- G. “Orders” means the Decision and Order and this Hold Separate Order.
- H. “Secondary Divestiture Assets” means the Hawaii Clinic Assets, Connecticut Clinic Assets, the New York Clinic Assets, and the Florida Viera Clinic Assets.
- I. “Secondary Divestiture Date” means each of the dates on which Secondary Divestiture Assets are divested to DSI, or the Acquirer pursuant to Paragraph II or Paragraph V of the Order.

**II. (Asset Maintenance)****IT IS FURTHER ORDERED** that:

- A. From the date Respondent Fresenius signs the Consent Agreement until the Divestiture Date and Secondary Divestiture Dates, Respondent Fresenius shall:
  - 1. Maintain each of the Fresenius Clinics and all Assets Associated with such Clinics in substantially the same condition (except for normal wear and tear) existing at the time Respondent Fresenius signs the Consent Agreement;
  - 2. Take such actions that are consistent with the past practices of Respondent Fresenius in connection with each of the Fresenius Clinics and the Assets Associated with each and that are taken in the Ordinary Course Of Business and in the normal day-today operations of Respondent Fresenius;
  - 3. Keep available the services of the current officers, employees, and agents of Respondent Fresenius; and maintain the relations and good will with Suppliers, Payors, Physicians, landlords, patients, employees, agents, and others having business

## Order to Hold Separate

relations with the Fresenius Clinics and the Assets Associated with them in the Ordinary Course Of Business;

4. Preserve the Fresenius Clinics and all Assets Associated with them as ongoing businesses and not take any affirmative action, or fail to take any action within Respondent Fresenius's control, as a result of which the viability, competitiveness, and marketability of the Fresenius's Clinics or the Assets Associated with them would be diminished;
  5. Not object to sharing with the Acquirer the Payor and Supplier contract terms Relating To the Clinics To Be Divested: (i) if the Payor or Supplier consents in writing to such disclosure upon a request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with Respondent Fresenius not to disclose the information to any third party; and
  6. Cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer, in obtaining all Third Party Approvals and Government Approvals For Divestiture, and all Government Approvals For Continued Operation, for each Clinic To Be Divested.
- B. From the date Respondent Fresenius signs the Consent Agreement until the Secondary Divestiture Dates, Respondent Fresenius shall:
1. appoint an executive responsible for overseeing and maintaining such Secondary Divestiture Assets to be the primary contact between Respondent Fresenius and Commission staff and the Monitor.
  2. maintain such assets until each of the Secondary Divestiture Dates in a business-as-usual manner and/or in accordance with the applicable business plan. The appointed executive shall compare past business plans, operating and capital budgets to

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current metrics to assure that the clinics are maintained appropriately.

- C. The purposes of this Paragraph II are to: (1) preserve the Fresenius Clinics as viable, competitive, and ongoing businesses until the divestitures required by the Decision and Order are achieved; (2) prevent interim harm to competition pending the relevant divestitures and other relief; and (3) help remedy any anticompetitive effects of the proposed Fresenius-Liberty Acquisition as alleged in the Commission's Complaint.

**III. (Liberty Hold Separate)****IT IS FURTHER ORDERED** that:

- A. For the Hold Separate Period, Respondent Fresenius shall hold the entirety of Liberty separate, apart, and independent of Respondent Fresenius. To hold Liberty separate, Respondent Fresenius shall, among other things:
1. Not offer Liberty employees positions with Respondent Fresenius, other than continuing the positions they have within Liberty; and
  2. Do nothing to prevent or discourage suppliers that, prior to the Effective Date, supplied goods and services to Liberty from continuing to supply goods and services to Liberty.
- Provided, however,* that Respondent Fresenius may divest any of the Appendix A Clinics to the Acquirer during the Hold Separate Period once all the approvals for divestiture pursuant to the Consent Agreement have been satisfied.
- B. At any time after the Effective Date, the Commission may appoint a Hold Separate Trustee to assure that Liberty is held separate from Respondent Fresenius.

## Order to Hold Separate

1. The Commission shall select the Hold Separate Trustee, subject to the consent of Respondent Fresenius which consent shall not be unreasonably withheld. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Hold Separate Trustee within five (5) business days after notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed Hold Separate Trustee, Respondent Fresenius shall be deemed to have consented to the selection of the proposed Hold Separate Trustee.
2. Not later than five (5) business days after appointment of the Hold Separate Trustee, Respondent Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Hold Separate Trustee all the rights and powers necessary to permit the Hold Separate Trustee to perform his duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of this Hold Separate Order.
3. Not later than ten (10) business days after appointment of the Hold Separate Trustee, Respondent Fresenius shall, pursuant to the Hold Separate Trustee Agreement, transfer to the Hold Separate Trustee all rights, powers, and authorities necessary to permit the Hold Separate Trustee to perform his/her duties and responsibilities, pursuant to this Hold Separate Order and consistent with the purposes of the Decision and Order.
4. Respondent Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Hold Separate Trustee:
  - a. The Hold Separate Trustee shall have the responsibility, consistent with the terms of this

## Order to Hold Separate

Hold Separate Order and the Decision and Order, for monitoring the organization of Liberty, for managing Liberty through the Manager, for maintaining the independence of Liberty, and for monitoring Respondent Fresenius's compliance with its obligations pursuant to the Orders.

- b. Subject to all applicable laws and regulations, the Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents and facilities of Liberty or to any other relevant information as the Hold Separate Trustee may reasonably request including, but not limited to, all documents and records kept by Respondent Fresenius in the ordinary course of business that relate to Liberty. Respondent Fresenius shall develop such financial or other information as the Hold Separate Trustee may request and shall cooperate with the Hold Separate Trustee. Respondent Fresenius shall take no action to interfere with or impede the Hold Separate Trustee's ability to monitor Respondent Fresenius's compliance with the Orders or otherwise to perform his/her duties and responsibilities consistent with the terms of this Hold Separate Order.
- c. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Respondent Fresenius, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
- d. The Commission may require the Hold Separate Trustee, and Persons hired by the Hold Separate Trustee, to sign an appropriate confidentiality agreement relating to Commission materials and information

## Order to Hold Separate

received in connection with performance of the Hold Separate Trustee's duties.

- e. Respondent Fresenius may require the Hold Separate Trustee, and Persons hired by the Hold Separate Trustee, to sign a confidentiality agreement prohibiting the disclosure of any Confidential Business Information gained as a result of his or her role as Hold Separate Trustee to anyone other than the Commission.
- f. Thirty (30) days after the appointment of the Hold Separate Trustee pursuant to this Paragraph III.B., and every thirty (30) days thereafter until the Hold Separate Order terminates, the Hold Separate Trustee shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate Order. Included within that report shall be the Hold Separate Trustee's assessment of the extent to which the businesses comprising Liberty are meeting (or exceeding) their projected goals as are reflected in operating plans, budgets, projections or any other regularly prepared financial statements.
- g. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Commission may appoint a substitute Hold Separate Trustee consistent with the terms of this paragraph, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of the substitute Hold Separate Trustee within five (5) business days after notice by the staff of the Commission to Respondent Fresenius of the identity of any substitute Hold Separate Trustee, Respondent Fresenius shall be deemed to have consented to

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the selection of the proposed substitute trustee. Respondent Fresenius and the substitute Hold Separate Trustee shall execute a new Hold Separate Trustee Agreement, subject to the approval of the Commission, consistent with this Paragraph III.B.

- C. Respondent Fresenius shall designate Mr. Mark Caputo, Chief Executive Officer of Liberty, to be Manager of Liberty for the duration of the Hold Separate Period.
1. Respondent Fresenius shall transfer all rights, powers, and authorities necessary to manage and maintain Liberty, to the Manager.
  2. The Manager shall report directly and exclusively to the Hold Separate Trustee, if one is appointed, or otherwise to Commission staff, and shall manage Liberty independently of the management of Respondent Fresenius. The Manager shall not be involved, in any way, in the operations of the other businesses of Respondent Fresenius during the term of this Hold Separate Order.
  3. The Monitor will monitor the activities of the Manager and the operations of Liberty during the Hold Separate Period unless and until a Hold Separate Trustee is appointed.
  4. The Manager shall have no financial interests (other than existing options and interests in securities of Respondent Fresenius) affected by Respondent Fresenius's revenues, profits or profit margins, except that the compensation of the Manager for managing Liberty may include economic incentives dependent on the financial performance of Liberty if there are also sufficient incentives for the Manager to operate Liberty at no less than current rates of operation (including, but not limited to, current rates of production and

## Order to Hold Separate

sales) and to achieve the objectives of this Hold Separate Order.

5. The Manager shall make no material changes in the present operation of Liberty except with the approval of the Hold Separate Trustee or Monitor, in consultation with the Commission staff, or Commission staff.
6. The Manager shall have the authority, with the approval of the Hold Separate Trustee or Commission staff, to remove employees and replace them with others of similar experience or skills. If any person ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Manager, in consultation with the Hold Separate Trustee or Commission staff, may request Respondent Fresenius to, and Respondent Fresenius shall, appoint a substitute person, which person the Manager shall have the right to approve.
7. In addition to those employees within Liberty, the Manager may employ such Persons as are reasonably necessary to assist the Manager in managing Liberty.
8. The Commission staff or the Hold Separate Trustee, in consultation with the Commission staff, shall be permitted, to remove the Manager for cause. Within fifteen (15) days after such removal of the Manager, Respondent Fresenius shall appoint a replacement Manager, subject to the approval of the Commission, on the same terms and conditions as provided in Paragraph III.C. of this Hold Separate Order.
9. In the event that the Manager ceases to act as Manager, then Respondent Fresenius shall select substitute Manager(s), subject to the approval of the Hold Separate Trustee, if appointed, and Commission staff, and transfer to the substitute

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Manager(s) all rights, powers and authorities necessary to permit the substitute Manager(s) to perform his/her/their duties and responsibilities, pursuant to this Hold Separate Order.

- D. No later than five (5) days after this Hold Separate Order becomes final, Respondent Fresenius shall circulate to the Liberty management and Regional Managers a copy of this Hold Separate Order and the Consent Agreement with the Commission's press release and analysis to aid public comment.
- E. The purposes of this Paragraph III are to: (1) preserve Liberty as a viable, competitive, and ongoing business independent of Respondent Fresenius until the divestitures required by the Decision and Order is achieved; (2) assure that no Confidential Business Information is exchanged between Respondent Fresenius and Liberty, except in accordance with the provisions of this Hold Separate Order; (3) prevent interim harm to competition pending the relevant divestitures and other relief; and (4) help remedy any anticompetitive effects of the proposed Fresenius-Liberty Acquisition as alleged in the Commission's Complaint.

**IV. (Acquisition Requirements)****IT IS FURTHER ORDERED** that:

- A. Respondent Fresenius shall not acquire Liberty until it has obtained for all the Appendix A Clinics:
  - 1. all approvals for the assignment of the Clinic's Physician Contracts, as required by the Decision and Order;
  - 2. all approvals by joint venture partners necessary for the Acquirer to acquire the Appendix A Clinics that are owned by a joint venture, and shall assign all such approvals to the Acquirer; and

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3. all approvals by joint venture partners necessary for the Acquirer of Appendix A Joint Venture Equity Interests to jointly own and operate the Appendix A Clinics that are owned by the joint venture, and shall assign all such approvals to the Acquirer.
- B. Respondent Fresenius shall hold separate the entirety of Liberty, pursuant to Paragraph III of this Hold Separate Order, and not take control over or possession of Liberty, until it has obtained for all the Appendix A Clinics, except for the Secondary Divestiture Assets, all approvals for the assignment of the rights, title, and interest to a lease for Real Property Of A Clinic To Be Divested to the Acquirer, and divested pursuant to Paragraph II of the Order and Paragraph V of this Hold Separate Order.

Copies of all approvals required by this Paragraph IV shall be incorporated into the Divestiture Agreements as appendices.

**V. (Divestiture Requirements)**

**IT IS FURTHER ORDERED** that at the Time Of Divestiture of each Clinic To Be Divested Respondent shall:

- A. assign to the Acquirer all rights, title, and interest to leases for the Real Property Of The Clinic, and shall obtain all approvals necessary for such assignments; *provided, however*, that (1) if the Acquirer obtains all rights, title, and interest to a lease for Real Property Of A Clinic To Be Divested before the Assets To Be Divested are divested pursuant to Paragraph II.A. of the Decision and Order, and (2) the Acquirer certifies its receipt of such lease and attaches it as part of the Divestiture Agreement, then Fresenius shall not be required to make the assignments for such Clinic To Be Divested as required by this Paragraph; and
- B. assign to the Acquirer all of the Clinic's Physician Contracts, and shall obtain all approvals necessary for such assignment; *provided, however*, that (1) if the

## Order to Hold Separate

Acquirer enters into a Clinic's Physician Contract for a Clinic To Be Divested before the Assets To Be Divested are divested pursuant to Paragraph II.A. of the Decision and Order, and (2) the Acquirer certifies its receipt of such contract and attaches it as part of the Divestiture Agreement, then Respondent Fresenius shall not be required to make the assignment for such Clinic To Be Divested as required by this Paragraph.

**VI. (Facilitate Hiring)**

**IT IS FURTHER ORDERED** that:

- A. Respondent Fresenius shall:
1. if requested by an Acquirer, facilitate interviews between each Designated Fresenius Employee and the Acquirer, and shall not discourage such employee from participating in such interviews;
  2. not interfere in employment negotiations between each Designated Fresenius Employee and an Acquirer.
  3. not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Designated Fresenius Employee from being employed by an Acquirer, and shall not offer any incentive to the Designated Fresenius Employee to decline employment with an Acquirer;
  4. cooperate with an Acquirer of a Clinic in effecting transfer of the Designated Fresenius Employee to the employ of the Acquirer, if the Designated Fresenius Employee accepts such offer of employment from an Acquirer;
  5. eliminate any contractual provisions or other restrictions that would otherwise prevent the Designated Fresenius Employee from being employed by an Acquirer;

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6. eliminate any confidentiality restrictions that would prevent the Designated Fresenius Employee who accepts employment with the Acquirer from using or transferring to an Acquirer any information Relating To the Operation Of The Clinic; and
7. pay, for the benefit of any Designated Fresenius Employee who accepts employment with an Acquirer, all accrued bonuses, vested pensions and other accrued benefits.

Respondent Fresenius shall comply with the terms of this Paragraph IV.A from the time Respondent Fresenius signs the Consent Agreement until sixty (60) days after the Time Of Divestiture of each Clinic To Be Divested for the employees who are Designated Fresenius Employees described in Paragraph I.Y.1.

Respondent Fresenius shall comply with the terms of this Paragraph IV.A. from the time Respondent Fresenius signs the Agreement Containing Consent Order until one-hundred twenty (120) days after the divestiture required pursuant to Paragraph II.A.1. of the Decision and Order is completed for the employees who are Designated Fresenius Employees described in Paragraph I.Y.2.

*Provided, however,* that the terms of this Paragraph IV.A. as it relates to the interviewing and hiring of Regional Managers shall not apply after the Acquirer has hired five (5) Regional Managers.

*Provided, however,* that if, at any time after the Time of Divestiture, DSI or the Acquirer of the Appendix A Clinic Assets gives Respondent Fresenius an unsolicited list of employees from the Non-Public Appendix G to whom the Acquirer does not intend to offer employment, then such employees may be hired by Respondent Fresenius as full time employees without violating this Paragraph IV.A. *Provided, further, however,* that no earlier than fifteen (15) days

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after the Time of Divestiture, Respondent Fresenius may submit a written request to the Acquirer identifying those persons from the Non-Public Appendix G to whom Respondent Fresenius wishes to offer full time employment; and if the Acquirer within fifteen (15) days of receipt of such request grants, in writing, such request, then Respondent Fresenius may offer employment to such employees; but if the Acquirer within fifteen (15) days of receipt of such request either: (i) chooses to hire such employees, or (ii) chooses to defer a hiring decision and keep the requested employees on the Non-Public Appendix G to the Decision and Order, then Respondent Fresenius shall continue to comply with the terms of this Paragraph IV.A. with regard to such employees.

- B. With respect to each Physician who has provided services to a Clinic To Be Divested pursuant to any of the Clinic's Physician Contracts in effect at any time during the four (4) months preceding the Time Of Divestiture of the Clinic ("Contract Physician"), Respondent Fresenius shall not offer any incentive to the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group to decline to provide services to the Clinic To Be Divested, and shall eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the Clinic To Be Divested any information Relating To the Operation Of The Clinic.

**VII. (Confidentiality)**

**IT IS FURTHER ORDERED** that:

- A. During the Hold Separate Period:
1. Respondent Fresenius shall not permit any of its employees, officers, or directors to be involved in

## Order to Hold Separate

the operations of Liberty, unless otherwise authorized by this Hold Separate Order.

2. Respondent Fresenius, and Respondent Fresenius's or Liberty's personnel operating Liberty, shall retain and maintain all Confidential Business Information of Liberty on a confidential basis, separate and apart from Respondent Fresenius and, except as is requested by Respondent Fresenius for purposes of the divestiture of the Appendix A Clinics as required by the Decision and Order, in this matter, such persons shall be prohibited from providing, discussing, exchanging, circulating, or otherwise furnishing any such information to Respondent Fresenius or with Respondent Fresenius's personnel.
3. Respondent Fresenius shall not, directly or indirectly, receive, disclose, or use any Confidential Business Information Related To Liberty to any Person except the Appendix A Clinics Acquirer or other persons specifically authorized by the Appendix A Clinics Acquirer to receive such information, or than as necessary to comply with the following:
  - a. the requirements of the Orders
  - b. applicable laws and regulations.
4. Respondent Fresenius shall not provide, disclose or otherwise make available, directly or indirectly, any such Confidential Business Information related to the operation of Liberty to Respondent Fresenius's employees, other than those employees operating Liberty pursuant to this Hold Separate Order.
5. Respondent Fresenius shall institute procedures and requirements to ensure that:

## Order to Hold Separate

- a. Confidential Business Information Related to Liberty is not provided to, or obtained by, Respondent Fresenius's employees, other than those employees operating Liberty pursuant to this Hold Separate Order;
  - b. Respondent Fresenius employees with access to Confidential Business Information Relating To Liberty do not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information in contravention of this Hold Separate Order; and
  - c. Respondent Fresenius's employees, other than those employees operating Liberty pursuant to this Hold Separate Order, do not solicit, access or use any Confidential Business Information that they are prohibited under this Hold Separate Order from receiving for any reason or purpose.
- B. During the Hold Separate Period, Respondent Fresenius shall require any Persons with access to Confidential Business Information Relating To Liberty not to disclose any such Confidential Business Information to Respondent Fresenius or to any third party except as otherwise permitted by this Hold Separate Order.
- C. Respondent Fresenius shall:
1. not disclose Confidential Business Information relating exclusively to any of the Clinics To Be Divested to any Person other than the Acquirer of such Clinic;
  2. after the Time Of Divestiture of such Clinic:
    - a. not use Confidential Business Information relating exclusively to any of the Clinics To Be Divested for any purpose other than complying

## Order to Hold Separate

with the terms of this Order or with any law;  
and

- b. destroy all records of Confidential Business Information relating exclusively to any of the Clinics To Be Divested , except to the extent that: (1) Respondent Fresenius is required by law to retain such information, and (2) Respondent Fresenius's inside or outside attorneys may keep one copy solely for archival purposes, but may not disclose such copy to the rest of Respondent Fresenius.
- D. The purposes of this Paragraph VII are to: (1) preserve Liberty as a viable, competitive, and ongoing business independent of Respondent Fresenius until the divestitures required by the Decision and Order are achieved; (2) assure that no Confidential Business Information is exchanged between Respondent Fresenius and Liberty, except in accordance with the provisions of this Hold Separate Order; (3) prevent interim harm to competition pending the relevant divestitures and other relief; and (4) help remedy any anticompetitive effects of the proposed Fresenius-Liberty Acquisition as alleged in the Commission's Complaint.

**VIII. (Monitor)****IT IS FURTHER ORDERED** that:

- A. Richard Shermer of R. Shermer & Co. shall be appointed Monitor to assure that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Hold Separate Order and the Decision and Order.
- B. No later than one (1) day after the Effective Date, Respondent Fresenius shall, pursuant to the Monitor Agreement, attached as Appendix A and Confidential Appendix A-1, and to this Hold Separate Order, transfer to the Monitor all the rights, powers, and

## Order to Hold Separate

authorities necessary to permit the Monitor to perform their duties and responsibilities in a manner consistent with the purposes of this Hold Separate Order.

- C. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed Monitor, Respondent Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondent Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Fresenius's compliance with the terms of this Hold Separate Order, the Decision and Order, and the Divestiture Agreements in a manner consistent with the purposes of this Order.
- D. Respondent Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent Fresenius's compliance with the terms of this Hold Separate Order, the Decision and Order, and the Divestiture Agreements, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission, including, but not limited to:
    - a. Assuring that Respondent Fresenius expeditiously complies with all of its obligations and perform all of its

## Order to Hold Separate

responsibilities as required by the this Hold Separate Order, the Decision and Order, and the Divestiture Agreements;

- b. Monitoring any transition services agreements;
  - c. Assuring that Confidential Business Information is not received or used by Respondent Fresenius or the Acquirer, except as allowed in this Hold Separate Order and in the Decision and Order, in this matter.
2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
  3. The Monitor shall serve for such time as is necessary to monitor Respondent Fresenius's compliance with the provisions of this Hold Separate Order, the Decision and Order, and the Divestiture Agreements.
  4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Fresenius's personnel, books, documents, records kept in the Ordinary Course Of Business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent Fresenius's compliance with its obligations under this Hold Separate Order, the Decision and Order, and the Divestiture Agreements. Respondent Fresenius shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Fresenius's compliance with this Hold Separate Order, the Decision and Order, and the Divestiture Agreements.
  5. The Monitor shall serve, without bond or other security, at the expense of Respondent Fresenius on such reasonable and customary terms and

## Order to Hold Separate

conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services rendered, subject to the approval of the Commission.

6. Respondent Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
7. Respondent Fresenius shall report to the Monitor in accordance with the requirements of this Hold Separate Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent Fresenius, and any reports submitted by the Acquirer with respect to the performance of Respondent Fresenius's obligations under this Hold Separate Order, the Decision and Order, and the Divestiture Agreements.
8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondent Fresenius of its obligations under this Hold Separate Order, the

## Order to Hold Separate

Decision and Order, and the Divestiture Agreements.

9. Respondent Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Monitor from providing any information to the Commission.
- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph VIII.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Hold Separate Order, the Decision and Order, and the Divestiture Agreements.
- H. The Monitor appointed pursuant to this Order may be the same Person appointed as a Hold Separate Trustee pursuant to Paragraph IV of this Order and may be the same Person appointed as Monitor or Divestiture Trustee under the Decision and Order.

**IX. (Compliance Reports)**

**IT IS FURTHER ORDERED** that within thirty (30) days after the date this Hold Separate Order becomes final, and every sixty (60) days thereafter until the Hold Separate Order

## Order to Hold Separate

terminates, Respondent Fresenius shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Hold Separate Order and the related Decision and Order; *Provided, however*, that, after the Decision and Order in this matter becomes final, the reports due under this Hold Separate Order shall be consolidated with, and submitted to the Commission at the same time as, the reports required to be submitted by Respondent Fresenius pursuant to the Decision and Order.

**X. (Change in Fresenius)**

**IT IS FURTHER ORDERED** that Respondent Fresenius shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Fresenius,
- B. Any proposed acquisition, merger or consolidation of Fresenius, or
- C. Any other change in Fresenius that may affect compliance obligations arising out of this Order, including but not limited to assignment, the creation or dissolution of subsidiaries, or any other change in Fresenius.

**XI. (Access)**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent Fresenius, Fresenius shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Fresenius and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Fresenius related to compliance with this Order, which copying services shall be provided by Respondent at

## Order to Hold Separate

the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and

- B. Upon five (5) days' notice to Fresenius and without restraint or interference from Fresenius, to interview officers, directors, or employees of Fresenius, who may have counsel present, regarding such matters.

**XII. (Termination)**

**IT IS FURTHER ORDERED** that this Hold Separate Order shall terminate on the earlier of:

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The latter of:
1. the end of the Hold Separate Period, or
  2. the day after the Commission otherwise directs that this Hold Separate Order is terminated.

By the Commission.

Order to Hold Separate

## APPENDIX A

### MONITOR AGREEMENT

#### MONITOR AGREEMENT

MONITOR AGREEMENT (this “**Agreement**”), dated as of January 21, 2012, between Fresenius Medical Care Holdings, Inc. (“**FMCH** or **Respondent**”), and Richard A. Shermer of R. Shermer & Company (“**Monitor**”).

#### PRELIMINARY STATEMENT

WHEREAS the Federal Trade Commission (the “**Commission**”) is considering for public comment an Agreement Containing Consent Orders with Respondent or its parent company, which provides, among other things, that Respondent divest a number of dialysis clinics and assets associated with those clinics, Respondent terminate management contracts Respondent has with certain dialysis clinics, enter into agreements – if necessary – providing the acquirers of the dialysis clinics with transition services, and engage a monitor to monitor Respondent’s compliance with its obligations under (a) the Decision and Order and (b) the Order to Maintain Assets (collectively, the “**Orders**”);

WHEREAS, the Commission is expected to issue the Agreement Containing Consent Orders and appoint the Monitor pursuant to the Orders to monitor Respondent’s compliance with the terms of the Orders, and the Monitor has consented to such appointment;

WHEREAS, the Orders further provide that Respondent shall execute an agreement, subject to prior approval of the Commission, conferring all the rights and powers necessary to permit Monitor to carry out its duties and responsibilities pursuant to the Orders;

WHEREAS, this Agreement, although executed by Monitor and Respondent, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondent or Monitor under the Orders, until the Order to Maintain Assets has been issued and this Agreement has been approved by the Commission;

WHEREAS, the parties to this Agreement intend to be legally bound, subject only to the Commission’s approval of this Agreement.

#### DEFINITIONS

1. “**Respondent**” means Fresenius Medical Care Holdings, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at 920 Winter Street, Waltham, MA 02451, its directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns; its joint ventures, divisions, groups and affiliates controlled by FMCH, and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each.

2. “**Other Parties**” means any Person that receives approval of the Commission to acquire any of the Assets to Be Divested or is a party to the Relevant Agreements pursuant to the Decision and Order.

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3. “**Acquisition Date**” means the date on which the first of the Relevant Agreements pursuant to the Decision and Order goes into effect.

4. “**Relevant Agreements**” means: all the divestiture agreements, management termination agreements, and transition services agreements entered into pursuant to the Decision and Order, including, but not limited to, the Divestiture Agreements, and the Transition Services Agreement between the Other Parties and FMCH or one of its subsidiaries.

5. All other capitalized words or phrases appearing in this Agreement that are not otherwise defined herein are deemed to have the defined meanings assigned to them in the Orders.

**ARTICLE I**

1.1 Powers of the Monitor. Monitor shall have the rights, duties, powers and authority conferred upon Monitor by the Orders that are necessary for Monitor to monitor Respondent’s compliance with the Orders. No later than one day after the Order to Maintain Assets becomes final, Respondent hereby transfers to Monitor all rights, powers, and authorities necessary to permit Monitor to perform its duties and responsibilities pursuant to the Order to Maintain Assets and consistent with the purposes of the Decision and Order. Any descriptions thereof contained in this Agreement in no way modify Monitor’s powers and authority or Respondent’s obligations under the Orders.

1.2 Monitor’s Duties. Monitor shall monitor Respondent’s compliance with the Orders, including, but not limited to:

- a. Assuring that Respondent expeditiously complies with all of the obligations, and performs all of responsibilities, of Respondent as required by the Orders in this matter;
- b. Monitoring Relevant Agreements; and
- c. Assuring that Confidential Business Information is not received or used by Respondent or Other Parties, except as allowed in the Orders in this matter.

1.3 Duration of Monitor’s Authority. Monitor shall have all powers and duties described above and consistent with the Orders for the term set forth in the Orders.

1.4 Confidential and Proprietary Information. Monitor shall enter into confidentiality agreements, in substantially the form attached hereto as Confidential Exhibit A, agreeing to be bound by the terms and conditions of the Orders. Monitor must retain and maintain all Material Confidential Information it receives from either Respondent or Other Parties on a confidential basis, except as is permitted by the Orders. Monitor may disclose confidential information only to persons employed by or working with Monitor under this Agreement, to persons employed at the Commission, and as permitted by Respondent or Other Parties with respect to information they provided Monitor. Monitor shall require any person retained by Monitor to assist in carrying out the duties and responsibilities of Monitor to execute a confidentiality agreement that

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requires the same standard of care and obligations of confidentiality to which Monitor must adhere under this Agreement. Monitor shall maintain the confidentiality, for a period of five (5) years after the termination of this Agreement, of all other aspects of the performance of its duties under this Agreement and shall not disclose any confidential information relating thereto.

1.5 Restrictions. Monitor shall not be involved in any way in the management, production, supply and trading, sales marketing, and financial operations of the competing products of Respondent.

1.6 Reports. Monitor shall report to the Commission pursuant to the terms of the Orders and as otherwise requested by the Commission staff.

1.7 Access to Records, Documents and Facilities. Subject to any demonstrated legally recognized privilege, Monitor shall have full and complete access to Respondent's personnel, to include those employees designated to be transferred to an acquirer, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as Monitor may reasonably request, related to Respondent's compliance with the obligations of Respondent under the Orders in this matter. Documents, records and other relevant information are to be provided in an electronic format if they exist in that form. Respondent shall cooperate with any reasonable request of Monitor and shall take no action to interfere with or impede Monitor's ability to monitor Respondent's compliance with the Orders.

### ARTICLE II

2.1 Retention and Payment of Counsel, Consultants, and other Assistants. Monitor shall have the authority to employ, at the cost and expense of the Respondent, such attorneys, consultants, accountants, and other representatives and assistants as are necessary to carry out the Monitor's duties and responsibilities as allowed pursuant to the Orders.

2.2 Compensation. Monitor shall be compensated by Respondent for his services under this Agreement, including all work in connection with the negotiation and preparation of this Monitor Agreement, pursuant to the fee schedule attached as Confidential Exhibit B for time spent in connection with the discharge of its duties under this Agreement and the Orders. In addition, Respondent will pay: (a) out-of-pocket expenses reasonably incurred by Monitor in the performance of its duties under the orders; and (b) fees and disbursements reasonably incurred by any advisor appointed by Monitor pursuant to the first paragraph in Article II. At its own expense, Respondent may retain an independent auditor to verify such invoices. Monitor shall provide Respondent with monthly invoices for time and expenses that include details and an explanation of all matters for which Monitor submits an invoice to Respondent. Respondent shall pay such invoices within thirty (30) days of receipt. The Monitor and Respondent shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

2.3 To the extent available, Respondent will provide the Monitor with temporary workspace and access to office equipment owned or used by Respondent at sites the Monitor is required to visit in order to fulfill its obligations under this Agreement. Monitor agrees to

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comply with all of Respondents' safety and security regulations, instructions and procedures while at Respondents' sites.

**ARTICLE III**

3.1 Monitor's Liabilities and Indemnification. Respondent shall indemnify the Monitor and hold Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by Monitor. The Monitor's maximum liability to Respondents relating to services rendered in accordance with this Agreement (regardless of form of action, whether in contract, statutory law, or tort) shall be limited to an amount equal to the total sum of the fees paid to the Monitor by the Respondent. Any claim arising from this Agreement that Respondents may have against the Monitor must be brought no later than one (1) year following the termination or expiration of this Agreement. In the performance of its duties under this Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs. The Monitor shall not be liable for any delays or other failures to perform resulting from circumstances or causes beyond its reasonable control, including, without limitation, fire or other casualty, act of God, strike or labor dispute, war or other violence, or any law, order or requirement of any governmental agency or authority. The Monitor warrants that it will perform its obligations hereunder in good faith. R. Shermer & Company disclaims other warranties, expressed or implied, other than those expressly agreed to in writing between the Parties.

3.2 Monitor's Removal. If the Commission determines that Monitor ceases to act or fail to act diligently and consistent with the purpose of the Orders, Respondent shall terminate this Agreement and appoint a substitute Monitor, subject to Commission approval and consistent with the Orders.

3.3 Approval by the Commission. This Agreement shall have no force or effect until approved by the Commission, other than Respondent obligations under Confidential Exhibit A and the confidentiality provisions herein.

3.4 Termination: This Agreement shall terminate the earlier of: (a) thirty (30) days following the termination date set forth in the applicable Order; (b) Respondent's receipt of written notice from the Commission that the Commission has determined that Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; (c) with at least thirty (30) days advance notice to be provided by Monitor to Respondent and to the Commission, upon resignation of the Monitor; or (d) when FMCH's last obligation under the Orders and the Relevant Agreements that pertains to the Monitors' service has been fully performed; provided, however, that the Commission may require that FMCH extend this Agreement or enter into an additional agreement with Monitor as may be necessary or appropriate to accomplish the purposes of the Orders. If this Agreement is terminated for any reason, the confidentiality obligations set forth in this Agreement will remain in force.

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3.5 Conflicts of Interest: If Monitor becomes aware during the term of this Agreement that it has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of its duties under this Agreement, Monitor shall promptly inform Respondent and the Commission of any such conflict.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

**MONITOR****R. SHERMER & COMPANY**

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NAME: Richard A. Shermer, President

**RESPONDENT****FRESENIUS MEDICAL CARE HOLDINGS, INC.**BY: NAME: DOUGLAS G. KRAFTTITLE: SENIOR VICE PRESIDENT

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**NON-PUBLIC APPENDIX A-1**

**MONITOR COMPENSATION**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**DECISION AND ORDER  
[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Fresenius Medical Care AG & Co. KGaA of Liberty Dialysis Holdings, Inc. (“Liberty”), and Fresenius Medical Care AG & Co. KGaA (hereafter referred to as “Respondent Fresenius”) having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent Fresenius with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent Fresenius, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent Fresenius of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent Fresenius that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent Fresenius has violated the said Acts, and that a Complaint should

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issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Hold Separate and Maintain Assets (“Hold Separate Order”), and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Fresenius Medical Care AG & Co. KGaA is a partnership limited by shares organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its office and principal place of business located at Else-Kröner-Straße 1, 61352 Bad Homburg, Germany. Fresenius Medical Care AG & Co. KGaA is the parent of Fresenius Medical Care Holdings, Inc., a New York corporation, d/b/a Fresenius Medical Care North America (“FMCNA”) with its office and principal place of business located at 920 Winter St., Waltham, MA 02451-1457.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondent Fresenius, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order, the following definitions shall apply:

- A. “Fresenius” means Fresenius Medical Care AG & Co. KGaA, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries (including, but not limited to Fresenius Medical Care AG & Co. KGaA, a partnership limited by shares organized under the laws of the Federal Republic of Germany, Fresenius

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Medical Care Holdings, Inc., and Florence Acquisition, Inc.), divisions, groups, and affiliates controlled by Fresenius Medical Care AG & Co. KGaA (including, after the Effective Date, Liberty Dialysis Holdings, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, “Fresenius” includes Liberty.

- B. “Liberty” means Liberty Dialysis Holdings, Inc., a corporation organized under the laws of Delaware, with its office and principal place of business located at 7650 SE 27th St., Suite 200, Mercer Island, WA 98040. Liberty Dialysis Holdings, Inc., includes Renal Advantage Inc. (“RAI”).
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer” and “Acquirers” means each Person that receives the prior approval of the Commission to acquire particular Clinic Assets pursuant to Paragraph II or Paragraph V of this Order.
- E. “Alaska Clinic Assets” means the Liberty Dialysis Clinic located at 901 East Dimond Blvd, Anchorage, Alaska, 99515, and all Assets Associated with that Clinic.
- F. “Alaska Clinic Assets Acquirer” means Alaska Investment Partners (HC) LLC, or any Person that receives the prior approval of the Commission to acquire the Alaska Clinic Assets pursuant to Paragraph II or Paragraph V of this Order.
- G. “Appendix A Clinics” means Clinics listed in Appendix A to this Order.
- H. “Appendix A Clinic Assets” means the Appendix A Clinics, the Appendix A-2 Joint Venture Equity Interests, and all Assets Associated with each of the Appendix A Clinics.

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- I. “Appendix A-2 Joint Venture Equity Interests” means the joint venture equity interest in Clinics owned by Liberty and Respondent Fresenius described in Appendix A-2.
- J. “Appendix F Clinics” means the clinics identified in Non-Public Appendix F that are (1) owned by Respondent Fresenius in locations proximate to the Liberty Clinics listed in Appendix A, or (2) Liberty Clinics in locations proximate to the Fresenius Clinics listed in Appendix A. In any given location, there may be a greater, smaller, or equal number of Fresenius Clinics in Non-Public Appendix F that correspond to Liberty Clinics in any given location, or greater, smaller, or equal number of Liberty Clinics in Non-Public Appendix F that correspond to Fresenius Clinics in any given location.
- K. “Appendix F Clinic Assets” means the Appendix F Clinics, the Appendix F-2 Joint Venture Equity Interests and all Assets Associated with each of the Appendix F Clinics.
- L. “Appendix F-2 Joint Venture Equity Interests” means the joint venture equity interest owned by Respondent Fresenius or Liberty described in Appendix F-2.
- M. “Assets Associated” means the following assets Relating To the Operation Of A Clinic:
1. all rights under the Clinic’s Physician Contracts;
  2. leases for the Real Property of the Clinic;
  3. consumable or disposable inventory consistent with the Ordinary Course of Business at the Clinics To Be Divested including, but not limited to, janitorial, office, medical supplies, dialysis supplies, and pharmaceuticals including, but not limited to, erythropoietin;

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4. all rights, title and interest of Respondent Fresenius or Liberty in any tangible property (except for consumable or disposable inventory) that has been on the premises of the Clinic at any time since July 1, 2011, including, but not limited to, all equipment, furnishings, fixtures, improvements, and appurtenances;
5. books, records, files, correspondence, manuals, computer printouts, databases, and other documents Relating To the Operation Of The Clinic located on the premises of the Clinic or in the possession of the Regional Manager responsible for such Clinic (or copies thereof where Respondent Fresenius or Liberty has a legal obligation to maintain the original document), including, but not limited to:
  - a. documents containing information Relating To patients (to the extent transferable under applicable law), including, but not limited to, medical records,
  - b. financial records,
  - c. personnel files,
  - d. Physician lists and other records of the Clinic's dealings with Physicians,
  - e. maintenance records,
  - f. documents Relating To policies and procedures,
  - g. documents Relating To quality control,
  - h. documents Relating To Payors,
  - i. documents Relating To Suppliers,
  - j. documents Relating To the Clinics to be Divested that are also Related To the Operation

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Of Clinics other than the Clinic To Be Divested, *Provided, however,* if such documents are located other than on the premises of the Clinic To Be Divested, Respondent Fresenius may submit a copy of the document with the portions not Relating To the Clinic To Be Divested redacted, and

- k. copies of contracts with Payors and Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of Respondent Fresenius to make such disclosure;
6. Respondent Fresenius's and Liberty's Medicare and Medicaid provider numbers, to the extent transferable;
7. all permits and licenses, to the extent transferable;
8. Intangible Property relating exclusively to the Operation Of The Clinic; and a royalty-free perpetual worldwide license for the use, without any limitation, of all other Intangible Property Relating To the Operation Of The Clinic (including the right to transfer or sublicense such Intangible Property, exclusively or nonexclusively, to others by any means); and
9. assets that are used in, or necessary for, the Operation Of The Clinic.

*Provided, however,* that "Assets Associated" does not include Excluded Assets.

- N. "Assets To Be Divested" means the Appendix A Clinic Assets, and any Appendix F Clinic Assets divested pursuant to Paragraph V.A. of the Order.
- O. "Clinic" means a facility that provides hemodialysis or peritoneal dialysis services to patients suffering from kidney disease.

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- P. “Clinic’s Physician Contracts” means all agreements to provide the services of a Physician to a Clinic, regardless of whether any of the agreements are with a Physician or with a medical group, including, but not limited to, agreements for the services of a medical director for the Clinic and “joinder” agreements with Physicians in the same medical practice as a medical director of the Clinic.
- Q. “Clinic To Be Divested” and “Clinics To Be Divested” means the Appendix A Clinics, the Appendix A-2 Joint Venture Equity Interests, and where applicable, the Alaska Clinic Assets, or the Dallas Clinics Joint Venture Interests, and any Appendix F Clinics or Appendix F-2 Joint Venture Equity Interests divested pursuant Paragraph V.A. of the Order.
- R. “Confidential Business Information” means competitively sensitive, proprietary, and all other information that is not in the public domain owned by or pertaining to a Person or a Person’s business, and includes, but is not limited to, all customer lists, price lists, contracts, cost information, marketing methods, patents, technologies, processes, or other trade secrets.
- S. “Connecticut Governmental Approvals For Divestiture” means any Governmental Approvals For Divestiture issued by the State of Connecticut.
- T. “Connecticut Clinic Assets” means the following: Liberty Orange Clinic, 240 Indian River Rd., Orange, CT; and Liberty North Haven Clinic, 510 Washington Avenue, North Haven, CT; and all Assets Associated with each of those Clinics.
- U. “Contract Services” means services performed pursuant to any Clinic’s Physician Contract.
- V. “Dallas Clinics Joint Ventures” means the following limited liability companies that own Clinics in and around Dallas, Texas: (1) Liberty Rockwall LLC; (2) Liberty Mesquite LLC; (3) WAXLD Holdings LLC;

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(4) Liberty Duncanville LLC; and (5) Liberty Lancaster LLC.

- W. “Dallas Clinics Joint Venture Interests” means all of Liberty’s equity and other interests held in each of the Dallas Joint Ventures.
- X. “Dallas Clinics Joint Venture Interests Acquirer” means Gibraltar 12 Holdings LLC, or the person who receives prior Commission approval to acquire the Dallas Clinics Joint Venture Interests pursuant to Paragraph II or Paragraph V of this Order.
- Y. “Designated Fresenius Employee” means:
1. each Fresenius Employee Of A Clinic To Be Divested for the Acquirer of the Assets To Be Divested, the Acquirer of the Alaska Clinic Assets, and the Acquirer of the Dallas Clinic Joint Venture Interests, and
  2. for the Acquirer of the Assets To Be Divested:
    - a. any Regional Manager of a Clinic To Be Divested, and
    - b. any of the additional Persons or a Person filling the job description (if the Person listed is no longer employed at that particular job) listed in Non-Public Appendix G to this Order.
- Z. “Divestiture Agreement” and “Divestiture Agreements” mean any agreement pursuant to which Respondent Fresenius or a Divestiture Trustee divests any of the Assets To Be Divested pursuant to this Order and with the prior approval of the Commission.
- AA. “Divestiture Trustee” means the person appointed to act as trustee by the Commission pursuant to Paragraph II.A or Paragraph V of this Order.
- BB. “DSI” means Dialysis Newco, Inc., a corporation organized, existing and doing business under and by

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virtue of the laws of the State of Delaware with its office and principal place of business located at 424 Church Street, Ste. 1900, Nashville, TN 37219.

CC. “DSI-Fresenius Divestiture Agreements” means the following agreements:

1. the Asset Purchase Agreement dated February 1, 2012, by and among DSI and Respondent Fresenius, and all attachments and exhibits, thereto, and
2. the Transition Services Agreement, which is an exhibit to the Asset Purchase Agreement, between DSI and Respondent Fresenius, and all attachments and exhibits, thereto.

The DSI-Fresenius Divestiture Agreements are attached as Non-Public Appendix E to this Order.

DD. “Effective Date” means the date on which Respondent Fresenius acquires Liberty.

EE. “Employee Of A Clinic To Be Divested” and “Employee Of The Clinic To Be Divested” mean any individual (including, but not limited to, a clinic director, manager, nurse, technician, clerk, dietician, or social worker) who is not a Regional Manager, who is employed by Respondent Fresenius, or before the Acquisition, by Liberty, by an Acquirer, or by another manager or owner of such Clinic To Be Divested, and who has worked part-time or full-time on the premises of such Clinic To Be Divested at any time since July 1, 2011, regardless of whether the individual has also worked on the premises of any other Clinic.

FF. “Excluded Assets” means:

1. all cash, cash equivalents, and short term investments of cash;
2. accounts receivable;

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3. income tax refunds and tax deposits due Respondent Fresenius or Liberty;
4. unbilled costs and fees, and Medicare bad debt recovery claims, arising before a Clinic is divested to an Acquirer;
5. rights to the names “Fresenius,” “Liberty Dialysis,” and “Renal Advantage,” (unless otherwise licensed to an Acquirer pursuant to the Order), and any variation of that name, and any names, phrases, marks, trade names, and trademarks to the extent they include the marks and designs in Exhibit D to this Order;
6. insurance policies and all claims thereunder;
7. prepaid expenses;
8. minute books (other than governing body minute books of the Clinic To Be Divested), tax returns, and other corporate books and records;
9. any inter-company balances due to or from Respondent Fresenius and Liberty or their affiliates;
10. all benefits plans;
11. all writings and other items that are protected by the attorney-client privilege, the attorney work product doctrine or any other cognizable privilege or protection, except to the extent such information is necessary to the Operation Of A Clinic that is divested;
12. telecommunication systems equipment and applications, and information systems equipment including, but not limited to computer hardware, not physically located at a Clinic To Be Divested but shared with the Clinic To Be Divested through local and/or wide area networking systems;

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13. e-mail addresses and telephone numbers of Respondent Fresenius's and Liberty's employees;
14. Software;
15. computer hardware used in the Operation Of The Clinic that is (a) not located at the Clinic, and (b) not otherwise to be divested pursuant to a Divestiture Agreement;
16. all Supplier or provider numbers issued to Respondent Fresenius or Liberty by a Supplier or Payor with respect to any Clinic To Be Divested, except for Respondent Fresenius's or Liberty's Medicare and Medicaid provider numbers for each Clinic To Be Divested;
17. rights under agreements with Payors and Suppliers that are not assignable even if Respondent Fresenius and Liberty approve such assignment;
18. office equipment and furniture that (a) is not, in the Ordinary Course Of Business, physically located at the Clinic To Be Divested, (b) is shared with Clinics other than the Clinic To Be Divested, and (c) is not necessary to the Operation Of The Clinic To Be Divested.
19. Licensed Intangible Property;
20. Fresenius Medical Protocols and Liberty Medical Protocols, subject to the licensing provisions in this Order;
21. Contracts to which Respondent Fresenius or Liberty or their affiliates (other than the Clinics To Be Divested) are a party and are not otherwise included in the Assets Associated with a Clinic To Be Divested; and

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22. strategic planning documents that
- a. relate to the Operation Of The Clinic other than the Clinic To Be Divested, and
  - b. are not located on the premises of the Clinic To Be Divested.
- GG. “Florida Governmental Approvals for Divestiture” means any Governmental Approvals for Divestiture issued by the State of Florida.
- HH. “Florida Viera Clinic Asset” means the FMC Viera Clinic, located at 8041 Spyglass Road, Viera, FL 32940; and all Assets Associated with such Clinic.
- II. “Fresenius Employee Of A Clinic To Be Divested” and “Fresenius Employee Of The Clinic To Be Divested” means an Employee Of A Clinic To Be Divested who is employed by Respondent Fresenius or, before the acquisition by Respondent Fresenius, by Liberty.
- JJ. “Fresenius’s Medical Protocols” means medical protocols promulgated by Respondent Fresenius, whether in hard copy or embedded in software, that have been in effect at any time since July 1, 2010. *Provided, however,* “Fresenius’s Medical Protocols” does not mean medical protocols adopted or promulgated, at any time, by any Physician or by any Acquirer, even if such medical protocols are identical, in whole or in part, to medical protocols promulgated by Respondent Fresenius.
- KK. “Good Samaritan Hospital” means a hospital that is part of the Bons Secours Charity Health System located at 255 Lafayette Ave. (Route 59), Suffern, NY 10901.
- LL. “Good Samaritan Hospital Dialysis Clinic” means the Regional Kidney Center Clinic owned by Good

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Samaritan Hospital and located at 331 Route 17M, Harriman, NY 10926.

- MM. “Good Samaritan Management Agreement” means collectively:
1. the Administrative Services Agreement dated January 1, 2010, by and between Good Samaritan Hospital and Renal Research Institute, LLC, an affiliate of Respondent Fresenius, and
  2. any other agreements between Good Samaritan Hospital and Respondent Fresenius Relating To the management of the dialysis clinics at Good Samaritan Hospital located at 255 Lafayette Ave. (Route 59), Suffern, NY 10901, and 331 Route 17M, Harriman, NY 10926.
- NN. “Good Samaritan Management Termination Letter” means the February 1, 2012, letter from Renal Research Institute, LLC, an affiliate of Respondent Fresenius, and Good Samaritan Hospital giving sixty (60) days advance notice of termination of the Good Samaritan Management Agreement.
- OO. “Governmental Approvals” means any permissions or sanctions issued by any government or governmental organization, including, but not limited to, licenses, permits, accreditations, authorizations, registrations, certifications, certificates of occupancy, and certificates of need.
- PP. “Government Approvals For Continued Operation” means any Governmental Approvals, other than Government Approvals For Divestiture, that an Acquirer must have to continue to operate a Clinic To Be Divested.
- QQ. “Governmental Approvals For Divestiture” means any Governmental Approvals that an Acquirer must have to own, and to initially operate, a Clinic To Be

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Divested, including, but not limited to, state-issued licenses and state-issued certificates of need.

- RR. “Hawaii Governmental Approvals For Divestiture” means any Governmental Approvals For Divestiture issued by the State of Hawaii.
- SS. “Hawaii Clinic Assets” means the following clinics and all Assets Associated with each of those Clinics:
1. FMC Aloha Clinic, 1520 Liliha Street, Honolulu, HI;
  2. FMC Kapahulu Clinic, 750 Palani Avenue, Honolulu, HI;
  3. FMC Pearlridge Clinic, 98-1005 Moanaloa Road, Suite 420, Aiea, HI;
  4. FMC Honolulu Clinic, 226 N. Kuakini Street, Honolulu, HI;
  5. FMC Kapolei Clinic, 555 Farrington Highway, Kapolei, HI;
  6. FMC Ko'Olau Clinic, 47-388 Hui Iwa Street, Kaneohe, HI;
  7. FMC Wahiawa Clinic, 850 Kilani Avenue, Wahiawa, HI;
  8. FMC Windward Clinic, 45-480 Kaneohe Bay Drive #D09, Kaneohe, HI; and
  9. FMC Waipahu Clinic (de novo), location to be determined, Waipahu, HI.
- TT. “Intangible Property” means intangible property Relating To the Operation Of A Clinic To Be Divested including, but not limited to, intellectual property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality

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control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property.

- UU. “Liberty’s Medical Protocols” means medical protocols promulgated by Liberty, whether in hard copy or embedded in software, that have been in effect at any time since July 1, 2010. *Provided, however*, “Liberty’s Medical Protocols” does not mean medical protocols adopted or promulgated, at any time, by any Physician or by any Acquirer, even if such medical protocols are identical, in whole or in part, to medical protocols promulgated by Liberty.
- VV. “Licensed Intangible Property” means intangible property licensed to Respondent Fresenius from a third party Relating To the Operation Of A Clinic To Be Divested including, but not limited to, intellectual property, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intangible property that are licensed to Respondent Fresenius. (“Licensed Intangible Property” does not mean modifications and improvements to intangible property that are not licensed to Respondent Fresenius.)
- WW. “Monitor Agreement” means the Monitor Agreement dated January 21, 2012, between Fresenius, and Richard A. Shermer, of R. Shermer & Company. (The Monitor Agreement is attached as Appendix C to this Order. The Monitor Agreement Compensation is attached as Confidential Appendix C-1 to this Order.)
- XX. “New York Governmental Approvals For Divestiture” means any Governmental Approvals For Divestiture issued by the State of New York.

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- YY. “New York Clinic Assets” means the FMC Dutchess Clinic located at 2585 South Rd., Poughkeepsie, NY, and all Assets Associated with that Clinic.
- ZZ. “Operation Of A Clinic” and “Operation Of The Clinic” mean all activities Relating To the business of a Clinic, including, but not limited to:
1. attracting patients to the Clinic for dialysis services, providing dialysis services to patients of the Clinic, and dealing with their Physicians, including, but not limited to, services Relating To hemodialysis and peritoneal dialysis;
  2. providing medical products to patients of the Clinic;
  3. maintaining the equipment on the premises of the Clinic, including, but not limited to, the equipment used in providing dialysis services to patients;
  4. purchasing supplies and equipment for the Clinic;
  5. negotiating leases for the premises of the Clinic;
  6. providing counseling and support services to patients receiving products or services from the Clinic;
  7. contracting for the services of medical directors for the Clinic;
  8. dealing with Payors that pay for products or services offered by the Clinic, including but not limited to, negotiating contracts with such Payors and submitting claims to such Payors; and
  9. dealing with Governmental Approvals Relating To the Clinic or that otherwise regulate the Clinic.
- AAA. “Ordinary Course Of Business” means actions taken by any Person in the ordinary course of the normal day-to-day Operation Of The Clinic that is consistent

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with past practices of such Person in the Operation Of The Clinic, including, but not limited to past practice with respect to amount, timing, and frequency.

- BBB. “Other Contracts Of Each Clinic To Be Divested” means all contracts Relating To the Operation Of A Clinic, where such Clinic is a Clinic To Be Divested – including, but not limited to, contracts for goods and services provided to the Clinic and contracts with Payors – but does not mean the Clinic’s Physician Contracts and the leases for the Real Property Of The Clinic.
- CCC. “Payor” means any Person that purchases, reimburses for, or otherwise pays for medical goods or services for themselves or for any other person, including, but not limited to: health insurance companies; preferred provider organizations; point of service organizations; prepaid hospital, medical, or other health service plans; health maintenance organizations; government health benefits programs; employers or other persons providing or administering self-insured health benefits programs; and patients who purchase medical goods or services for themselves.
- DDD. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- EEE. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- FFF. “Real Property Of The Clinic” means real property on which, or in which, the Clinic is located, including real property used for parking and for other functions Relating To the Operation Of The Clinic.
- GGG. “Regional Manager” means any individual who has been employed by Respondent Fresenius, RAI, or Liberty with a geographic regional, or area supervisory, or management responsibility for one or

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more Clinics. A Regional Manager may go by various names including, but not limited to, director of operations.

- HHH. “Regional Manager Of A Clinic To Be Divested” and “Regional Manager Of The Clinic To Be Divested” mean a Regional Manager with a geographic regional, or area supervisory, or management responsibility for a Clinic To Be Divested at any time since July 1, 2011.
- III. “Relating To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- JJJ. “Software” means executable computer code and the documentation for such computer code, but does not mean data processed by such computer code.
- KKK. “Supplier” means any Person that has sold to Respondent Fresenius, RAI, or Liberty any goods or services, other than Physician services, for use in a Clinic To Be Divested.
- LLL. “Time Of Divestiture” means the date upon which an Appendix A Clinic or an Appendix F Clinic is divested to an Acquirer pursuant to this Order.
- MMM. “University of California, San Diego Clinic” means the Clinic currently located at 200 W. Arbor Dr., San Diego, CA 92103.

**II.****IT IS FURTHER ORDERED** that:

- A. Respondent Fresenius shall:
1. within thirty-two (32) days after the Effective Date, divest to DSI, absolutely, and in good faith, pursuant to and in accordance with the DSI-Fresenius Divestiture Agreements all the Appendix A Clinic Assets, except for the Connecticut Clinic Assets, Hawaii Clinic Assets, the New York Clinic

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Assets, and the Florida Viera Clinic Assets, as on-going businesses, and grant to the Acquirer a royalty-free, worldwide non-exclusive license for the use, without any limitation, of the Fresenius Medical Protocols and the Liberty Medical Protocols (including the right to transfer or sublicense such protocols, exclusively or nonexclusively, to others by any means). Any failure by Respondent Fresenius to comply with the DSI-Fresenius Divestiture Agreements shall constitute a failure to comply with the Order. The DSI-Fresenius Divestiture Agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order. Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of DSI, or any obligations of Respondent Fresenius, under the DSI-Fresenius Divestiture Agreements.

2. within ninety (90) days after the Effective Date, divest to DSI, absolutely, and in good faith, pursuant to and in accordance with the DSI-Fresenius Divestiture Agreements, the Connecticut Clinic Assets, as an on-going business;
3. within ninety (90) days after the Effective Date, divest to DSI, absolutely, and in good faith, pursuant to and in accordance with the DSI-Fresenius Divestiture Agreements, the Hawaii Clinic Assets, as an on-going business;
4. within one (1) year after the Effective Date, divest to DSI, absolutely, and in good faith, pursuant to and in accordance with the DSI-Fresenius Divestiture Agreements, the New York Clinic Assets, as an on-going business;
5. within sixty (60) days after the Effective Date, divest to DSI, absolutely, and in good faith, pursuant to and in accordance with the DSI-Fresenius Divestiture Agreements, the Florida Viera Clinic Assets, as an on-going business;

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6. within fifteen (15) days after the Effective Date:
  - a. pursuant to and in accordance with the Good Samaritan Management Termination Letter, give notice to terminate the Good Samaritan Management Agreement, and pursuant to such letter and such management agreement, transfer management of the Good Samaritan Hospital Dialysis Clinic to Good Samaritan Hospital, who will either operate the Good Samaritan Hospital Dialysis Clinic itself or seek a new operator through a request for proposal process.
  - b. enter into a transition services agreement with Good Samaritan Hospital which shall be submitted to the Commission for approval within the fifteen-day time period, and shall include, but not be limited to:
    - i. providing services consistent with, or similar to, the services currently provided to Good Samaritan under the Good Samaritan Management Agreement;
    - ii. a term not to extend beyond December 31, 2012;
    - iii. the unilateral option of Good Samaritan Hospital to terminate such agreement or phase out particular services or parts of such agreement upon notice as determined by Good Samaritan Hospital;
    - iv. assigning values or costs for particular services, such that if the services are phased out before the end of the transition services agreement, there will be no dispute on remaining costs;

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- v. a firewall to protect Confidential Business Information Relating To the Good Samaritan Dialysis Clinic; and
- vi. a prohibition on Respondent Fresenius from assigning such agreement.

The Good Samaritan Management Termination Letter and the Good Samaritan transition services agreement, when final and approved by the Commission, are incorporated by reference into this Order and made a part hereof as Non-Public Appendix J. If Respondent Fresenius fails to submit an executed transition services agreement to the Commission for approval within fifteen (15) days after the Effective Date, or if the Commission denies its approval of any agreement submitted for approval, then the Monitor, in consultation with Commission staff, shall be given the immediate and absolute authority to negotiate all terms of the transition services agreement with Good Samaritan, consistent with the terms of this Order, and subject to the Commission's prior approval. After the Effective Date and until the transition services agreement terminates, Respondent Fresenius shall not disclose Confidential Business Information Relating To the Good Samaritan Hospital Dialysis Clinic; and Respondent Fresenius shall assure that any employee who obtains or possesses Confidential Business Information Relating To the Good Samaritan Hospital Dialysis Clinic shall not disclose it to any employee who does not have primary responsibility for providing transition services to the Good Samaritan Hospital Dialysis Clinic.

Any failure by Respondent Fresenius to comply with the Good Samaritan Management Termination Letter and the final Good Samaritan transition services agreement shall constitute a failure to comply with the Order. The Good Samaritan Management Termination Letter and the final Good Samaritan transition services agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order. Nothing

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in this Order shall reduce, or be construed to reduce, any rights or benefits of the Good Samaritan Hospital, or any obligations of Respondent Fresenius, under the Good Samaritan Management Termination Letter and the final Good Samaritan transition services agreement.

7. Within ten (10) days after the Effective Date, divest to the Alaska Clinic Acquirer, absolutely, and in good faith, pursuant to and in accordance with the Alaska Clinic Divestiture Agreement, the Alaska Clinic Assets as an on-going business, and grant to the Acquirer a royalty-free, worldwide non-exclusive license for the use, without any limitation, of the Liberty Medical Protocols (including the right to transfer or sublicense such protocols, exclusively or nonexclusively, to others by any means). The Alaska Clinic Divestiture Agreement is incorporated by reference into this Order and made a part hereof as Non-Public Appendix H. Any failure by Respondent Fresenius to comply with the Alaska Clinic Divestiture Agreement shall constitute a failure to comply with the Order. However, in the event that the Alaska Clinic Divestiture Agreement varies from or contradicts, or be construed to vary or contradict, the terms of this Order, the terms of this Order shall control. Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of the Alaska Clinic Acquirer, or any obligations of Respondent Fresenius, under the Alaska Clinic Divestiture Agreement.
8. Within thirty-two (32) days after the Effective Date, divest to the Dallas Clinics Joint Venture Interests Acquirer, absolutely, and in good faith, pursuant to and in accordance with the Dallas Clinics Joint Venture Interests Divestiture Agreement, the Dallas Clinics Joint Venture Interests, and grant to the Dallas Clinics Joint Venture Interests Acquirer a royalty-free, worldwide non-exclusive license for the use,

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without any limitation, of the Liberty Medical Protocols (including the right to transfer or sublicense such protocols, exclusively or nonexclusively, to others by any means). The Dallas Clinics Joint Venture Interests Divestiture Agreement is incorporated by reference into this Order and made a part hereof as Non-Public Appendix I. Any failure by Respondent Fresenius to comply with the Dallas Clinics Joint Venture Interests Divestiture Agreement shall constitute a failure to comply with the Order. The Dallas Clinics Joint Venture Interests Divestiture Agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order. Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of the Dallas Clinics Joint Venture Interests Acquirer, or any obligations of Respondent Fresenius, under the Dallas Clinics Joint Venture Interests Divestiture Agreement.

*Provided, however,* if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Fresenius that DSI, the Dallas Clinics Joint Venture Interests Acquirer, or the Alaska Clinic Acquirer is not an acceptable Acquirer then, after receipt of such written notification: (1) Respondent Fresenius shall immediately notify DSI, the Dallas Clinics Joint Venture Interests Acquirer, or the Alaska Clinic Acquirer of the notice received from the Commission and shall as soon as practicable, but no later than within five (5) business days, effect the rescission of the applicable Divestiture Agreement; and (2) Respondent Fresenius shall, within six (6) months of the date Respondent Fresenius receives notice of such determination from the Commission, divest the Appendix A Clinic Assets, the Dallas Clinics Joint Venture Interests, or the Alaska Clinic Assets, as applicable, absolutely and in good faith, at no minimum price, as on-going businesses to an Acquirer or Acquirers that receive the prior approval

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of the Commission and only in a manner that receives the prior approval of the Commission.

*Provided further, however,* that if Respondent Fresenius has complied with the terms of this Paragraph before the date on which this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent Fresenius that the manner in which any of the divestitures accomplished is not acceptable, the Commission may direct Respondent Fresenius or appoint the Divestiture Trustee, to effect such modifications to the manner of divestiture including, but not limited to, entering into additional agreements or arrangements, as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Respondent Fresenius shall not acquire Liberty until it has obtained for all the Appendix A Clinics:
1. all approvals for the assignment of the Clinic's Physician Contracts to the Acquirer;
  2. all approvals by joint venture partners necessary for the Acquirer to acquire the Appendix A Clinics that are owned by a joint venture; and
  3. all approvals by joint venture partners necessary for the Acquirer of Appendix A-2 Joint Venture Equity Interests to jointly own and operate the Clinics that are owned by the joint venture.

Copies of all such approvals shall be incorporated into the DSI-Fresenius Divestiture Agreements as appendices.

- C. Respondent Fresenius shall hold separate the entirety of Liberty, and not take control over or possession of Liberty, until it has obtained for all the Appendix A Clinics all approvals for the assignment of the rights, title, and interest to a lease for Real Property Of A

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Clinic To Be Divested to the Acquirer. The specific terms of the hold separate are in the Order to Maintain Assets and Hold Separate attached to the Agreement Containing Consent Orders.

- D. Respondent Fresenius shall:
1. place no restrictions on the use by any Acquirer of any of the Assets To Be Divested to such Acquirer or any of the Clinics To Be Divested to such Acquirer, or interfere with or otherwise attempt to interfere with any Acquirer's use of any of the Assets To Be Divested to such Acquirer or any of the Clinics To Be Divested to such Acquirer including, but not limited to, seeking or requesting the imposition of Governmental Approvals or other governmental restrictions on the Acquirer's business operations relating to the Assets To Be Divested or any of the Clinics To Be Divested.
  2. cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer,
    - a. at the Time Of Divestiture of each Clinic To Be Divested, in obtaining all Government Approvals For Divestiture, and
    - b. all Government Approvals For Continued Operation, for each Clinic To Be Divested to such Acquirer.
  3. at the Time Of Divestiture of each Clinic To Be Divested:
    - a. assign to the Acquirer all rights, title, and interest to leases for the Real Property Of The Clinic divested to such Acquirer. *Provided, however,* that (1) if the Acquirer obtains all rights, title, and interest to a lease for Real Property Of A Clinic To Be Divested before the Assets To Be Divested are divested to such Acquirer pursuant to Paragraph II.A. of this

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Order, and (2) the Acquirer certifies its receipt of such lease and attaches it as part of the Divestiture Agreement, then Respondent Fresenius shall not be required to make the assignments for such Clinic To Be Divested as required by this Paragraph; and

- b. assign to the Acquirer all of the Clinic's Physician Contracts for the Clinics divested to such Acquirer. *Provided however*, that (1) if the Acquirer enters into a Clinic's Physician Contract for a Clinic To Be Divested before the Assets To Be Divested are divested pursuant to Paragraph II.A. of this Order, and (2) the Acquirer certifies its receipt of such contract and attaches it as part of the Divestiture Agreement, then Respondent Fresenius shall not be required to make the assignment for such Clinic To Be Divested as required by this Paragraph.
  - c. assign to the Acquirer all approvals by joint venture partners necessary for the Acquirer to acquire the Appendix A Clinics that are owned by a joint venture; and
  - d. assign to the Acquirer all approvals by joint venture partners necessary for the Acquirer of Appendix A Joint Venture Equity Interests to jointly own and operate the Appendix A Clinics that are owned by the joint venture.
4. With respect to all Other Contracts Of Each Clinic To Be Divested, at the Acquirer's option and at the Time Of Divestiture of each Clinic To Be Divested:
- a. if such contract can be assigned without third party approval, assign Respondent Fresenius's rights under the contract to the Acquirer; and

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- b. if such contract can be assigned to the Acquirer only with third party approval, assist and cooperate with the Acquirer in obtaining:
    - i. such third party approval and in assigning the contract to the Acquirer; or
    - ii. a new contract.
- E. Respondent Fresenius shall:
- 1. at the Time Of Divestiture of each Clinic To Be Divested, provide to the Acquirer of such Clinic contact information about Payors and Suppliers for the Clinic, and
  - 2. not object to the sharing of Payor and Supplier contract terms Relating To the Clinics To Be Divested: (i) if the Payor or Supplier consents in writing to such disclosure upon a request by the Acquirer, and (ii) if the Acquirer enters into a confidentiality agreement with Respondent Fresenius not to disclose the information to any third party.
- F. Respondent Fresenius shall:
- 1. if requested by an Acquirer, facilitate interviews between each Designated Fresenius Employee and the Acquirer, and shall not discourage such employee from participating in such interviews;
  - 2. not interfere in employment negotiations between each Designated Fresenius Employee and an Acquirer.
  - 3. not prevent, prohibit or restrict or threaten to prevent, prohibit or restrict the Designated Fresenius Employee from being employed by an Acquirer, and shall not offer any incentive to the Designated Fresenius Employee to decline employment with an Acquirer;

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4. cooperate with an Acquirer of a Clinic in effecting transfer of the Designated Fresenius Employee to the employ of the Acquirer, if the Designated Fresenius Employee accepts such offer of employment from an Acquirer;
5. eliminate any contractual provisions or other restrictions that would otherwise prevent the Designated Fresenius Employee from being employed by an Acquirer;
6. eliminate any confidentiality restrictions that would prevent the Designated Fresenius Employee who accepts employment with the Acquirer from using or transferring to an Acquirer any information Relating To the Operation Of The Clinic; and
7. pay, for the benefit of any Designated Fresenius Employee who accepts employment with an Acquirer, all accrued bonuses, vested pensions and other accrued benefits.

Respondent Fresenius shall comply with the terms of this Paragraph II.F. from the time Respondent Fresenius signs the Agreement Containing Consent Order until sixty (60) days after the Time Of Divestiture of each Clinic To Be Divested for the employees who are Designated Fresenius Employees described in Paragraph I.Y.1.

Respondent Fresenius shall comply with the terms of this Paragraph II.F. from the time Respondent Fresenius signs the Agreement Containing Consent Order until one-hundred twenty (120) days after the divestiture required pursuant to Paragraph II.A.1. is completed for the employees who are Designated Fresenius Employees described in Paragraph I.Y.2.

*Provided, however,* that the terms of this Paragraph II.F. as it relates to the interviewing and hiring of

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Regional Managers shall not apply after the Acquirer has hired five (5) Regional Managers.

*Provided, further, however,* that if, at any time after the Time of Divestiture, DSI or the Acquirer of the Appendix A Clinic Assets gives Respondent Fresenius an unsolicited list of employees from the Non-Public Appendix G to whom the Acquirer does not intend to offer employment, then such employees may be hired by Respondent Fresenius as full time employees without violating this Paragraph II.F. *Provided, further, however,* that no earlier than fifteen (15) days after the Time of Divestiture, Respondent Fresenius may submit a written request to the Acquirer identifying those persons from the Non-Public Appendix G to whom Respondent Fresenius wishes to offer full time employment; and if the Acquirer within fifteen (15) days of receipt of such request grants, in writing, such request, then Respondent Fresenius may offer employment to such employees; but if the Acquirer within fifteen (15) days of receipt of such request either: (i) chooses to hire such employees, or (ii) chooses to defer a hiring decision and keep the requested employees on the Non-Public Appendix G, then Respondent Fresenius shall continue to comply with the terms of this Paragraph II.F. with regard to such employees.

- G. For a period of:
1. two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Respondent Fresenius shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any employee who is employed by any of the Acquirers to terminate his or her employment relationship with such Acquirer, unless that employment relationship has already been terminated by the Acquirer; *Provided, however,* Respondent Fresenius may make general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at

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any of an Acquirer's employees; *Provided, further, however,* Respondent Fresenius may hire employees who apply for employment with Respondent Fresenius, as long as such employees were not solicited by Respondent Fresenius in violation of this Paragraph; *Provided, further, however,* Respondent Fresenius may offer employment to a Designated Fresenius Employee who is employed by the Acquirer in only a part-time capacity, if the employment offered by Respondent Fresenius would not, in any way, interfere with the employee's ability to fulfill his or her employment responsibilities to the Acquirer; and

2. six (6) months following the Time Of Divestiture of each Clinic To Be Divested, Respondent Fresenius shall not, directly or indirectly, employ, directly or indirectly, including as a paid or unpaid consultant, any Person who owns any interest in any of the Clinics or interests in Clinics divested pursuant to Paragraph II or Paragraph V of this Order; *Provided however,* for purposes of this Paragraph II.G.2., a Person does not include an individual who is part of the Alaska Clinic Assets Acquirer or the Dallas Clinics Joint Venture Interests Acquirer, and is employed or engaged as a medical director at a Respondent Fresenius Clinic, or otherwise engaged as a medical advisor for Respondent Fresenius.

H. With respect to each Physician who has provided services to a Clinic To Be Divested pursuant to any of the Clinic's Physician Contracts in effect at any time during the four (4) months preceding the Time Of Divestiture of the Clinic ("Contract Physician"):

1. Respondent Fresenius shall not offer any incentive to the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group to decline to provide services to the Clinic To Be Divested, and shall

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eliminate any confidentiality restrictions that would prevent the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group from using or transferring to the Acquirer of the Clinic To Be Divested any information Relating To the Operation Of The Clinic; and

2. For a period of three (3) years following the Time Of Divestiture of each Clinic To Be Divested, Respondent Fresenius shall not contract for the services of the Contract Physician, the Contract Physician's practice group, or other members of the Contract Physician's practice group for the provision of Contract Services to be performed in any of the areas listed in Appendix B of this Order that correspond to such Clinic. *Provided, however,* if the Contract Physician, or the Contract Physician's practice group, or other members of the Contract Physician's practice group were providing services to a Clinic pursuant to a contract with Respondent Fresenius or Liberty in effect as of July 1, 2011, then Respondent Fresenius may contract with such Contract Physicians, or the Contract Physician's practice group, or other members of the Contract Physician's practice group for services to be provided to that particular Clinic.
- I. Respondent Fresenius shall:
    1. not disclose Confidential Business Information relating exclusively to any of the Clinics To Be Divested to any Person other than the Acquirer of such Clinic;
    2. after the Time Of Divestiture of such Clinic:
      - a. shall not use Confidential Business Information relating exclusively to any of the Clinics To Be Divested for any purpose other than complying

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with the terms of this Order or with any law;  
and

- b. shall destroy all records of Confidential Business Information relating exclusively to any of the Clinics To Be Divested, except to the extent that: (1) Respondent Fresenius is required by law to retain such information, and (2) Respondent Fresenius's inside or outside attorneys may keep one copy solely for archival purposes, but may not disclose such copy to the rest of Respondent Fresenius.
- J. At the Time Of Divestiture of each Clinic To Be Divested, Respondent Fresenius shall provide the Acquirer of the Clinic with manuals, instructions, and specifications sufficient for the Acquirer to access and use any information,
1. divested to the Acquirer pursuant to this Order, or
  2. in the possession of the Acquirer, and previously used by Respondent Fresenius or Liberty in the Operation Of The Clinic.
    - a. For two (2) years following the Time Of Divestiture of each Clinic To Be Divested, Respondent Fresenius shall not solicit the business of any patient who received any goods or services from such Clinic between July 1, 2011, and the date of such divestiture, *Provided, however*, Respondent Fresenius may (i) make general advertisements for the business of such patients including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at such patients, and (ii) provide advertising and promotions directly to any patient that initiates discussions with, or makes a request to, any Respondent Fresenius employee.

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- K. Respondent Fresenius shall convey to each Acquirer of a Clinic To Be Divested the right to use any Licensed Intangible Property (to the extent permitted by the third-party licensor), if such right is needed for the Operation Of The Clinic by the Acquirer and if the Acquirer is unable, using commercially reasonable efforts, to obtain equivalent rights from other third parties on commercially reasonable terms and conditions.
- L. Respondent Fresenius shall do nothing to prevent or discourage Suppliers that, prior to the Time Of Divestiture of any Clinic To Be Divested, supplied goods and services for use in any Clinic To Be Divested from continuing to supply goods and services for use in such Clinic.
- M. Respondent Fresenius shall not terminate any transition services agreement that is a part of any of the Divestiture Agreements before the end of the term approved by the Commission without:
1. the written agreement of the Acquirer and thirty (30) days prior notice to the Commission; or,
  2. in the case of a proposed unilateral termination by Respondent Fresenius due to an alleged breach of an agreement by the Acquirer, sixty (60) days notice of such termination. *Provided, however,* such sixty (60) days notice shall be given only after the parties have:
    - a. attempted to settle the dispute between themselves, and
    - b. engaged in arbitration and received an arbitrator's decision, or
    - c. received a final court decision after all appeals.
- N. The purpose of Paragraph II of this Order is to ensure the continuation of the Clinics To Be Divested as, or

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as part of, an ongoing viable enterprises engaged in the same business in which such assets were engaged at the time of the announcement of the acquisition by Respondent Fresenius of Liberty, to ensure that the Clinics To Be Divested are operated independently of, and in competition with, Respondent Fresenius, and to remedy the lessening of competition alleged in the Commission's Complaint.

**III.****IT IS FURTHER ORDERED** that:

- A. For a period of five (5) years from the date this Order is issued, Respondent Fresenius shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly:
1. acquire any assets of or financial interest in any Clinic located in any of the areas listed in Appendix B of this Order; or
  2. enter into any contract to participate in the management or Operation Of A Clinic located in any of the areas listed in Appendix B of this Order, except to the extent that the contract relates exclusively to:
    - a. off-site lab services or social worker support materials; or
    - b. billing services, collection services, bookkeeping services, accounting services, supply purchasing and logistics services, or the preparation of financial reports and accounts receivable reports (collectively "Such Services"), where appropriate firewalls and confidentiality agreements are implemented to prevent Confidential Business Information of the Clinic from being disclosed to anyone participating in any way in the operation or

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management of any Clinic owned by Respondent Fresenius or any Clinic other than the Clinic to which Such Services are being provided.

Said advance written notification shall contain (i) either a detailed term sheet for the proposed acquisition or the proposed agreement with all attachments, and (ii) documents that would be responsive to Item 4(c) of the Premerger Notification and Report Form under the Hart-Scott-Rodino Premerger Notification Act, Section 7A of the Clayton Act, 15 U.S.C. § 18a, and Rules, 16 C.F.R. § 801-803, Relating To the proposed transaction (hereinafter referred to as “the Notification), *Provided, however,* (i) no filing fee will be required for the Notification, (ii) an original and one copy of the Notification shall be filed only with the Secretary of the Commission and need not be submitted to the United States Department of Justice, and (iii) the Notification is required from Respondent Fresenius and not from any other party to the transaction. Respondent Fresenius shall provide the Notification to the Commission at least thirty (30) days prior to consummating the transaction (hereinafter referred to as the “first waiting period”). If, within the first waiting period, representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Respondent Fresenius shall not consummate the transaction until thirty days after submitting such additional information or documentary material. Early termination of the waiting periods in this paragraph may be requested and, where appropriate, granted by letter from the Bureau of Competition.

*Provided, however,* that prior notification shall not be required by this paragraph for a transaction for which Notification is required to be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.indirectly:

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- B. For the duration of the Order, Respondent Fresenius shall not:
1. acquire, directly or indirectly, any interest in the University of California, San Diego Clinic, where currently located, or wherever subsequently located within San Diego County, California; or
  2. enter into any agreement or otherwise agree to manage, operate, expand, or move such University of California, San Diego Clinic, wherever it may be located within San Diego County, California.
  3. shall not acquire, directly or indirectly, without receiving prior Commission approval, any interest in the Clinics divested, or any Clinics divested, pursuant to the terms of this Order including, but not limited to, entering into a management or operation agreement with such Clinics.

**IV.****IT IS FURTHER ORDERED** that:

- A. Richard A. Shermer, of R. Shermer & Company, shall be appointed Monitor to assure that Respondent Fresenius expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order.
- B. No later than one (1) day after the Effective Date, Respondent Fresenius shall, pursuant to the Monitor Agreement and to this Order, transfer to the Monitor all the rights, powers, and authorities necessary to permit the Monitor to perform their duties and responsibilities in a manner consistent with the purposes of this Order.
- C. In the event a substitute Monitor is required, the Commission shall select the Monitor, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. If Respondent

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Fresenius has not opposed, in writing, including the reasons for opposing, the selection of a proposed Monitor within ten (10) days after notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed Monitor. Respondent Fresenius shall be deemed to have consented to the selection of the proposed Monitor. Not later than ten (10) days after appointment of a substitute Monitor, Respondent Fresenius shall execute an agreement that, subject to the prior approval of the Commission, confers on the Monitor all the rights and powers necessary to permit the Monitor to monitor Respondent Fresenius's compliance with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements in a manner consistent with the purposes of this Order.

- D. Respondent Fresenius shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:
1. The Monitor shall have the power and authority to monitor Respondent Fresenius's compliance with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements, and shall exercise such power and authority and carry out the duties and responsibilities of the Monitor in a manner consistent with the purposes of this Order and in consultation with the Commission, including, but not limited to:
    - a. Assuring that Respondent Fresenius expeditiously complies with all of its obligations and perform all of its responsibilities as required by the this Order, the Order to Maintain Assets, and the Divestiture Agreements;
    - b. Monitoring any transition services agreements;
    - c. Assuring that Confidential Business Information is not received or used by

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Respondent Fresenius or the Acquirers, except as allowed in this Order and in the Order to Maintain Assets, in this matter.

2. The Monitor shall act in a fiduciary capacity for the benefit of the Commission.
3. The Monitor shall serve for such time as is necessary to monitor Respondent Fresenius's compliance with the provisions of this Order, the Order to Maintain Assets, and the Divestiture Agreements.
4. Subject to any demonstrated legally recognized privilege, the Monitor shall have full and complete access to Respondent Fresenius's personnel, books, documents, records kept in the Ordinary Course Of Business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondent Fresenius's compliance with its obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements. Respondent Fresenius shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondent Fresenius's compliance with this Order, the Order to Maintain Assets, and the Divestiture Agreements.
5. The Monitor shall serve, without bond or other security, at the expense of Respondent Fresenius on such reasonable and customary terms and conditions as the Commission may set. The Monitor shall have authority to employ, at the expense of Respondent Fresenius, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities. The Monitor shall account for all expenses incurred, including fees for services

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rendered, subject to the approval of the Commission.

6. Respondent Fresenius shall indemnify the Monitor and hold the Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Monitor's duties, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Monitor.
7. Respondent Fresenius shall report to the Monitor in accordance with the requirements of this Order and/or as otherwise provided in any agreement approved by the Commission. The Monitor shall evaluate the reports submitted to the Monitor by Respondent Fresenius, and any reports submitted by the Acquirer with respect to the performance of Respondent Fresenius's obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements.
8. Within one (1) month from the date the Monitor is appointed pursuant to this paragraph, every sixty (60) days thereafter, and otherwise as requested by the Commission, the Monitor shall report in writing to the Commission concerning performance by Respondent Fresenius of its obligations under this Order, the Order to Maintain Assets, and the Divestiture Agreements.
9. Respondent Fresenius may require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *Provided, however,* such agreement shall not

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restrict the Monitor from providing any information to the Commission.

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement Relating To Commission materials and information received in connection with the performance of the Monitor's duties.
- F. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor in the same manner as provided in this Paragraph IV.
- G. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Order, the Order to Maintain Assets, and the Divestiture Agreements.
- H. A Monitor appointed pursuant to this Order may be the same Person appointed as a trustee pursuant to Paragraph V of this Order and may be the same Person appointed as Monitor under the Order to Maintain Assets.

**V.****IT IS FURTHER ORDERED** that:

- A. If Respondent Fresenius has not divested, absolutely and in good faith and with the Commission's prior approval,
  - 1. all of the Appendix A Assets pursuant to Paragraph II of this Order, the Commission may appoint a trustee to (1) divest any of the Appendix A Assets that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the

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requirements of Paragraph II of this Order, which may include negotiations with landlords holding leases to the Assets to be Divested; or, in the event the Appendix A Clinics cannot be divested for whatever reason, (2) divest selected Appendix F Clinic Assets at the option of the Divestiture Trustee and the Commission.

2. all of the Dallas Clinics Joint Venture Interests pursuant to Paragraph II of this Order, the Commission may appoint a trustee to (1) divest the Dallas Clinics Joint Venture Interests that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the requirements of Paragraph II of this Order; or, in the event the Dallas Clinics Joint Venture Interests cannot be divested for whatever reason, (2) divest the Appendix F-3 Clinics in the Dallas area at the option of the Divestiture Trustee and the Commission.
3. all of the Alaska Clinic Assets pursuant to Paragraph II of this Order, the Commission may appoint a trustee to (1) divest the Alaska Clinic Assets that have not been divested pursuant to Paragraph II of this Order in a manner that satisfies the requirements of Paragraph II of this Order; or, in the event the Alaska Clinic Assets cannot be divested for whatever reason, (2) divest the Appendix F-4 Clinics in the Alaska area at the option of the Divestiture Trustee and the Commission.

In the event that the Commission or the Attorney General brings an action pursuant to Section 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent Fresenius shall consent to the appointment of a trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a trustee nor a decision not to appoint a trustee under this Paragraph shall preclude the

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Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondent Fresenius to comply with this Order.

- B. The Commission shall select the trustee, subject to the consent of Respondent Fresenius, which consent shall not be unreasonably withheld. The trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondent Fresenius has not opposed, in writing, including the reasons for opposing, the selection of any proposed trustee within ten (10) days after receipt of notice by the staff of the Commission to Respondent Fresenius of the identity of any proposed trustee, Respondent Fresenius shall be deemed to have consented to the selection of the proposed trustee.
- C. Within ten (10) days after appointment of a trustee, Respondent Fresenius shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the trustee all rights and powers necessary to permit the trustee to effect the divestitures required by this Order.
- D. If a trustee is appointed by the Commission or a court pursuant to this Order, Respondent Fresenius shall consent to the following terms and conditions regarding the trustee's powers, duties, authority, and responsibilities:
  - 1. Subject to the prior approval of the Commission, the trustee shall have the exclusive power and authority to divest any of the Appendix A Assets that have not been divested pursuant to Paragraph II of this Order and, subject to the provisions of Paragraph V.A. of the Order, divest Appendix F Clinic Assets.

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2. The trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the trustee has submitted a divestiture plan or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *Provided, however*, the Commission may extend the divestiture period only two (2) times.
3. Subject to any demonstrated legally recognized privilege, the trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be divested by this Order and to any other relevant information, as the trustee may request. Respondent Fresenius shall develop such financial or other information as the trustee may request and shall cooperate with the trustee. Respondent Fresenius shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent Fresenius shall extend the time for divestiture under this Paragraph V in an amount equal to the delay, as determined by the Commission or, for a court-appointed trustee, by the court.
4. The trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent Fresenius's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer or Acquirers that receives the prior approval of the Commission, as required by this Order; *Provided, however*, if the trustee receives

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bona fide offers for particular assets from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity for such assets, the trustee shall divest the assets to the acquiring entity selected by Respondent Fresenius from among those approved by the Commission; *Provided, further, however,* that Respondent Fresenius shall select such entity within five (5) days of receiving notification of the Commission's approval.

5. The trustee shall serve, without bond or other security, at the cost and expense of Respondent Fresenius, on such reasonable and customary terms and conditions as the Commission or a court may set. The trustee shall have the authority to employ, at the cost and expense of Respondent Fresenius, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the trustee's duties and responsibilities. The trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission and, in the case of a court-appointed trustee, by the court, of the account of the trustee, including fees for the trustee's services, all remaining monies shall be paid at the direction of Respondent Fresenius, and the trustee's power shall be terminated. The compensation of the trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.
6. Respondent Fresenius shall indemnify the trustee and hold the trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim,

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whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from misfeasance, gross negligence, willful or wanton acts, or bad faith by the trustee.

7. The trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
  8. The trustee shall report in writing to Respondent Fresenius and to the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture.
  9. Respondent Fresenius may require the trustee and each of the trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *Provided, however,* such agreement shall not restrict the trustee from providing any information to the Commission.
- E. If the Commission determines that a trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute trustee in the same manner as provided in this Paragraph V.
- F. The Commission or, in the case of a court-appointed trustee, the court, may on its own initiative or at the request of the trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.
- G. The trustee appointed pursuant to this Paragraph may be the same Person appointed as the Monitor pursuant to the relevant provisions of this Order or the Order to Maintain Assets.

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**VI.****IT IS FURTHER ORDERED** that:

- A. Beginning thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until Respondent Fresenius has fully complied with Paragraphs II.A., II.B., II.C., II.D.1., II.D.2.a., II.D.3., II.D.4., II.E., II.F., II.G.2., II.I.2., II.J., II.L., and IV.B. of this Order, Respondent Fresenius shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the terms of this Order, the Order to Maintain Assets, and the Divestiture Agreements. Respondent Fresenius shall submit at the same time a copy of these reports to the Monitor.
- B. Beginning twelve (12) months after the date this Order becomes final, and annually thereafter on the anniversary of the date this Order becomes final, for the next four (4) years, Respondent Fresenius shall submit to the Commission verified written reports setting forth in detail the manner and form in which it is complying and has complied with this Order, the Order to Maintain Assets, and the Divestiture Agreements. Respondent Fresenius shall submit at the same time a copy of these reports to the Monitor.

**VII.**

**IT IS FURTHER ORDERED** that Respondent Fresenius shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent Fresenius,
- B. Any proposed acquisition, merger or consolidation of Respondent Fresenius, or
- C. Any other change in Respondent Fresenius that may affect compliance obligations arising out of this Order, including but not limited to assignment, the creation or

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dissolution of subsidiaries, or any other change in Respondent Fresenius.

**VIII.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent Fresenius, Respondent Fresenius shall permit any duly authorized representative of the Commission:

- A. Access, during office hours of Fresenius and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of Fresenius related to compliance with this Order, which copying services shall be provided by Respondent at the request of the authorized representative(s) of the Commission and at the expense of the Respondent; and
- B. Upon five (5) days' notice to Fresenius and without restraint or interference from Fresenius, to interview officers, directors, or employees of Fresenius, who may have counsel present, regarding such matters.

**IX.**

**IT IS FURTHER ORDERED** that this Order shall terminate ten (10) years from the date the Order is made final.

By the Commission.

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**APPENDIX A****APPENDIX A CLINICS**

	<b>Clinic Name</b>	<b>Clinic Address</b>
1	Liberty Flagstaff De Novo	2268 North Walgreens Street Flagstaff, AZ 86004
2	FMC Berkeley	2895 7 <sup>th</sup> Street Berkeley, CA 94710
3	Liberty Broadway Chula Vista	1181 Broadway, Suite 5 Chula Vista, CA 91911
4	Liberty El Camino Real	2227 South El Camino Real, Suite B Oceanside, CA 92054
5	Liberty Pueblo	850 Eagleridge Boulevard Pueblo, CO 81008
6	Liberty Orange	240 Indian River Road Orange, CT 6477
7	Liberty North Haven	510 Washington Avenue North Haven, CT 6473
8	Liberty Seaford	600 Health Service Drive Seaford, DE 19973
9	Liberty Wilmington	913 Delaware Avenue Wilmington, DE 19806
10	Liberty Sarasota	1921 Waldemere Street, Suite 107 Sarasota, FL 34239
11	FMC Viera	8041 Spyglass Road Viera, FL 32940
12	FMC Pine Street	745 Pine Street Macon, GA 31210

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13	BMA of Macon Inc.	280 Clinton Street Macon, GA 31217
14	FMC South Macon Dialysis	2500 Second Street Macon, GA 31205
15	FMC Milledgeville	411 North Jefferson Street Milledgeville, GA 31061
16	Liberty Drayton Savannah	1020 Drayton Street Savannah, GA 31401
17	FMC Aloha	1520 Liliha Street Honolulu, HI 96817
18	FMC Kapahulu	750 Palani Avenue Honolulu, HI 96816
19	FMC Pearlridge	98-1005 Moanaloa Road, Suite 420 Aiea, HI 96701
20	FMC Honolulu	226 North Kuakini Street Honolulu, HI 96817
21	FMC Kapolei	555 Farrington Highway Kapolei, HI 96707
22	FMC Ko'Olau	47-388 Hui Iwa Street Kaneohe, HI 96744
23	FMC Wahiawa	850 Kilani Avenue Wahiawa, HI 96786
24	FMC Waipahu De Novo	TBD Waipahu, HI 96797
25	FMC Windward	45-480 Kaneohe Bay, Drive D09 Kaneohe, HI 96744
26	FMC Idaho Panhandle	204 North Triangle Drive Ponderay, ID 83852
27	Liberty Hayden	7600 Mineral Drive Coeur D'Alene, ID 83815

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28	Liberty Daleville	14520 West Davis Drive Daleville, IN 47334
29	Liberty North Granville Ave	3001 North Granville Avenue Muncie, IN 47303
30	Liberty North Street Muncie	2705 West North Street Muncie, IN 47303
31	Liberty Duneland Coffee Creek	3100 Village Point, Suite 101 Chesterton, IN 46304
32	Liberty Kokomo	3760 South Reed Road Kokomo, IN 46902
33	FMC Lafayette	915 Mezzanine Drive Lafayette, IN 47905
34	Liberty Duneland LaPorte	1007 Lincolnway LaPorte, IN 46350
35	Liberty Old Alexandria Clinton	7201 Old Alexandria Ferry Road Clinton, MD 20735
36	Liberty Silver Hill	5652 Silver Hill Road District Heights, MD 20747
37	Liberty Indian Head Oxon Hill	5410 Indian Head Highway Oxon Hill, MD 20745
38	FMC Kent County De Novo	TBD Wyoming, MI
39	Liberty South East Jackson	200 South East Avenue Jackson, MI 49201
40	FMC Watervliet	8816 Red Arrow Highway Watervliet, MI 49098
41	FMC Dutchess	2585 South Road Poughkeepsie, NY 12601
42	Liberty Latrobe Charlotte	3515 Latrobe Drive Charlotte, NC 28211

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43	Liberty Glenwater Charlotte	9030 Glenwater Drive #B Charlotte, NC 28262
44	Liberty Sooner Dialysis Lawton	924 Southwest 28 <sup>th</sup> Street Lawton, OK 73505
45	Liberty Uniontown	201 Mary Higginson Lane, Suite A Uniontown, PA 15401
46	Liberty Sparta Drive McMinnville	1524 Sparta Street McMinnville, TN 37110
47	Liberty Pace Road	4185 Pace Road Memphis, TN 38116
48	Liberty Poplar Avenue	1333 Poplar Avenue Memphis, TN 38104
49	Liberty Gallatin	270 East Main Street, Suite 100 Gallatin, TN 37066
50	Liberty Manchester	367 Interstate Drive Manchester, TN 37355
51	FMC Bryan	1612 North Texas Avenue Bryan, TX 77803
52	FMC West Laredo	4151 Bob Bullock Loop, Suite 105 Laredo, TX 78046
53	FMC South Laredo	802 Guadalupe Street Laredo, TX 78040
54	FMC Laredo	5501 Springfield Avenue Laredo, TX 78041

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**APPENDIX A-2****APPENDIX A-2 JOINT VENTURES**(Joint Ventures From Which Fresenius Will Divest Its Joint  
Venture Equity Interests and Clinics Owned by Joint Ventures)

	<b>Joint Venture Name</b>	<b>Clinic Name (Medicare Provider)</b>	<b>Clinic Address</b>
1	LDFS LLC	Liberty Flagstaff De Novo	2268 North Walgreens Street Flagstaff, AZ 86004
2	Liberty Dialysis – Pueblo LLC	Liberty Pueblo	850 Eagleridge Boulevard Pueblo, CO 81008
3	LDO LLC	Liberty Orange	240 Indian River Road Orange, CT 6477
4	Liberty Dialysis – North Haven LLC	Liberty North Haven	510 Washington Avenue North Haven, CT 6473
5	LDSO LLC	Liberty Seaford	600 Health Service Drive Seaford, DE 19973
6	Liberty Wilmington LLC	Liberty Wilmington	913 Delaware Avenue Wilmington, DE 19806
7	Liberty Dialysis – Hayden LLC	Liberty Hayden	7600 Mineral Drive Coeur D’Alene, ID 83815
8	Liberty Dialysis – Duneland LLC	Liberty Duneland Coffee Creek	3100 Village Point, Suite 101 Chesterton, IN 46304

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	<b>Joint Venture Name</b>	<b>Clinic Name (Medicare Provider)</b>	<b>Clinic Address</b>
9	Liberty Dialysis – Kokomo, LLC	Liberty Kokomo	3760 South Reed Road Kokomo, IN 46902
10	FMC Clarian Arnett, LLC	FMC Lafayette	915 Mezzanine Drive Lafayette, IN 47905
11	Liberty Dialysis – Duneland LLC	Liberty Duneland LaPorte	1007 Lincolnway La Porte, IN 46350
12	RAI Care Centers of Clinton, LLC	Liberty Old Alexandria Clinton	7201 Old Alexandria Ferry Road Clinton, MD 20735
13	Lawton Med Partners, LLC	Liberty Sooner Dialysis Lawton	924 Southwest 28 <sup>th</sup> Street Lawton, OK 73505
14	RAI Care Centers of Uniontown, LLC	Liberty Uniontown	201 Mary Higginson Lane, Suite A Uniontown, PA 15401
15	NRA-Memphis (Midtown), Tennessee, LLC	Liberty Pace Road	4185 Pace Road Memphis, TN 38116
16	NRA-Memphis (Midtown), Tennessee, LLC	Liberty Poplar Avenue	1333 Poplar Avenue Memphis, TN 38104
17	RAI Care Centers of Gallatin I, LLC	Liberty Gallatin	270 East Main Street, Suite 100 Gallatin, TN 37066

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**APPENDIX B****AREA DEFINITIONS TO APPENDIX A CLINICS, THE DALLAS  
JOINT VENTURE INTERESTS CLINICS, AND THE ALASKA CLINIC  
ASSETS****AREA DEFINITIONS**

- Five digit numbers refer to zip codes.
- Geographic areas bounded by roads include all properties abutting the referenced road (*i.e.*, properties on both sides of the road).
- Zip codes or other areas fully surrounded by areas included in the area definition shall be considered part of the area definition.
- Area definitions are based on maps submitted to the Commission staff by Fresenius.

	<b>Divested Clinics</b>	<b>Corresponding Area Definition</b>
1	Liberty Alaska LLC	The area in and/or near Anchorage, AK, consisting of: 99501; 99502; 99503; 99504; 99505; 99506; 99507; 99508; 99515; 99516; 99517; 99518; 99520; 99540; 99567; 99577; 99587; 99654; and the portion of 99645 that lies south and west of Chickaloon, AK.
2	Liberty Flagstaff De Novo	The area in and/or near Flagstaff, AZ, consisting of: 86001, 86004, 86030, 86031, 86033, 86034, 86035, 86039, 86040, 86042, 86043, 86044, 86045, 86046, 86047, 86048, 86053, 86054, 86435, and 86510.

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3	FMC Berkeley	The area in and/or near Berkeley, CA, consisting of: 94051; 94501; 94530; 94547; 94564; 94601; 94602; the portion of 94605 that lies north of 66 <sup>th</sup> Avenue; 94606; 94607; 94608; 94609; 94610; 94611; 94612; 94613; 94618; 94619; 94702; 94703; 94704; 94705; 94706; 94707; 94708; 94709; 94710; 94611; 94613; 94618; 94619; 94801; 94803; 94804; 94805; and 94806.
4	Liberty Broadway Chula Vista	The area in and/or near Chula Vista, CA, consisting of: the portion of 91901 that lies south of Japatul Road; 91905; 91906; 91910; 91911; 91913; 91914; 91915; 91917; 91932; 91934; 91935; 91945; 91950; 91962; 91963; 91977; 91978; 92101; 92102; the portion of 92103 that lies south of West Washington Street; 92104; 92105; 92113; 92114; the portion of 92115 that lies south of University Avenue; 92118; 92135; 92136; 92139; 92154; 91962; 91963; 92173; and 92174.

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5	Liberty El Camino Real Oceanside	The area in and/or near Oceanside, CA, consisting of: the portions of 91901, 91962, and 92021 that lie north of 8, 91916, 91948, 92003, 92004, 92007, 92008, 92009, 92010, 92011, 92014, 92024, 92025, 92026, 92027, 92028, 92029, 92036, 92037, 92040, 92054, 92055, 92056, 92057, 92058, 92059, 92060, 92061, 92064, 92065, 92066, 92067, 92069, 92070, the portions of 92071, 92111, 92123, and 92124 that lie north of Route 52, 92075, 92078, 92081, 92082, 92083, 92084, 92086, 92121, 92122, 92126, 92127, 92128, 92129, 92130, 92131, 92137, and 92145.
6	Liberty Pueblo	The area in and/or near Pueblo, CO, consisting of: 81001, 81002, 81003, 81004, 81005, 81006, 81007, 81008, 81022, 81023, and 81069.
7	Liberty Orange and Liberty North Haven	The area in and/or near New Haven, CT, consisting of: 06405, 06460, 06461, 06471, 06472, 06473, 06477, the portions of 06410 and 06492 that lie south of Route 68, 06511, 06512, 06513, 06514, 06515, 06516, 06517, 06518, and 06519.
8	Liberty Seaford	The area in and/or near Seaford, DE, consisting of: 19931, 19933, 19939, 19940, 19947, 19950, 19956, 19966, and 19973.

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9	Liberty Wilmington	The area in and/or near Wilmington, DE, consisting of: 19701, 19702, 19703, 19706, 19707, 19709, 19711, 19713, 19720, 19733, 19801, 19802, 19803, 19805, 19806, 19807, 19808, 19809, and 19810.
10	Liberty Sarasota	The area in and/or near Sarasota, FL, consisting of: 34201, 34203, 34207, 34231, 34232, 34233, 34234, 34235, 34236, 34237, 34238, 34239, 34240, 34243, the portion of 34202 that lies to the south of State Road 64, the portion of 34208 that lies to the east of 57 <sup>th</sup> Street East, the portion of 34241 that lies to the north of Clark Road/State Road 72.
11	FMC Viera	The area in and/or near Merritt Island, FL, consisting of: 32920, 32922, 32924, 32926, 32927, 32931, 32940, 32952, 32953, 32954, 32955, and the portion of 32937 that lies north of Route 404.
12	FMC Pine Street, BMA of Macon Inc., and FMC South Macon Dialysis	The area in and/or near Macon, GA, consisting of: 31017, 31020, 31032, 31033, 31044, 31052, 31066, 31201, 31203, 31204, 31206, 31210, 31211, 31216, 31217, 31218, and 31220.

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13	FMC Milledgeville	The area in and/or near Milledgeville, GA, consisting of: 31024, 31031, 31042, 31054, 31061, the portion of 31082 that lies to the west of North Indian Trail Road and South Indian Trail Road, 31087, and 31090.
4	Liberty Drayton Savannah	The area in and/or near Savannah, GA, consisting of: the portion of Chatham County, GA that lies to the east of I-95, and the portion of 29927 that lies to the south of the line formed by Route 170.
15	FMC Aloha, FMC Kapahulu, FMC Pearlridge, FMC Honolulu, FMC Kapolei, FMC Ko'Olau, FMC Wahiawa, FMC Waipahu De Novo, FMC Windward	The area in and/or near Honolulu, HI, consisting of the island of Oahu, HI.
16	FMC Idaho Panhandle	The area in and/or near Bonner, ID, consisting of: 83801, 83804, 83805, 83809, 83811, 83813, 83821, 83822, 83836, 83845, 83846, 83848, 83853, the portion of 83856 that lies in Idaho, 83864, and 83860.

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17	Liberty Hayden	The area in and/or near Coeur d'Alene, ID, consisting of: 83801, 83802, 83804, 83808, 83810, 83812, 83814, 83824, 83830, 83833, 83835, 83837, 83839, 83846, 83850, 83851, 83854, 83858, 83861, 83869, 83870, 83873, and 83876.
18	Liberty Daleville	The area in and/or near Daleville, IN, consisting of: 46001, 46011, 46012, 46013, 46015, 46016, 46017, 46018, 47334, and 47356.
19	Liberty North Granville Avenue and Liberty North Street Muncie	The area in and/or near Muncie, IN, consisting of: 47302, 47303, 47304, 47305, 47306, 47320, 47336, 47338, 47342, 47348, 47356, 47383, and 47396.
20	Liberty Duneland Coffee Creek	The area in and/or near Gary, IN, consisting of: 46304, 46342, 46347, 46360, 46368, 46383, 46384, 46385, 46403, 46405, 46410, and the portions of 46307, 46410, and 46341 that lie east of Highway 65.
21	Liberty Kokomo	The area in and/or near Kokomo, IN, consisting of: 46901, 46902, 46936, and 46979.

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22	FMC Lafayette	The area in and/or near Lafayette, IN, consisting of: 46923, 47901, 47904, 47905, 47906, 47907, 47909, 47917, 47918, 47920, 47921, 47923, 47929, 47930, 47942, 47944, 47948, 47951, 47970, 47971, 47975, 47977, 47981, 47991, 47992, 47993, and the portions of 47980, 47960, and 47995 that lie south of Highway 24.
23	Liberty Duneland La Porte	The area in and/or near La Porte, IN, consisting of: 46350, 46552, 46360, 46365, 46371, 46390, and 46391.
24	Liberty Old Alexandria Clinton, Liberty Silver Hill District Heights, Liberty Indian Head Oxon Hill	The area in and/or near Oxon Hill, MD, consisting of: 20019, 20020, 20032, 20623, 20731, 20735, 20743, 20744, 20745, 20746, 20747, 20748, 20749, 20762, and the portion of 20772 that lies south of Highway 4 and east of U.S. Route 301, and the portion of 20774 that lies south of Highway 214 and east of U.S. Route 301.
25	FMC Kent County De Novo	The area in and/or near Grand Rapids, MI, consisting of: 49301, 49302, 49306, 49315, 49316, 49319, 49321, 49323, 49330, 49331, 49335, 49339, 49341, 39343, 49344, 49345, 49348, 49418, 49426, 49428, 49503, 49504, 49505, 49506, 49507, 49508, 49509, 49512, 49519, 49525, 49534, 49544, 49546, and 49548.

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26	Liberty South East Jackson	The area in and/or near Jackson, MI, consisting of: 49201, 49202, 49203, 49204, 49224, 49230, 49234, 49237, 49240, 49241, 49245, 49246, 49259, the portion of 49264 south of Wilcox Lane, 49269, 49272, 49277, 49283, and 49284.
27	FMC Watervliet	The area in and/or near Watervliet, MI, consisting of: 49013, 49022, 49038, 49043, 49045, 49047, 49057, 49064, 49085, 49098, 49101, 49102, 49103, 49106, 49107, 49111, 49113, 49117, 49120, 49125, 49126, 49127, 49128, and 49129.
28	Fresenius Medical Director Agreement	The area in and/or near Atlantic City, NJ, consisting of: 08201, 08203, 08205, 08221, 08225, 08226, 08330, 08232, 08234, 08241, 08244, 08401, 08402, 08403, 08406, the portion of 08037 that lies east of Ellwood Road, and the portion of 08215 that lies south of Mullica River.
29	FMC Dutchess	The area in and/or near Poughkeepsie, NY, consisting of: 12501, 12507, 12508, 12514, 12522, 12524, 12527, 12531, 12533, 12538, 12540, 12545, 12546, 12564, 12567, 12569, 12570, 12571, 12572, 12578, 12580, 12581, 12582, 12585, 12590, 12592, 12594, 12601, 12603, and 12604.

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30	Fresenius' Samaritan Management Contract      Good	The area in and/or near Newburgh, NY, consisting of: 10916, 10917, 10919, 10928, 10930, 10941, 10950, 10992, 10996, 12429, 12493, 12515, 12518, 12520, 12525, 12528, 12542, 12547, 12548, 12549, 12550, 12551, 12553, 12561, 12566, 12575, 12577, 12586, 12589 and the portions of 10918 and 10924 that lie north of Brookside Avenue, the portion of 10926 that lies north of and includes Route 17M, the portion of 10940 that lies north of Route 84, east of County Road 78, south of Ingrassia Road, and east of Route 17M, the portion of 10950 that lies north of and includes Route 17M, and the portion of 10958 that lies north of Route 17M.
31	RAI Latrobe, RAI Glenwater	The area in and/or near Charlotte, NC, consisting of Mecklenburg County, NC.
32	Liberty Lawton	The area in and/or near Lawton, OK, consisting of: 73501, 73503, 73505, 73507, 73527, 73528, 73530, 73531, 73538, 73540, 73541, 73542, 73543, 73546, 73548, 73551, 73552, 73553, 73557, 73562, 73566, 73568, 73570, and 73572.

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33	RAI Uniontown	The area in and/or near Uniontown, PA, consisting of: 15401, 15416, 15422, 15425, 15431, 15435, 15436, 15437, 15440, 15443, 15445, 15451, 15456, 15458, 15459, 15461, 15468, 15470, 15474, 15478, 15480, 15484, 15486, and 15488.
34	RAI McMinnville	The area in and/or near McMinnville, TN, consisting of: 37110, 37166, 37357, 37190, 38581, and 38585.
35	RAI Pace Road, RAI Poplar Avenue	The area in and/or near Memphis, TN, consisting of: 38103, 38104, 38105, 38106, 38107, 38108, 38109, 38111, 38112, 38113, 38114, 38116, 38122, 38126, 38127, 38128, 38131, and 38132.
36	RAI Gallatin	The area in and/or near Gallatin, TN consisting of: 37022, 37031, 37048, 37066, 37074, 37075, 37186, and the portions of 37072, 37148, and 37188 that lie east of Interstate 65.
37	RAI Manchester	The area in and/or near Tullahoma, TN, consisting of: 37183, 37144, 37160, 37318, 37324, 37330, 37334, 37342, 37348, 37349, 37352, 37355, 37359, 37360, 37388, 37398, the portions of 37306, 37335, and 37345 that lie north of Route 64, and the portion of 37375 that lies north of Sewanee Highway.

## Decision and Order

38	FMC Bryan	The area in and/or near Bryan, TX, consisting of: 75852, 76629, 77363, 77801, 77802, 77803, 77807, 77808, 77830, 77831, 77836, 77837, 77840, 77845, 77856, 77859, 77861, 77864, 77868, 77872, and 77879.
39	FMC West Laredo, FMC South Laredo, FMC Laredo	The area in and/or near Laredo, TX, consisting of: 78040, 78041, 78043, 78044, 78045, 78046, 78067, 78076, 78344, 78360, 78361, and 78369.
40	Liberty Duncanville, Liberty Lancaster	The area in and/or near Duncanville and Lancaster, TX, consisting of: 75052, 75104, 75115, 75116, 75125, 75134, 75137, 75141, 75146, 75172, 75203, 75211, 75215, 75216, 75224, 75232, 75233, 75236, 75237, 75241, 75249, and the portion of 75154 that lies within Dallas County.
41	Liberty Mesquite	The area in and/or near Mesquite, TX, consisting of: 75043, 75149, 75150, 75159, 75180, 75181, 75182, 75210, 75217, 75223, 75227, 75228, and 75253.
42	Liberty Rockwall	The area in and/or near Rockwall, TX, consisting of: 75032, 75040, 75041, 75043, 75048, 75087, 75088, 75089, 75098, 75132, 75166, 75173, 75228, and the portion of 75189 that lies within Rockwall County.

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43	Liberty Waxahachie	The area in and/or near Waxahachie, TX, consisting of: 75119, 75125, 75152, 75154, 75165, 75167, 76041, 76064, 76065, 76084, and 76651.
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## Decision and Order

**APPENDIX C****MONITOR AGREEMENT****MONITOR AGREEMENT**

MONITOR AGREEMENT (this “**Agreement**”), dated as of January 21, 2012, between Fresenius Medical Care Holdings, Inc. (“**FMCH** or **Respondent**”), and Richard A. Shermer of R. Shermer & Company (“**Monitor**”).

**PRELIMINARY STATEMENT**

WHEREAS the Federal Trade Commission (the “**Commission**”) is considering for public comment an Agreement Containing Consent Orders with Respondent or its parent company, which provides, among other things, that Respondent divest a number of dialysis clinics and assets associated with those clinics, Respondent terminate management contracts Respondent has with certain dialysis clinics, enter into agreements – if necessary – providing the acquirers of the dialysis clinics with transition services, and engage a monitor to monitor Respondent’s compliance with its obligations under (a) the Decision and Order and (b) the Order to Maintain Assets (collectively, the “**Orders**”);

WHEREAS, the Commission is expected to issue the Agreement Containing Consent Orders and appoint the Monitor pursuant to the Orders to monitor Respondent’s compliance with the terms of the Orders, and the Monitor has consented to such appointment;

WHEREAS, the Orders further provide that Respondent shall execute an agreement, subject to prior approval of the Commission, conferring all the rights and powers necessary to permit Monitor to carry out its duties and responsibilities pursuant to the Orders;

WHEREAS, this Agreement, although executed by Monitor and Respondent, is not effective for any purpose, including but not limited to imposing rights and responsibilities on Respondent or Monitor under the Orders, until the Order to Maintain Assets has been issued and this Agreement has been approved by the Commission;

WHEREAS, the parties to this Agreement intend to be legally bound, subject only to the Commission’s approval of this Agreement.

**DEFINITIONS**

1. “**Respondent**” means Fresenius Medical Care Holdings, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of New York, with its office and principal place of business located at 920 Winter Street, Waltham, MA 02451, its directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns; its joint ventures, divisions, groups and affiliates controlled by FMCH, and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each.

2. “**Other Parties**” means any Person that receives approval of the Commission to acquire any of the Assets to Be Divested or is a party to the Relevant Agreements pursuant to the Decision and Order.

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3. “**Acquisition Date**” means the date on which the first of the Relevant Agreements pursuant to the Decision and Order goes into effect.

4. “**Relevant Agreements**” means: all the divestiture agreements, management termination agreements, and transition services agreements entered into pursuant to the Decision and Order, including, but not limited to, the Divestiture Agreements, and the Transition Services Agreement between the Other Parties and FMCH or one of its subsidiaries.

5. All other capitalized words or phrases appearing in this Agreement that are not otherwise defined herein are deemed to have the defined meanings assigned to them in the Orders.

## ARTICLE I

1.1 Powers of the Monitor. Monitor shall have the rights, duties, powers and authority conferred upon Monitor by the Orders that are necessary for Monitor to monitor Respondent’s compliance with the Orders. No later than one day after the Order to Maintain Assets becomes final, Respondent hereby transfers to Monitor all rights, powers, and authorities necessary to permit Monitor to perform its duties and responsibilities pursuant to the Order to Maintain Assets and consistent with the purposes of the Decision and Order. Any descriptions thereof contained in this Agreement in no way modify Monitor’s powers and authority or Respondent’s obligations under the Orders.

1.2 Monitor’s Duties. Monitor shall monitor Respondent’s compliance with the Orders, including, but not limited to:

- a. Assuring that Respondent expeditiously complies with all of the obligations, and performs all of responsibilities, of Respondent as required by the Orders in this matter;
- b. Monitoring Relevant Agreements; and
- c. Assuring that Confidential Business Information is not received or used by Respondent or Other Parties, except as allowed in the Orders in this matter.

1.3 Duration of Monitor’s Authority. Monitor shall have all powers and duties described above and consistent with the Orders for the term set forth in the Orders.

1.4 Confidential and Proprietary Information. Monitor shall enter into confidentiality agreements, in substantially the form attached hereto as Confidential Exhibit A, agreeing to be bound by the terms and conditions of the Orders. Monitor must retain and maintain all Material Confidential Information it receives from either Respondent or Other Parties on a confidential basis, except as is permitted by the Orders. Monitor may disclose confidential information only to persons employed by or working with Monitor under this Agreement, to persons employed at the Commission, and as permitted by Respondent or Other Parties with respect to information they provided Monitor. Monitor shall require any person retained by Monitor to assist in carrying out the duties and responsibilities of Monitor to execute a confidentiality agreement that

## Decision and Order

requires the same standard of care and obligations of confidentiality to which Monitor must adhere under this Agreement. Monitor shall maintain the confidentiality, for a period of five (5) years after the termination of this Agreement, of all other aspects of the performance of its duties under this Agreement and shall not disclose any confidential information relating thereto.

1.5 Restrictions. Monitor shall not be involved in any way in the management, production, supply and trading, sales marketing, and financial operations of the competing products of Respondent.

1.6 Reports. Monitor shall report to the Commission pursuant to the terms of the Orders and as otherwise requested by the Commission staff.

1.7 Access to Records, Documents and Facilities. Subject to any demonstrated legally recognized privilege, Monitor shall have full and complete access to Respondent's personnel, to include those employees designated to be transferred to an acquirer, books, documents, records kept in the normal course of business, facilities and technical information, and such other relevant information as Monitor may reasonably request, related to Respondent's compliance with the obligations of Respondent under the Orders in this matter. Documents, records and other relevant information are to be provided in an electronic format if they exist in that form. Respondent shall cooperate with any reasonable request of Monitor and shall take no action to interfere with or impede Monitor's ability to monitor Respondent's compliance with the Orders.

## ARTICLE II

2.1 Retention and Payment of Counsel, Consultants, and other Assistants. Monitor shall have the authority to employ, at the cost and expense of the Respondent, such attorneys, consultants, accountants, and other representatives and assistants as are necessary to carry out the Monitor's duties and responsibilities as allowed pursuant to the Orders.

2.2 Compensation. Monitor shall be compensated by Respondent for his services under this Agreement, including all work in connection with the negotiation and preparation of this Monitor Agreement, pursuant to the fee schedule attached as Confidential Exhibit B for time spent in connection with the discharge of its duties under this Agreement and the Orders. In addition, Respondent will pay: (a) out-of-pocket expenses reasonably incurred by Monitor in the performance of its duties under the orders; and (b) fees and disbursements reasonably incurred by any advisor appointed by Monitor pursuant to the first paragraph in Article II. At its own expense, Respondent may retain an independent auditor to verify such invoices. Monitor shall provide Respondent with monthly invoices for time and expenses that include details and an explanation of all matters for which Monitor submits an invoice to Respondent. Respondent shall pay such invoices within thirty (30) days of receipt. The Monitor and Respondent shall submit any disputes about invoices to the Commission for assistance in resolving such disputes.

2.3 To the extent available, Respondent will provide the Monitor with temporary workspace and access to office equipment owned or used by Respondent at sites the Monitor is required to visit in order to fulfill its obligations under this Agreement. Monitor agrees to

## Decision and Order

comply with all of Respondents' safety and security regulations, instructions and procedures while at Respondents' sites.

**ARTICLE III**

3.1 **Monitor's Liabilities and Indemnification.** Respondent shall indemnify the Monitor and hold Monitor harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of Monitor's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by Monitor. The Monitor's maximum liability to Respondents relating to services rendered in accordance with this Agreement (regardless of form of action, whether in contract, statutory law, or tort) shall be limited to an amount equal to the total sum of the fees paid to the Monitor by the Respondent. Any claim arising from this Agreement that Respondents may have against the Monitor must be brought no later than one (1) year following the termination or expiration of this Agreement. In the performance of its duties under this Agreement, the Monitor shall exercise the standard of care and diligence that would be expected of a reasonable person in the conduct of his own business affairs. The Monitor shall not be liable for any delays or other failures to perform resulting from circumstances or causes beyond its reasonable control, including, without limitation, fire or other casualty, act of God, strike or labor dispute, war or other violence, or any law, order or requirement of any governmental agency or authority. The Monitor warrants that it will perform its obligations hereunder in good faith. R. Shermer & Company disclaims other warranties, expressed or implied, other than those expressly agreed to in writing between the Parties.

3.2 **Monitor's Removal.** If the Commission determines that Monitor ceases to act or fail to act diligently and consistent with the purpose of the Orders, Respondent shall terminate this Agreement and appoint a substitute Monitor, subject to Commission approval and consistent with the Orders.

3.3 **Approval by the Commission.** This Agreement shall have no force or effect until approved by the Commission, other than Respondent obligations under Confidential Exhibit A and the confidentiality provisions herein.

3.4 **Termination:** This Agreement shall terminate the earlier of: (a) thirty (30) days following the termination date set forth in the applicable Order; (b) Respondent's receipt of written notice from the Commission that the Commission has determined that Monitor has ceased to act or failed to act diligently, or is unwilling or unable to continue to serve as Monitor; (c) with at least thirty (30) days advance notice to be provided by Monitor to Respondent and to the Commission, upon resignation of the Monitor; or (d) when FMCH's last obligation under the Orders and the Relevant Agreements that pertains to the Monitors' service has been fully performed; provided, however, that the Commission may require that FMCH extend this Agreement or enter into an additional agreement with Monitor as may be necessary or appropriate to accomplish the purposes of the Orders. If this Agreement is terminated for any reason, the confidentiality obligations set forth in this Agreement will remain in force.

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3.5 Conflicts of Interest: If Monitor becomes aware during the term of this Agreement that it has or may have a conflict of interest that may affect or could have the appearance of affecting performance by the Monitor of any of its duties under this Agreement, Monitor shall promptly inform Respondent and the Commission of any such conflict.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

**MONITOR**

**R. SHERMER & COMPANY**



\_\_\_\_\_  
NAME: Richard A. Shermer, President

**RESPONDENT**

**FRESENIUS MEDICAL CARE HOLDINGS, INC.**

BY:   
NAME: DOUGLAS G. KOST  
TITLE: SENIOR VICE PRESIDENT

Decision and Order

**NON-PUBLIC APPENDIX C-1****COMPENSATION PROVISIONS OF MONITOR AGREEMENT****[Redacted From the Public Record Version, But Incorporated  
By Reference]****APPENDIX D****EXCLUDED TRADEMARKS & DESIGNS****[None]****NON-PUBLIC APPENDIX E****DSI-FRESENIUS DIVESTITURE AGREEMENTS****[Redacted From the Public Record Version, But Incorporated  
By Reference]****NON-PUBLIC APPENDIX F****LIST OF ALTERNATIVE CLINICS TO APPENDIX A CLINICS TO  
DIVEST****[Redacted From the Public Record Version, But Incorporated  
By Reference]**

Decision and Order

**NON-PUBLIC APPENDIX F-2**

**LIST OF ALTERNATIVE JOINT VENTURES TO APPENDIX A-2  
JOINT VENTURES**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX F-3**

**LIST OF ALTERNATIVE CLINICS TO DIVEST IN DALLAS, TEXAS  
AREA**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX F-4**

**LIST OF ALTERNATIVE CLINIC TO DIVEST IN ANCHORAGE,  
ALASKA AREA**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

Decision and Order

**NON-PUBLIC APPENDIX G**

**DESIGNATED FRESENIUS EMPLOYEES:**

**ADDITIONAL FRESENIUS, RAI, AND LIBERTY EMPLOYEES LIST**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX H**

**ALASKA CLINIC DIVESTITURE AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX I**

**DALLAS CLINICS JOINT VENTURE INTERESTS DIVESTITURE  
AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

Analysis to Aid Public Comment

**NON-PUBLIC APPENDIX J**

**GOOD SAMARITAN MANAGEMENT TERMINATION LETTER,  
GOOD SAMARITAN MANAGEMENT AGREEMENT,  
AND FINAL GOOD SAMARITAN TRANSITION SERVICES  
AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Fresenius Medical Care AG & Co. KGaA (“Fresenius”). The purpose of the Consent Agreement is to remedy the anticompetitive effects resulting from Fresenius’s purchase of Liberty Dialysis Holdings, Inc. (“Liberty”). Under the terms of the Consent Agreement, Fresenius is required to divest 60 dialysis clinics and terminate one management contract in 43 geographic markets across the United States.

The Consent Agreement has been placed on the public record for 30 days to solicit comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will again review the Consent Agreement and the comments received, and will decide whether it should withdraw from the Consent Agreement or make it final.

Pursuant to an agreement dated August 1, 2011, Fresenius proposes to acquire Liberty for approximately \$2.1 billion. The Commission’s complaint alleges that the proposed acquisition, if

## Analysis to Aid Public Comment

consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in 43 markets for the provision of outpatient dialysis services.

### **The Parties**

Headquartered in Bad Homburg, Germany, Fresenius is the largest provider of outpatient dialysis services in the United States. Fresenius operates more than 1,800 outpatient dialysis clinics in all 50 states and the District of Columbia treating approximately 131,000 patients. In 2010, Fresenius's revenues were approximately \$8 billion.

Liberty, headquartered in Mercer Island, Washington, is a privately held company and the third-largest provider of outpatient dialysis services in the United States. Liberty operates 260 dialysis centers, providing dialysis services to approximately 19,000 patients in 32 states and the District of Columbia.

### **Outpatient Dialysis Services**

Outpatient dialysis services is the relevant product market in which to assess the effects of the proposed transaction. For patients suffering from End Stage Renal Disease ("ESRD"), dialysis treatments are a life-sustaining therapy that replaces the function of the kidneys by removing toxins and excess fluid from the blood. Most ESRD patients receive dialysis treatment three times per week in sessions lasting between three and five hours. Kidney transplantation is the only alternative to dialysis for ESRD patients. However, the wait-time for donor kidneys – during which ESRD patients must receive dialysis treatments – can exceed five years. Additionally, many ESRD patients are not viable transplant candidates. As a result, ESRD patients have no alternative to dialysis treatments. ESRD patients who are not hospitalized must obtain dialysis treatments from outpatient dialysis clinics.

Dialysis services are provided in local geographic markets limited by the distance ESRD patients are able to travel to receive treatments. ESRD patients are often very ill and suffer from

## Analysis to Aid Public Comment

multiple health problems, making travel further than 30 miles or 30 minutes very difficult. As a result, competition among dialysis clinics occurs at a local level, corresponding to metropolitan areas or subsets thereof. The exact contours of each market vary depending on traffic patterns, local geography, and the patient's proximity to the nearest center.

Entry into the outpatient dialysis services markets identified in the Commission's Complaint is not likely to occur in a timely manner at a level sufficient to deter or counteract the likely anticompetitive effects of the proposed transaction. The primary barrier to entry is the difficulty associated with locating nephrologists with established patient pools to serve as medical directors. By law, each dialysis clinic must have a nephrologist medical director. As a practical matter, medical directors are also essential to the success of a clinic because they are the primary source of referrals. The lack of available nephrologists with an established referral stream is a significant barrier to entry into each of the relevant markets. Beyond that, the attractiveness of entry is diminished where certain attributes, including a rapidly growing ESRD population, a favorable regulatory environment, average or below nursing and labor costs, and a low penetration of managed care are not present, as is the case in many of the geographic markets identified in the Commission's complaint.

Each of the geographic markets identified in the Complaint is highly concentrated. The proposed acquisition represents a merger-to-monopoly in 17 markets and would cause the number of providers to drop from three to two in 24 other markets. Additionally, in the remaining two markets identified in the Complaint, concentration is already very high and would increase significantly. In these two markets, the fourth market participant is small and does not meaningfully impact competition. Further, the evidence shows that health insurance companies and other private payors who pay for dialysis services used by their members benefit from direct competition between Fresenius and Liberty when negotiating rates charged by dialysis providers. The high post-acquisition concentration levels, along with the elimination of Fresenius's and Liberty's head-to-head competition in these markets suggest the proposed combination likely would

## Analysis to Aid Public Comment

result in higher prices and diminished service and quality for outpatient dialysis services in many geographic markets.

**The Consent Agreement**

The Consent Agreement remedies the proposed acquisition's anticompetitive effects in 43 markets where both Fresenius and Liberty operate dialysis clinics by requiring Fresenius to divest 54 outpatient dialysis clinics to Dialysis Newco, Inc. (d/b/a DSI Renal) ("New DSI"); divest one outpatient dialysis clinic to Alaska Investment Partners LLC ("AIP"), and five outpatient dialysis clinics to Dallas Renal Group ("DRG"). The Consent Agreement also requires Fresenius to terminate one management services agreement pursuant to which it manages an outpatient dialysis clinic on behalf of a third-party owner. As with the divestitures, termination of this management services agreement will ensure that this clinic remains a viable independent competitor.

As part of these divestitures, Fresenius is required to obtain the agreement of the medical directors affiliated with the divested clinics to continue providing physician services after the transfer of ownership to the buyers. Similarly, the Consent Agreement requires Fresenius to obtain the consent of all lessors necessary to assign the leases for the real property associated with the divested clinics to the buyers. These provisions ensure that each buyer will have the assets necessary to operate the divested clinics in a competitive manner.

The Consent Agreement contains several additional provisions designed to ensure that the divestitures are successful. First, the Consent Agreement provides each buyer with the opportunity to interview and hire employees affiliated with the divested clinics and prevents Fresenius from offering these employees incentives to decline any buyer's offer of employment. This will ensure that each buyer has access to patient care and supervisory staff who are familiar with the clinics' patients and the local physicians. Second, the Consent Agreement prevents Fresenius from contracting with the medical directors (or their practice groups) affiliated with the divested clinics for three years. This provides each buyer with sufficient time to build goodwill and a working relationship with its medical directors before Fresenius can

## Analysis to Aid Public Comment

attempt to capitalize on its prior relationships in soliciting their services. Third, to ensure continuity of patient care and records as each buyer implements its quality care, billing, and supply systems, the Consent Agreement allows Fresenius to provide transition services for a period of 12 months. Firewalls and confidentiality agreements have been established to ensure that competitively sensitive information is not exchanged. Fourth, the Consent Agreement requires Fresenius to provide each buyer with a license to use Fresenius's policies, procedures, and medical protocols, as well as the option to obtain Fresenius's medical protocols, which will further enhance the buyer's ability to continue to care for patients in the clinics that will be divested. Finally, the Consent Agreement requires Fresenius to provide notice to the Commission prior to any acquisitions of dialysis clinics in the markets addressed by the Consent Agreement in order to ensure that subsequent acquisitions do not adversely impact competition in the markets at issue or undermine the remedial goals of the proposed order.

The Commission is satisfied that New DSI is a qualified acquirer of the majority of the divested assets. New DSI is currently a significant operator of dialysis clinics, having been formed to acquire the divested assets resulting from the 2011 DaVita/DSI investigation. The company was formed by Frazier Healthcare, a firm with a dedicated focus on healthcare, and New Enterprise Associates, the world's largest venture capital firm with over \$10.5 billion under management.

Similarly, the Commission is satisfied that AIP is a qualified acquirer of divested assets in Alaska. AIP is a limited liability company wholly-owned by Dr. Mary Dittrich, the divested clinic's medical director, and Dr. William Dittrich. AIP has received financial support from Crystal Cascades LLC, an investment fund that manages \$100 million.

Finally, the Commission is satisfied that DRG is a qualified acquirer of divested assets in the Dallas, Texas area. DRG is an integrated care provider in Dallas, Texas with nine nephrologists on staff and whose nephrologists currently serve as the medical directors of these divested assets. DRG holds the majority ownership interest in the five Liberty clinics in Dallas that would be divested, and has a strong reputation in the Dallas area.

*Analysis to Aid Public Comment*

The Commission has appointed Richard Shermer of R. Shermer & Co. as an Interim Monitor to oversee the transition service agreements, and the implementation of, and compliance with, the Consent Agreement. Mr. Shermer assists client companies undergoing ownership transitions, and has specific experience with transitions of outpatient dialysis clinics.

The purpose of this analysis is to facilitate public comment on the Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Decision and Order or the Order to Maintain Assets, or to modify their terms in any way.

## Complaint

## IN THE MATTER OF

**KINDER MORGAN, INC.**CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4355; File No. 121 0014*  
*Complaint, May 1, 2012 – Decision, June 12, 2012*

This consent order addresses the \$38 billion acquisition by Kinder Morgan, Inc. of certain assets of El Paso Corporation. The complaint alleges that the acquisition, if consummated, would violate Section 5 of the Federal Trade Commission Act and Section 7 of the Clayton Act by significantly reducing competition in the market for pipeline transportation services. The consent order requires Respondent to divest its own Rockies Express (REX), Kinder Morgan Interstate Gas Transmission, and Trailblazer pipelines, as well as associated processing and storage capacity.

*Participants*

For the *Commission: Nathan Chubb, Keitha Clopper, Philip Eisenstat, and Terry Thomas.*

For the *Respondent: Vadim Brusser, Steve Newborn, Megan Peloquin, and Laura Wilkinson, Weil, Gotshal & Manges LLP.*

**COMPLAINT**

Pursuant to the provisions of the Federal Trade Commission Act, and by virtue of the authority vested in it by said Act, the Federal Trade Commission, having reason to believe that Respondent Kinder Morgan, Inc., and El Paso Corporation have entered into an acquisition agreement which, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Federal Trade Commission that a proceeding by it in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

## Complaint

**I. RESPONDENT AND JURISDICTION**

1. Kinder Morgan, Inc. is a publically traded corporation principally engaged in midstream petroleum and natural gas services. Kinder Morgan, Inc. is organized, existing, and doing business under and by virtue of the laws of Delaware, with its headquarters and principal place of business at 500 Dallas Street, Suite 1000, Houston, Texas 77002.

2. Kinder Morgan, Inc. is the general partner of the master-limited partnership Kinder Morgan Energy Partners.

3. Kinder Morgan Energy Partners owns or has interests in over 38,000 miles of pipelines in North America for the transportation of natural gas, refined petroleum products, crude oil, and carbon dioxide.

4. Kinder Morgan, Inc. and its relevant operating entities are, and at all relevant times have been, engaged in the business of transporting natural gas by pipeline in Colorado and Wyoming.

5. Kinder Morgan, Inc. and its relevant operating entities are, and at all relevant times have been, engaged in the business of providing natural gas storage services to customers located in Colorado.

6. Kinder Morgan, Inc. and its relevant operating entities are, and at all relevant times have been, engaged in the business of processing natural gas produced in Wyoming.

7. Kinder Morgan, Inc. and its relevant operating entities are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12, and Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**II. THE PROPOSED ACQUISITION**

8. El Paso Corporation is a publically traded corporation principally engaged in natural gas transportation, natural gas gathering and processing, and natural gas exploration and production. El Paso Corporation and its affiliates own or have

## Complaint

interests in over 43,000 miles of natural gas pipelines and gathering systems. El Paso Corporation is organized, existing, and doing business under and by virtue of the laws of Delaware with its headquarters and principal place of business at 1001 Louisiana Street, Houston, Texas 77002.

9. Pursuant to an agreement dated October 16, 2011, Kinder Morgan, Inc. intends to acquire the outstanding stock of El Paso Corporation for a combination of cash and Kinder Morgan, Inc. stock and warrants collectively valued at \$21.1 billion. Kinder Morgan, Inc. will also assume \$17 billion of debt from El Paso Corporation.

**III. THE RELEVANT MARKETS****A. PIPELINE TRANSPORTATION OF NATURAL GAS TO UTILITIES AND OTHER CUSTOMERS IN THE COLORADO FRONT RANGE**

10. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

11. The Front Range region in eastern Colorado, which runs from the Cheyenne Hub in Weld County, Colorado in the north to Pueblo, Colorado in the south, is a relevant geographic market for the delivery of natural gas to utilities and other customers.

12. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas delivered to utilities and other customers in the Colorado Front Range region.

**B. PIPELINE TRANSPORTATION OF NATURAL GAS FROM WELLS IN THE DENVER/JULESBURG/NIORARA PRODUCTION BASIN**

13. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

14. The Denver/Julesburg/Niobrara production basin, covering parts of northwestern Colorado, western Nebraska, and southeastern Wyoming, is a relevant geographic market for the shipment of natural gas.

## Complaint

15. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas shipped from wells in the Denver/Julesburg/Niobrara production basin.

**C. PIPELINE TRANSPORTATION OF NATURAL GAS  
FROM WELLS IN THE POWDER RIVER PRODUCTION  
BASIN**

16. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

17. The Powder River production basin, covering parts of northeast Wyoming, is a relevant geographic market for the shipment of natural gas.

18. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas shipped from wells in the Powder River production basin.

**D. PIPELINE TRANSPORTATION OF NATURAL GAS  
FROM WELLS IN THE WIND RIVER PRODUCTION  
BASIN**

19. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

20. The Wind River production basin, covering parts of central Wyoming, is a relevant geographic market for the shipment of natural gas.

21. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas from wells in the Wind River production basin.

**E. PIPELINE TRANSPORTATION OF NATURAL GAS  
FROM WELLS IN THE WESTERN WYOMING  
PRODUCTION BASINS**

22. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

23. The Western Wyoming production basins, the Green River, Red Desert and Washakie production basins, each covering

## Complaint

portions of southwestern Wyoming, taken together are a relevant geographic market for the shipment of natural gas.

24. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas from wells in the Western Wyoming production basins.

**F. PIPELINE TRANSPORTATION OF NATURAL GAS FROM WELLS IN THE PICEANCE PRODUCTION BASIN**

25. The transportation of natural gas by pipeline is a relevant product market in which to analyze the proposed acquisition.

26. The Piceance production basin, covering parts of northwestern Colorado, is a relevant geographic market for the shipment of natural gas.

27. A relevant market in which to analyze the proposed acquisition is pipeline transportation of natural gas from wells in the Piceance production basin.

**G. NO NOTICE NATURAL GAS DELIVERY SERVICE TO THE FRONT RANGE REGION IN EASTERN COLORADO**

28. Shippers on interstate natural gas pipelines must give advance notice to the pipeline operator when the shipper plans to inject natural gas into the pipeline. Some pipelines offer a premium service at extra cost, allowing shippers to ship natural gas without the normal notice period. Such service is called “no-notice” service.

29. No notice natural gas delivery service is a relevant product market.

30. The Front Range region in eastern Colorado, which runs from the Cheyenne Hub in Weld County, Colorado in the north to Pueblo, Colorado in the south, is a relevant geographic market for the receipt of natural gas.

31. A relevant market in which to analyze the proposed acquisition is the provision of no notice natural gas delivery

## Complaint

service to utility companies and local distribution companies in the Colorado Front Range region.

**H. NATURAL GAS PROCESSING IN THE WIND RIVER BASIN**

32. Natural gas processing is a relevant product market.

33. The Wind River Basin is a relevant geographic market.

34. A relevant market in which to analyze the proposed acquisition is the processing of natural gas produced in the Wind River production basin in Wyoming.

**VI. ANTICOMPETITIVE EFFECTS**

35. The acquisition may substantially lessen competition in the relevant markets by, among other things: (a) eliminating actual, direct, and substantial competition between Kinder Morgan, Inc. and El Paso Corporation; and (b) increasing the likelihood that Kinder Morgan, Inc. will exercise market power unilaterally.

**VII. ENTRY CONDITIONS**

36. Post-acquisition, entry or expansion into the relevant markets would not be timely, likely, and sufficient in scope to deter or negate the anticompetitive effects of the proposed acquisition.

**VI. VIOLATIONS CHARGED**

37. The agreement described in Paragraph 9 constitutes a violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

38. The acquisition described in Paragraph 9, if consummated, would constitute a violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

## Order to Hold Separate

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this first day of May, 2012, issues its Complaint against Respondent.

By the Commission, Commissioner Ramirez recused.

**ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS  
[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Kinder Morgan, Inc. (“Kinder Morgan” or “Respondent”) of the outstanding voting securities of El Paso Corporation (“El Paso”), and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent

## Order to Hold Separate

Agreement containing the Decision and Order on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings, and issues this Order to Hold Separate and Maintain Assets (“Hold Separate Order”):

1. Respondent Kinder Morgan is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 500 Dallas Street, Suite 1000, Houston, Texas 77002.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

**ORDER****I.**

**IT IS HEREBY ORDERED** that, as used in this Hold Separate Order, the following definitions shall apply:

- A. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger, dated as of October 16, 2011, among Kinder Morgan, Inc., Sherpa Merger Sub, Inc., Sherpa Acquisition, LLC, Sirius Holdings Merger Corporation, Sirius Merger Corporation, and El Paso Corporation.
- B. “Acquisition Date” means the date the Acquisition is consummated.
- C. “Confidential Business Information” means competitively sensitive, proprietary, and all other business information of any kind, except for any information that Respondent demonstrates (i) was or becomes generally available to the public other than as a result of a disclosure by Respondent, or (ii) was

## Order to Hold Separate

available, or becomes available, to Respondent on a non-confidential basis, but only if, to the knowledge of Respondent, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information.

- D. “Decision and Order” means the:
1. Proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission.
  2. Final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission.
- E. “Direct Cost” means the actual cost of labor, including employee benefits, materials, resources, and services plus the actual cost of any third-party charges.
- F. “Divestiture Date” means, with regard to any of the KM Pipeline Assets, the date on which Respondent (or a Divestiture Trustee) closes on the divestiture of those assets completely and as required by Paragraph II. (or Paragraph IV.) of the Decision and Order.
- G. “El Paso Rockies Pipeline Business” means El Paso’s business of providing natural gas transportation services and any related natural gas processing, treatment, storage, and pipeline operating services through the Cheyenne Plains Gas pipeline system (“CPG”), Colorado Interstate Gas pipeline system (“CIG”), and the Wyoming Interstate Company gas pipeline system (“WIC”).
- H. “Employment Information” means employment information relating to a relevant employee, to the extent permitted by law, including, but not limited to, name, job title, date of hire, description of job

## Order to Hold Separate

responsibilities, salary or wages, and employment benefits.

- I. “Hold Separate Business” means (i) the commercial/account services, regulatory, gas control, gas accounting, scheduling, storage, and field operations functions of the KM Pipeline Business; (ii) the KM Pipeline Assets; and (iii) the KM Pipeline Employees depicted on the Hold Separate Business organizational chart attached to this Hold Separate Order as Confidential Appendix A; *provided, however*, that the functional areas of the Hold Separate Business and the organizational chart depicted in Confidential Appendix A may be revised by the Hold Separate Trustee, if necessary, to accomplish the purposes of this Hold Separate Order, in consultation with Commission staff.
- J. “Hold Separate Employee” means any Person employed in the Hold Separate Business; *provided, however*, that Hold Separate Employees shall not include the employees listed in Confidential Appendix B.
- K. “Hold Separate Manager” means any Person appointed to manage and maintain the operations of the Hold Separate Business pursuant to Paragraph IV.A. of this Hold Separate Order.
- L. “Hold Separate Trustee” means any Person appointed pursuant to Paragraph III. of this Hold Separate Order.
- M. “Interstate Pipeline Systems” means:
  - 1. Kinder Morgan Interstate Gas Transmission LLC (“KMIGT”), which includes approximately 5,100 miles of transmission lines in Colorado, Kansas, Nebraska, Missouri, and Wyoming;
  - 2. Rockies Express Pipeline LLC (“REX”), a natural gas pipeline system in which Kinder Morgan owns a fifty (50) percent membership interest, which

## Order to Hold Separate

includes an approximately 1,679 mile natural gas pipeline originating at a point near Meeker, in Rio Blanco County, Colorado and terminating at a point near Clarington, in Monroe county, Ohio; and

3. Trailblazer Pipeline Company LLC (“Trailblazer”), a natural gas pipeline system that includes a 436-mile natural gas pipeline originating at an interconnection with Wyoming Interstate Company, LLC’s pipeline system near Rockport, Colorado and runs through southeastern Wyoming to a terminus near Beatrice, Nebraska.
- N. “KM Pipeline Assets” means all of Kinder Morgan’s right, title, and interest in and to all property and assets, tangible or intangible, of every kind and description, wherever located, and any improvements or additions thereto, relating to operation of the KM Pipeline Business.
- O. “KM Pipeline Business” means Kinder Morgan’s business of providing natural gas transportation services and any related natural gas processing, treatment, storage, and pipeline operating services through and/or in connection with the Interstate Pipeline Systems.
- P. “KM Pipeline Employees” means any full-time, part-time, or contract Person (i) employed by Respondent at any time from the date Respondent signs the Consent Agreement, and (ii) whose job responsibilities primarily relate to the KM Pipeline Business.
- Q. “Support Services” means the gas pipeline and corporate functions that support a range of Respondent’s businesses (including the KM Pipeline Business), including, but not limited to, engineering and technical services, project management, land and right of way, operations support, environmental, health and safety, information technology, human resources, administrative, corporate communications, financial

## Order to Hold Separate

reporting and corporate accounting, and legal and risk management services.

- R. “Support Services Employee” means any Respondent employee who provides Support Services to the Hold Separate Business pursuant to Paragraph V.B. of this Hold Separate Order.

**II.**

**IT IS FURTHER ORDERED** that:

- A. Respondent shall:
1. Hold the Hold Separate Business separate, apart, and independent of Respondent’s other businesses and assets as required by this Hold Separate Order and shall vest the Hold Separate Business with all rights, powers, and authority necessary to conduct its business;
  2. Not exercise direction or control over, or influence directly or indirectly, the Hold Separate Business or any of its operations, the Hold Separate Trustee, or the Hold Separate Manager except to the extent that Respondent must exercise direction and control over the Hold Separate Business as is necessary to assure compliance with this Hold Separate Order, the Consent Agreement, the Decision and Order, and all applicable laws; and
  3. Take such actions as are necessary to maintain and assure the continued viability, marketability, and competitiveness of the Hold Separate Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear, and shall not sell, transfer, encumber, or otherwise impair the Hold Separate Business (except as required by the Decision and Order).

## Order to Hold Separate

- B. The purpose of this Hold Separate Order is to (1) preserve the Hold Separate Business as a viable, competitive, and ongoing business independent of Respondent until the divestiture required by the Decision and Order is achieved; (2) assure that no Confidential Business Information is exchanged between Respondent and the Hold Separate Business, except in accordance with the provisions of this Hold Separate Order; and (3) prevent interim harm to competition pending the divestiture and other relief.

**III.****IT IS FURTHER ORDERED** that:

- A. At any time after Respondent signs the Consent Agreement, the Commission may appoint Robert E. Ogle as Hold Separate Trustee to monitor and supervise the management of the Hold Separate Business and ensure that Respondent complies with its obligations under this Hold Separate Order and the Decision and Order.
- B. Respondent shall enter into an agreement with the Hold Separate Trustee that shall become effective no later than one (1) day after the Acquisition Date that, subject to the prior approval of the Commission, transfers to and confers upon the Hold Separate Trustee all rights, powers, and authority necessary to permit the Hold Separate Trustee to perform his duties and responsibilities pursuant to this Hold Separate Order in a manner consistent with the purposes of this Hold Separate Order and the Decision and Order and in consultation with Commission staff, and shall require that the Hold Separate Trustee shall act in a fiduciary capacity for the benefit of the Commission:
1. The Hold Separate Trustee shall have the responsibility for monitoring the organization of the Hold Separate Business and maintenance of the independence of the Hold Separate Business; supervising the management of the Hold Separate

## Order to Hold Separate

Business; and monitoring Respondent's compliance with its obligations pursuant to this Hold Separate Order and the Decision and Order.

2. The Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents, and facilities of the Hold Separate Business, and to any other relevant information as the Hold Separate Trustee may reasonably request, including, but not limited to, all documents and records kept by Respondent in the ordinary course of business that relate to the Hold Separate Business. Respondent shall develop such financial or other information as the Hold Separate Trustee may reasonably request.
3. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
4. The Commission may require the Hold Separate Trustee and each of the Hold Separate Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with performance of the Hold Separate Trustee's duties.
5. Respondent may require the Hold Separate Trustee and each of the Hold Separate Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign a confidentiality agreement, *provided, however*, that such agreement shall not restrict the Hold Separate Trustee from providing any information to the Commission.

## Order to Hold Separate

6. The Hold Separate Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on reasonable and customary terms and conditions commensurate with the Hold Separate Trustee's experience and responsibilities.
  7. Respondent shall indemnify the Hold Separate Trustee and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from the Hold Separate Trustee's gross negligence or willful misconduct.
  8. Thirty (30) days after the Acquisition Date, and every thirty (30) days thereafter until this Hold Separate Order terminates, the Hold Separate Trustee shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate Order and Respondent's compliance with its obligations under the Hold Separate Order and the Decision and Order. - Included within each report shall be the Hold Separate Trustee's assessment of the extent to which the Hold Separate Business is meeting (or exceeding) its projected goals as are reflected in operating plans, budgets, projections, or any other regularly prepared financial statements.
- C. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate Order, the Commission may appoint a substitute Hold Separate Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld, as follows:
1. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of

## Order to Hold Separate

the substitute Hold Separate Trustee within five (5) days after notice by the staff of the Commission to Respondent of the identity of any substitute Hold Separate Trustee, then Respondent shall be deemed to have consented to the selection of the proposed substitute trustee.

2. Respondent shall, no later than five (5) days after the Commission appoints a substitute Hold Separate Trustee, enter into an agreement with the substitute Hold Separate Trustee that, subject to the approval of the Commission, confers on the substitute Hold Separate Trustee all the rights, powers, and authority necessary to permit the substitute Hold Separate Trustee to perform his or her duties and responsibilities on the same terms and conditions as provided in Paragraph III. of this Hold Separate Order.
- D. The Hold Separate Trustee shall serve until the day after the Divestiture Date; *provided, however*, that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Hold Separate Order and the Decision and Order.

**IV.****IT IS FURTHER ORDERED** that:

- A. No later than three (3) days after the Acquisition Date, Respondent shall appoint Rockford G. Meyer as the Hold Separate Manager to manage and maintain the operations of the Hold Separate Business in the regular and ordinary course of business and in accordance with past practice.
- B. Respondent shall enter into a management agreement with the Hold Separate Manager that shall become effective no later than three (3) days after the Acquisition Date and that, subject to the approval of the Hold Separate Trustee, in consultation with the

## Order to Hold Separate

Commission staff, transfers all rights, powers, and authority necessary to permit the Hold Separate Manager to perform his or her duties and responsibilities pursuant to this Hold Separate Order:

1. The Hold Separate Manager shall be responsible for managing the operation of the Hold Separate Business and shall report directly and exclusively to the Hold Separate Trustee, and shall manage the Hold Separate Business independently of the management of Respondent and its other businesses.
2. The Hold Separate Manager shall make no material changes in the ongoing operations of the Hold Separate Business except with the approval of the Hold Separate Trustee, in consultation with the Commission staff.
3. The Hold Separate Manager, in consultation with the Hold Separate Trustee, shall have the authority to employ such Persons as are reasonably necessary to assist the Hold Separate Manager in managing the Hold Separate Business, including consultants, accountants, attorneys, and other representatives and assistants.
4. Respondent shall provide the Hold Separate Manager with reasonable financial incentives to undertake this position. Such incentives shall include a continuation of all applicable employee benefits, including regularly scheduled raises, bonuses, vesting of retirement benefits (as permitted by law), and additional incentives as may be necessary to assure the continuation and prevent any diminution of the Hold Separate Business's viability, marketability and competitiveness, and as may otherwise be necessary to achieve the purposes of this Hold Separate Order.

## Order to Hold Separate

5. The Hold Separate Manager shall serve, without bond or other security, at the cost and expense of Respondent, on reasonable and customary terms commensurate with the person's experience and responsibilities.
  6. Respondent shall indemnify the Hold Separate Manager and hold him harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of his duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from the Hold Separate Manager's gross negligence or willful misconduct.
  7. Respondent shall assure that Commission staff shall have access to and be permitted to communicate with, contact, and be contacted by the Hold Separate Manager without prior notice to Respondent or the presence of Respondent's employees or counsel, except as expressly required by law.
- C. The Hold Separate Manager shall have the authority, in consultation with the Hold Separate Trustee, to:
1. Staff the Hold Separate Business with sufficient employees to maintain the viability and competitiveness of the Hold Separate Business, including:
    - a. Replacing any departing or departed Hold Separate Employee with a person who has similar experience and expertise or determine not to replace such departing or departed employee.
    - b. Removing any Hold Separate Employee who ceases to act or fails to act diligently and

## Order to Hold Separate

consistent with the purposes of this Hold Separate Order and replacing such employee with another person of similar experience or skills.

- c. Ensuring that no Hold Separate Employee shall (i) be involved in any way in the operations of Respondent's other businesses, and (ii) receive or have access to, or use or continue to use, any Confidential Business Information pertaining to Respondent's other businesses.
  - d. Providing each Hold Separate Employee with reasonable financial incentives, including continuation of all employee benefits and regularly scheduled raises and bonuses, to continue in his or her position pending divestiture of the KM Pipeline Assets.
2. Facilitate the transfer of any Hold Separate Employee to the Acquirer in connection with the divestiture of the KM Pipeline Assets, including allowing an Acquirer access to (i) each Hold Separate Employee to interview and (ii) Employment Information relating to each Hold Separate Employee, in the course of due diligence performed in connection with Respondent's efforts to divest the KM Pipeline Assets pursuant to the Decision and Order.
- D. The Hold Separate Manager may be removed for cause by the Hold Separate Trustee in consultation with the Commission staff. If the Hold Separate Manager is removed, resigns, or otherwise ceases to act as Hold Separate Manager, Respondent shall, within three (3) days after such termination, (i) appoint a substitute Hold Separate Manager and (ii) enter into an agreement with the substitute Hold Separate Manager, subject to the approval of the Hold Separate Trustee and in consultation with Commission staff, on the same terms and conditions as provided in Paragraph IV. of this Hold Separate Order.

## Order to Hold Separate

**V.****IT IS FURTHER ORDERED** that:

- A. Respondent shall cooperate with, and take no action to interfere with or impede the ability of: (i) the Hold Separate Trustee, (ii) the Hold Separate Manager, (iii) any Hold Separate Employee, or (iv) any Support Services Employee to perform their duties and responsibilities pursuant to this Hold Separate Order.
- B. Respondent shall continue to provide, or offer to provide, Support Services and goods to the Hold Separate Business as are being provided to such business by Respondent as of the date the Consent Agreement is signed by Respondent:
  - 1. For Support Services and goods that Respondent provided to the Hold Separate Business as of the date the Consent Agreement is signed by Respondent, Respondent may charge no more than the same price, if any, charged by Respondent for such Support Services and goods as of the date the Consent Agreement is signed by Respondent.
  - 2. For any other Support Services and goods that Respondent may provide to the Hold Separate Business, Respondent may charge no more than Respondent's Direct Cost for the same or similar Support Services and goods.
  - 3. Notwithstanding the above, the Hold Separate Business shall have, at the option of the Hold Separate Manager and in consultation with the Hold Separate Trustee, the ability to acquire Support Services and goods from third parties unaffiliated with Respondent.
- C. Respondent shall not permit:
  - 1. Any of its employees, officers, agents, or directors, other than (i) the Hold Separate Manager, (ii) any

## Order to Hold Separate

Hold Separate Employee, and (iii) any Support Services Employee, to be involved in the operations of the Hold Separate Business, except to the extent otherwise provided in this Hold Separate Order.

2. The Hold Separate Manager or any Hold Separate Employee to be involved, in any way, in the operations of Respondent's businesses other than the Hold Separate Business.
  3. Any Support Services Employee to be involved in the operations of the El Paso Rockies Pipeline Business.
- D. Respondent shall (i) not offer any incentive to any Hold Separate Employee to decline employment with the Acquirer, (ii) remove any impediments that may deter or prevent any Hold Separate Employee from accepting employment with the Acquirer or that would affect the ability of such employee to be employed by the Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondent that would affect the ability of such employee to be employed by the Acquirer, and (iii) not otherwise interfere with the recruitment of any Hold Separate Employee by the Acquirer.
- E. Respondent shall provide the Hold Separate Business with sufficient financial and other resources as are appropriate in the judgment of the Hold Separate Trustee to:
1. Operate the Hold Separate Business at least as it is currently staffed and operated (including efforts to generate new business) consistent with the practices of the Hold Separate Business in place prior to the Acquisition Date.
  2. Perform all maintenance to, and replacements or remodeling of, the assets of the Hold Separate

## Order to Hold Separate

Business in the ordinary course of business and in accordance with past practice and current plans.

3. Carry on such capital projects, physical plant improvements, and business plans as are already underway or planned for which all necessary regulatory and legal approvals have been obtained, including but not limited to existing or planned renovation, remodeling, or expansion projects.
4. Maintain the viability, competitiveness, and marketability of the Hold Separate Business.

Such financial resources to be provided to the Hold Separate Business shall include, but shall not be limited to: (i) general funds, (ii) capital, (iii) working capital, and (iv) reimbursement for any operating losses, capital losses, or other losses; *provided, however,* that, consistent with the purposes of the Decision and Order and in consultation with the Hold Separate Trustee, the Hold Separate Manager may reduce in scale or pace any capital or research and development project, or substitute any capital or research and development project for another of the same cost.

- F. No later than ten (10) days after the Acquisition Date, Respondent shall establish written procedures, subject to the approval of the Hold Separate Trustee, covering the management, maintenance, and independence of the Hold Separate Business consistent with the provisions of this Hold Separate Order.
- G. No later than ten (10) days after the date the Acquisition Date, Respondent shall circulate to each Hold Separate Employee and to persons who are employed in Respondent's businesses that compete with the Hold Separate Business, a notice of this Hold Separate Order and the Consent Agreement, in a form approved by the Hold Separate Trustee and in consultation with Commission staff.

## Order to Hold Separate

**VI.****IT IS FURTHER ORDERED** that:

- A. Respondent's employees shall not receive, have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the Hold Separate Business except in the course of:
1. Performing their obligations or as permitted under this Hold Separate Order or the Decision and Order.
  2. Performing their obligations under any Divestiture Agreement.
  3. Complying with financial reporting requirements, obtaining legal advice, defending legal claims, investigations, or enforcing actions threatened or brought against the KM Pipeline Assets and KM Pipeline Business, or as required by law.

For purposes of this Paragraph VI.A., Respondent's employees who provide Support Services or staff the Hold Separate Business shall be deemed to be performing obligations under this Hold Separate Order.

- B. If access or disclosure of Confidential Business Information of the Hold Separate Business to Respondent's employees is necessary, and permitted, under Paragraph VI.A. of this Hold Separate Order, Respondent shall:
1. Implement and maintain a process and procedures, as approved by the Hold Separate Trustee, pursuant to which Confidential Business Information of the Hold Separate Business may be disclosed or used (i) only to those employees who require such information, (ii) only to the extent such Confidential Business Information is required, and (iii) only after such employees have

## Order to Hold Separate

signed an appropriate agreement in writing to maintain the confidentiality of such information.

2. Enforce the terms of this Paragraph VI. as to any of Respondent's employees and take such action as is necessary to cause each such employee to comply with the terms of this Paragraph VI., including training of Respondent's employees and all other actions that Respondent would take to protect its own trade secrets and proprietary information.
- C. Respondent shall implement, and maintain in operation, a system, as approved by the Hold Separate Trustee, of access and data controls to prevent unauthorized access to or dissemination of Confidential Business Information of the Hold Separate Business, including, but not limited to, the opportunity by the Hold Separate Trustee, on terms and conditions agreed to with Respondent, to audit Respondent's networks and systems to verify compliance with this Hold Separate Order.

**VII.**

**IT IS FURTHER ORDERED** that the Commission may on its own initiative or at the request of the Hold Separate Trustee issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of this Hold Separate Order.

**VIII.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to any proposed:

- A. dissolution of Respondent;
- B. acquisition, merger or consolidation of Respondent; or
- C. any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution

## Order to Hold Separate

of subsidiaries, if such change might affect compliance obligations arising out of the Order.

**IX.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Hold Separate Order, and subject to any legally recognized privilege, and upon written request with five (5) days' notice to Respondent made to its principal United States office, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda, and other records and documents in the possession or under the control of Respondent related to compliance with the Consent Agreement and/or this Hold Separate Order, which copying services shall be provided by Respondent at the request of the authorized representative of the Commission and at the expense of Respondent; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from them, to interview officers, directors, or employees of Respondent, who may have counsel present.

**X.**

**IT IS FURTHER ORDERED** that this Hold Separate Order shall terminate at the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after Respondent has completed its obligations to provide Transitional Assistance under Paragraph II.D. of the Decision and Order.

Decision and Order

By the Commission, Commissioner Ramirez recused.

**Confidential Appendix A**

[Hold Separate Organizational Chart]

**[Redacted From the Public Record Version, But Incorporated  
By Reference]****Confidential Appendix B****[Redacted From the Public Record Version, But Incorporated  
By Reference]****DECISION AND ORDER  
[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Kinder Morgan, Inc. (“Kinder Morgan” or “Respondent”) of the outstanding voting securities of El Paso Corporation (“El Paso”), and Respondent having been furnished thereafter with a copy of the draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondent with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C.

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§ 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondent, its attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondent of all the jurisdictional facts set forth in the aforesaid draft of Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondent that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waives and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondent has violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and its Order to Hold Separate and Maintain Assets (“Hold Separate Order”) and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Kinder Morgan is a corporation organized, existing, and doing business under, and by virtue of, the laws of the State of Delaware, with its office and principal place of business located at 500 Dallas Street, Suite 1000, Houston, Texas 77002.
2. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and the proceeding is in the public interest.

## Decision and Order

**ORDER****I.**

**IT IS HEREBY ORDERED** that, as used in this Order, the following definitions, and all other definitions used in the Hold Separate Order, shall apply:

- A. “Kinder Morgan” means Kinder Morgan, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and the joint ventures, subsidiaries, partnerships, divisions, groups, and affiliates in each case controlled by Kinder Morgan, Inc. (including, but not limited to, Kinder Morgan Energy Partners L.P. and Kinder Morgan Management LLC), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. Kinder Morgan includes El Paso, after the Acquisition Date.
- B. “Commission” means the Federal Trade Commission.
- C. “Acquirer” means any Person that receives the prior approval of the Commission to acquire any of the KM Pipeline Assets pursuant to this Decision and Order.
- D. “Acquisition” means the proposed acquisition described in the Agreement and Plan of Merger, dated as of October 16, 2011, among Kinder Morgan, Inc., Sherpa Merger Sub, Inc., Sherpa Acquisition, LLC, Sirius Holdings Merger Corporation, Sirius Merger Corporation, and El Paso Corporation.
- E. “Acquisition Date” means the date the Acquisition is consummated.
- F. “Business Records” means all originals and all copies of any operating, financial or other information, documents, data, computer files (including files stored on a computer’s hard drive or other storage media), electronic files, books, records, ledgers, papers, instruments, and other materials, whether located,

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stored, or maintained in traditional paper format or by means of electronic, optical, or magnetic media or devices, photographic or video images, or any other format or media, including, without limitation: distributor files and records; customer files and records, customer lists, customer product specifications, customer purchasing histories, customer service and support materials, customer approvals, and other information; credit records and information; correspondence; referral sources; supplier and vendor files and lists; advertising, promotional, and marketing materials, including website content; sales materials; research and development data, files, and reports; technical information; data bases; studies; drawings, specifications and creative materials; production records and reports; service and warranty records; equipment logs; operating guides and manuals; employee and personnel records; education materials; financial and accounting records; and other documents, information, and files of any kind.

- G. “Confidential Business Information” means competitively sensitive, proprietary and all other business information of any kind, except for any information that Respondent demonstrates (i) was or becomes generally available to the public other than as a result of a wrongful disclosure by Respondent, or (ii) was available, or becomes available, to Respondent on a non-confidential basis, but only if, to the knowledge of Respondent, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information.
- H. “Direct Cost” means the actual cost of labor, including employee benefits, materials, resources, and services plus the actual cost of any third-party charges.
- I. “Divestiture Agreement” means any agreement that receives the prior approval of the Commission between Respondent (or between a Divestiture Trustee appointed pursuant to Paragraph IV. of this Order) and

## Decision and Order

an Acquirer to purchase all or any of the KM Pipeline Assets, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission.

- J. “Divestiture Date” means, with regard to any of the KM Pipeline Assets, the date on which Respondent (or a Divestiture Trustee) closes on the divestiture of those assets completely and as required by Paragraph II. (or Paragraph IV.) of this Order.
- K. “El Paso” means El Paso Corporation, a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware with its office and principal place of business located at 1001 Louisiana Street, Houston, Texas 77002.
- L. “El Paso Rockies Pipeline Business” means El Paso’s business of providing natural gas transportation services and any related natural gas processing, treatment, storage, and pipeline operating services through the Cheyenne Plains Gas pipeline system (“CPG”), Colorado Interstate Gas pipeline system (“CIG”), and the Wyoming Interstate Company gas pipeline system (“WIC”).
- M. “Hold Separate Business” means the business that Respondent shall hold separate pursuant to the Hold Separate Order.
- N. “Intellectual Property” means all intellectual property owned or licensed (as licensor or licensee) by Kinder Morgan, in which Kinder Morgan has a proprietary interest, including (i) commercial names, trade names, “doing business as” (d/b/a) names, registered and unregistered trademarks, logos, service marks and applications; (ii) all patents, patent applications and inventions, and discoveries that may be patentable; (iii) all registered and unregistered copyrights in both published works and unpublished works; (iv) all know-how, trade secrets, confidential or proprietary information, protocols, quality control information,

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customer lists, software, technical information, data, process technology, plans, drawings, and blue prints; (v) and all rights in internet web sites and internet domain names presently used by Kinder Morgan.

- O. “Interstate Pipeline Systems” means:
1. Kinder Morgan Interstate Gas Transmission LLC (“KMIGT”), which includes approximately 5,100 miles of transmission lines in Colorado, Kansas, Nebraska, Missouri, and Wyoming;
  2. Rockies Express Pipeline LLC (“REX”), a natural gas pipeline system in which Kinder Morgan owns a fifty (50) percent membership interest, which includes an approximately 1,679 mile natural gas pipeline originating at a point near Meeker, in Rio Blanco County, Colorado and terminating at a point near Clarington, in Monroe county, Ohio; and
  3. Trailblazer Pipeline Company LLC (“Trailblazer”), a natural gas pipeline system that includes a 436-mile natural gas pipeline originating at an interconnection with Wyoming Interstate Company, LLC’s pipeline system near Rockport, Colorado and runs through southeastern Wyoming to a terminus near Beatrice, Nebraska.
- P. “IP License-Back” means (i) a worldwide, royalty-free, paid-up, perpetual, irrevocable, transferable, sublicensable, non-exclusive license under all Intellectual Property included in the KM Pipeline Assets relating to Respondent’s operation of a business that Respondent is not required to divest under this Order; and (ii) such tangible embodiments of the licensed rights (including but not limited to physical and electronic copies) as may be necessary or appropriate to enable Respondent to use the rights.
- Q. “KM Key Employee” means any KM Pipeline Employee identified by agreement between

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Respondent and an Acquirer and made a part of a Divestiture Agreement.

- R. “KM Pipeline Assets” means all of Kinder Morgan’s right, title, and interest in and to all property and assets, tangible or intangible, of every kind and description, wherever located, and any improvements or additions thereto, relating to operation of the KM Pipeline Business, including but not limited to:
1. All real property interests (including fee simple interests and real property leasehold interests), including all easements, appurtenances, licenses, and permits, together with all buildings and other structures, facilities, and improvements located thereon, owned, leased, or otherwise held;
  2. All Tangible Personal Property, including any Tangible Personal Property removed from any location of the KM Pipeline Business since the date of the announcement of the Acquisition, and not replaced, if such property was used in connection with the operations of the KM Pipeline Business prior to the Acquisition Date;
  3. All inventories, wherever located;
  4. All (a) trade accounts receivable and other rights to payment from customers of Kinder Morgan and the full benefit of all security for such accounts or rights to payment, (b) all other accounts or notes receivable by Kinder Morgan and the full benefit of all security for such accounts or notes and (c) any claim, remedy, or other right related to any of the foregoing;
  5. All agreements and contracts with customers (including but not limited to agreements, contracts, and understandings for transportation, storage, and other services), suppliers, vendors, representatives, agents, licensees and licensors; and all leases, mortgages, notes, bonds, and other binding

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commitments, whether written or oral, and all rights thereunder and related thereto;

6. All consents, licenses, certificates, registrations, or permits issued, granted, given, or otherwise made available by or under the authority of any governmental body or pursuant to any legal requirement, and all pending applications therefor or renewals thereof;
7. All intangible rights and property, including Intellectual Property (subject to an IP License-Back to Respondent), going concern value, goodwill, telephone, telecopy, and e-mail addresses and listings;
8. All Business Records; *provided, however*, that where documents or other materials included in the Business Records to be divested contain information: (a) that relates both to the KM Pipeline Assets to be divested and to Respondents' retained assets or other products or businesses and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the KM Pipeline Assets to be divested; or (b) for which the relevant party has a legal obligation to retain the original copies, the relevant party shall be required to provide only copies or relevant excerpts of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the relevant party shall provide the Acquirer access to original documents under circumstances where copies of the documents are insufficient for evidentiary or regulatory purposes.
9. All insurance benefits, including rights and proceeds; and
10. All rights relating to deposits and prepaid expenses, claims for refunds, and rights to offset in respect thereof.

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*Provided, however,* that the KM Pipeline Assets need not include:

- a. Assets whose use is shared between the KM Pipeline Business and other Kinder Morgan businesses unless such assets are primarily related to the operation of the KM Pipeline Business; and
  - b. Any part of the KM Pipeline Assets if not needed by an Acquirer and the Commission approves the divestiture without such assets.
- S. “KM Pipeline Business” means Kinder Morgan’s business of providing natural gas transportation services and any related natural gas processing, treatment, storage, and pipeline operating services through and/or in connection with the Interstate Pipeline Systems.
- T. “KM Pipeline Employee” means any full-time, part-time, or contract Person (i) employed by Respondent at any time from the date Respondent signs the Consent Agreement, and (ii) whose job responsibilities primarily relate to the KM Pipeline Business.
- U. “KMPB License” means (i) a worldwide, royalty-free, paid-up, perpetual, irrevocable, transferable, sublicensable, non-exclusive license under all Intellectual Property relating to operation of the KM Pipeline Business other than Intellectual Property already included in the KM Pipeline Assets; and (ii) such tangible embodiments of the licensed rights (including but not limited to physical and electronic copies) as may be necessary or appropriate to enable an Acquirer to use the rights.
- V. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization, or other business entity.

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- W. “Tangible Personal Property” means all machinery, equipment, tools, furniture, office equipment, computer hardware, supplies, materials, vehicles, rolling stock, and other items of tangible personal property (other than inventories) of every kind owned or leased by Kinder Morgan, together with any express or implied warranty by the manufacturers or sellers or lessors of any item or component part thereof and all maintenance records and other documents relating thereto.
- X. “Transitional Assistance” means any (i) administrative assistance (including, but not limited to, order processing, shipping, accounting, and information transitioning services) or (ii) technical assistance with respect to the provision of natural gas transportation, processing, storage, and pipeline operating services.

**II.****IT IS FURTHER ORDERED** that:

- A. Respondent shall divest the KM Pipeline Assets at no minimum price, absolutely and in good faith, as an on-going business, no later than 180 days from the Acquisition Date, to an Acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission.
- B. No later than the Divestiture Date, Respondent shall:
1. Grant to the Acquirer a KMPB License for any use in any business, and shall take all actions necessary to facilitate the unrestricted use of the license; and
  2. Secure all consents, assignments, and waivers from all Persons that are necessary for the divestiture of such business or assets to the Acquirer.
- C. In the event Respondent is unable to obtain any consents, licenses, certificates, registrations, permits, or other authorizations granted by:

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1. Any governmental entity that are necessary to operate the KM Pipeline Assets, Respondent shall provide such assistance as Acquirer may reasonably request in Acquirer's efforts to obtain a comparable authorization; and
  2. Any other Person that are necessary to divest the KM Pipeline Assets, Respondent shall, with the acceptance of Acquirer and the prior approval of the Commission, substitute equivalent assets or arrangements.
- D. At the request of the Acquirer, pursuant to an agreement that receives the prior approval of the Commission, Respondent shall, for a period not to exceed nine (9) months from the date Respondent divests the KM Pipeline Assets, provide Transitional Assistance to the Acquirer:
1. Sufficient to enable the Acquirer to operate the divested assets and business in substantially the same manner that Respondent conducted the divested assets and business prior to the divestiture; and
  2. At substantially the same level and quality as such services are provided by Respondent in connection with its operation of the divested assets and business prior to the divestiture.

*Provided, however,* that Respondent shall not (i) require the Acquirer to pay compensation for Transitional Assistance that exceeds the Direct Cost of providing such goods and services, (ii) terminate its obligation to provide Transitional Assistance because of a material breach by the Acquirer of any agreement to provide such assistance, in the absence of a final order of a court of competent jurisdiction, or (iii) seek to limit the damages (such as indirect, special, and consequential damages) which an Acquirer would be entitled to receive in the event of Respondent's breach of any agreement to provide Transitional Assistance.

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*Provided further*, that, if Respondent provides Transitional Assistance pursuant to this Paragraph II.D., Respondent shall have no role in negotiating or setting rates, terms, or conditions of service, making expansion or interconnection decisions, or marketing any services relating to the transportation of natural gas (or related products) through each of the Interstate Pipeline Systems; *provided, however*, that Respondent, in providing Transitional Assistance may assist in submitting any necessary regulatory filings and facilitating expansions or interconnections.

- E. From the date Respondent executes the Consent Agreement, Respondent shall provide a proposed Acquirer with the opportunity to recruit and employ any KM Pipeline Employee in conformance with the following:
1. No later than ten (10) days after a request from a proposed Acquirer, or staff of the Commission, Respondent shall provide a proposed Acquirer with the following information for each KM Pipeline Employee, as and to the extent permitted by law:
    - a. name, job title or position, date of hire and effective service date;
    - b. a specific description of the employee's responsibilities;
    - c. the base salary or current wages;
    - d. the most recent bonus paid, aggregate annual compensation for Respondent's last fiscal year and current target or guaranteed bonus, if any;
    - e. employment status (*i.e.*, active or on leave or disability; full-time or part-time);
    - f. any other material terms and conditions of employment in regard to such employee that

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are not otherwise generally available to similarly-situated employees; and

- g. at a proposed Acquirer's option, copies of all employee benefit plans and summary plan descriptions (if any) applicable to the relevant KM Pipeline Employee(s).
2. No later than ten (10) days after a request from a proposed Acquirer, Respondents shall provide the proposed Acquirer with (i) an opportunity to meet, personally and outside the presence or hearing of any employee or agent of the Respondent, with any KM Pipeline Employee, (ii) an opportunity to inspect the personnel files and other documentation relating to any such employee, to the extent permissible under applicable laws, and (iii) to make offers of employment to any KM Pipeline Employee.
3. Respondent shall (i) not interfere, directly or indirectly, with the hiring or employing by a proposed Acquirer of any KM Pipeline Employee, (ii) not offer any incentive to any KM Pipeline Employee to decline employment with a proposed Acquirer, (iii) not make any counteroffer to any KM Pipeline Employee who receives a written offer of employment from a proposed Acquirer; *provided, however*, that nothing in this Order shall be construed to require Respondent to terminate the employment of any employee or prevent Respondent from continuing the employment of any employee; and (iv) remove any impediments within the control of Respondent that may deter any KM Pipeline Employee from accepting employment with a proposed Acquirer, including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts with Respondent that would affect the ability of such employee to be employed by a proposed Acquirer.

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4. Respondent shall provide each KM Key Employee to whom the Acquirer has made a written offer of employment with a financial incentive to accept a position with the Acquirer at the time of divestiture of the KM Pipeline Assets, pursuant to the terms set forth in Confidential Appendix A attached to this Order.
- F. For a period of two (2) years after the Divestiture Date, Respondent shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any KM Pipeline Employee who has accepted an offer of employment with an Acquirer, or who is employed by an Acquirer, to terminate his or her employment relationship with an Acquirer; *provided, however*, the Respondent may:
1. Advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, so long as these actions are not targeted specifically at any KM Pipeline Employees; and
  2. Hire KM Pipeline Employees who apply for employment with Respondent, so long as such individuals were not solicited by the Respondent in violation of this paragraph; *provided further*, that this sub-Paragraph shall not prohibit the Respondent from making offers of employment to or employing any KM Pipeline Employees if an Acquirer has notified the Respondent in writing that an Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer, or where the individual's employment has been terminated by an Acquirer.
- G. In the event that the employee listed in Confidential Appendix B attached to this Order ("Excluded Employee") continues his employment with Respondent after the Acquisition Date, then Respondent is prohibited from assigning the Excluded

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Employee any work relating to, and shall assure that he is not involved with the operation or management of, the El Paso Rockies Pipeline Business until after the Divestiture Date; *provided, however*, that nothing herein shall prohibit a proposed Acquirer from making an offer of employment to or employing the Excluded Employee pursuant to the provisions of Paragraph II.E. of this Order; *provided further*, that the prohibitions in this Paragraph may terminate prior to the Divestiture Date if a proposed Acquirer has notified the Respondent in writing that the proposed Acquirer does not intend to make an offer of employment to the Excluded Employee and that the proposed Acquirer has no objection to the Excluded Employee engaging in work relating to the operation or management of the El Paso Rockies Pipeline Business prior to the Divestiture Date.

- H. The purpose of the divestiture of the KM Pipeline Assets is to ensure the continued use of the assets in the same businesses in which such assets were engaged at the time of the announcement of the Acquisition by Respondent and to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint.

**III.****IT IS FURTHER ORDERED** that:

- A. Respondent's employees shall not receive, have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the KM Pipeline Assets or the KM Pipeline Business except in the course of:
1. Performing their obligations as permitted under this Order or the Hold Separate Order;
  2. Performing their obligations under any Divestiture Agreement; or

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3. Complying with financial reporting requirements, obtaining legal advice, defending legal claims, investigations, or enforcing actions threatened or brought against the KM Pipeline Assets and KM Pipeline Business, or as required by law.

For purposes of this Paragraph III.A., Respondent's employees who provide Support Services under the Hold Separate Order or staff the Hold Separate Business shall be deemed to be performing obligations under the Hold Separate Order.

- B. If the receipt, access to, use, or disclosure of Confidential Business Information pertaining to the KM Pipeline Assets or the KM Pipeline Business is permitted to
- C. Respondent's employees under Paragraph III.A. of this Order, Respondent shall limit such information (i) only to those Persons who require such information for the purposes permitted under Paragraph III.A., (ii) only to the extent such Confidential Business Information is required, and (iii) only after such Persons have signed an appropriate agreement in writing to maintain the confidentiality of such information.
- D. Respondent shall enforce the terms of this Paragraph III. as to any Person other than the Acquirer of the KM Pipeline Assets and take such action as is necessary to cause each such Person to comply with the terms of this Paragraph III., including training of Respondent's employees and all other actions that Respondent would take to protect its own trade secrets and proprietary information.

**IV.**

**IT IS FURTHER ORDERED** that:

- A. If Respondent has not divested all of the KM Pipeline Assets and otherwise fully complied with the obligations as required by Paragraph II.A. of this

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Order, the Commission may appoint a Divestiture Trustee to divest the KM Pipeline Assets and/or perform Respondent's other obligations in a manner that satisfies the requirements of this Order. The Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Hold Separate Trustee pursuant to the relevant provisions of the Hold Separate Order.

- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(l) of the Federal Trade Commission Act, 15 U.S.C. § 45(l), or any other statute enforced by the Commission, Respondent shall consent to the appointment of a Divestiture Trustee in such action to divest the relevant assets in accordance with the terms of this Order. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to § 5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by the Respondent to comply with this Order.
- C. The Commission shall select the Divestiture Trustee, subject to the consent of Respondent, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent has not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondent of the identity of any proposed Divestiture Trustee, Respondent shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- D. Within ten (10) days after appointment of a Divestiture Trustee, Respondent shall execute a trust agreement that, subject to the prior approval of the Commission,

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transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or transfer required by the Order.

- E. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, Respondent shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver, or otherwise convey the relevant assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered, or otherwise conveyed.
  2. The Divestiture Trustee shall have twelve (12) months from the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the twelve (12) month period, the Divestiture Trustee has submitted a plan of divestiture or believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission, or in the case of a court-appointed Divestiture Trustee, by the court.
  3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records, and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered, or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as the Divestiture Trustee may request and shall

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cooperate with the Divestiture Trustee. Respondent shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondent shall extend the time for divestiture under this Paragraph IV in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable best efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondent's absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however,* if the Divestiture Trustee receives bona fide offers from more than one acquiring entity, and if the Commission determines to approve more than one such acquiring entity, the Divestiture Trustee shall divest to the acquiring entity selected by Respondent from among those approved by the Commission; *provided further, however,* that Respondent shall select such entity within five (5) days of receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses

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incurred. After approval by the Commission and, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for the Divestiture Trustee's services, all remaining monies shall be paid at the direction of the Respondent, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence or willful misconduct by the Divestiture Trustee. For purposes of this Paragraph IV.E.6., the term "Divestiture Trustee" shall include all Persons retained by the Divestiture Trustee pursuant to Paragraph IV.E.5. of this Order.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order.
8. The Divestiture Trustee shall report in writing to Respondent and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondent may require the Divestiture Trustee and each of the Divestiture Trustee's consultants,

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accountants, attorneys, and other representatives and assistants to sign a customary confidentiality agreement; *provided, however*, such agreement shall not restrict the Divestiture Trustee from providing any information to the Commission.

- F. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph IV.
- G. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

**V.****IT IS FURTHER ORDERED** that:

- A. The Divestiture Agreement shall not limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of the Respondent under such agreement.
- B. The Divestiture Agreement shall be incorporated by reference into this Order and made a part hereof.
- C. Respondent shall comply with all provisions of the Divestiture Agreement, and any breach by Respondent of any term of such agreement shall constitute a violation of this Order. If any term of the Divestiture Agreement varies from the terms of this Order (“Order Term”), then to the extent that Respondent cannot fully comply with both terms, the Order Term shall determine Respondent’s obligations under this Order. Any failure by the Respondent to comply with any

## Decision and Order

term of such Divestiture Agreement shall constitute a failure to comply with this Order.

- D. Respondent shall not modify or amend any of the terms of the Divestiture Agreement without the prior approval of the Commission.

**VI.****IT IS FURTHER ORDERED** that:

- A. Within thirty (30) days after the date this Order becomes final and every thirty (30) days thereafter until Respondent has fully complied with the provisions of Paragraph II of this Order, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with this Order and the Hold Separate Order. Respondent shall include in its compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with this Order and the Hold Separate Order, including a description of all substantive contacts or negotiations relating to the divestiture and approval, and the identities of all parties contacted. Respondent shall include in its compliance reports copies, other than of privileged materials, of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning the divestiture and approval, and, as applicable, a statement that any divestiture approved by the Commission has been accomplished, including a description of the manner in which Respondent completed such divestiture and the date the divestiture was accomplished.
- B. One (1) year after the date this Order becomes final and annually thereafter until this Order terminates, and at such other times as the Commission may request, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and

## Decision and Order

form in which it has complied and is complying with this Order and any Divestiture Agreement.

**VII.**

**IT IS FURTHER ORDERED** that Respondent shall notify the Commission at least thirty (30) days prior to any proposed:

- A. dissolution of Respondent;
- B. acquisition, merger, or consolidation of Respondent; or
- C. any other change in the Respondent, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

**VIII.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent, with respect to any matter contained in this Order, Respondent shall permit any duly authorized representative of the Commission:

- A. Access, during office hours and in the presence of counsel, to all facilities and access to inspect and copy all non-privileged books, ledgers, accounts, correspondence, memoranda and other records and documents in the possession or under the control of Respondent related to compliance with the Consent Agreement and/or this Order and the Hold Separate Order, which copying services shall be provided by Respondent at the request of the authorized representative of the Commission and at the expense of Respondent;
- B. Upon five (5) days' notice to Respondent and without restraint or interference from them, to interview officers, directors, or employees of Respondent, who may have counsel present.

## Analysis to Aid Public Comment

**IX.**

**IT IS FURTHER ORDERED** that this Order shall terminate when all of the obligations of the Divestiture Agreement required in Paragraph II. or Paragraph IV. of this Order have been accomplished.

By the Commission, Commissioner Ramirez recused.

**Confidential Appendix A**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**Confidential Appendix B**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC  
COMMENT****I. Introduction**

The Federal Trade Commission (the “Commission”), subject to its final approval, has accepted for public comment an Agreement Containing Consent Orders (Consent Agreement) with

## Analysis to Aid Public Comment

Kinder Morgan, Inc. (“KMI” or “Respondent”) and El Paso Corporation (“El Paso”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that otherwise would likely result from Respondent’s acquisition of El Paso. Under the terms of the agreement, Respondent will divest its own Rockies Express (REX), Kinder Morgan Interstate Gas Transmission, and Trailblazer pipelines, as well as associated processing and storage capacity.

On October 16, 2011, KMI announced that it had entered into a definitive agreement whereby KMI will acquire all of the outstanding shares of El Paso for approximately \$38 billion, including the assumption of \$17 billion in debt (the “Acquisition”). The Acquisition would combine the nation’s largest two natural gas pipeline owners. Separately from any Commission action, El Paso will sell its exploration and production (“E&P”) assets to another company, delivering its midstream components and the proceeds from the E&P sale to KMI.

Without some form of relief, the Acquisition is likely to result in anticompetitive effects in areas in the Rocky Mountains where the combination of the KMI pipelines and the El Paso pipelines threatens to lessen competition substantially in pipeline transportation. The Acquisition is also likely to result in anticompetitive effects in other markets related to pipelines: gas processing and “no-notice” service. The proposed Consent Agreement effectively remedies these possible anticompetitive effects by requiring KMI to divest three of its natural gas pipelines and two natural gas processing plants.

## **II. The Parties**

### **A. Kinder Morgan, Inc.**

KMI is a publicly traded corporation principally engaged in midstream petroleum and natural gas services. KMI is the general partner in the master-limited partnership (“MLP”) Kinder Morgan Energy Partners (KMEP) (collectively, “Kinder Morgan”). KMEP owns over 38,000 miles of pipelines and 180 terminals in North America for the transportation and storage of natural gas, refined petroleum products, crude oil, and carbon dioxide.

## Analysis to Aid Public Comment

**B. El Paso Corporation**

El Paso is a publically traded corporation principally engaged in natural gas transportation, natural gas gathering and processing, and E&P. El Paso is the general partner in the MLP, El Paso Pipeline Partners (EPPP), into which El Paso placed some of its pipelines. Between El Paso and EPPP, El Paso owns or has interests in over 43,000 miles of natural gas pipelines and gathering systems.

**III. Market Structure and Competitive Effects in Pipeline Transportation**

Natural gas pipelines provide the critical connection between natural gas wells, which produce natural gas, and consumers who use natural gas to generate heat and power. Pipeline transportation is the only economical means to transport natural gas between the producers and consumers. Pipelines that cross state lines are regulated by the Federal Energy Regulatory Commission (“FERC”). FERC regulates maximum-allowable interstate natural gas pipeline transportation fees, but does not eliminate competition between pipelines. So long as the pipelines comply with their tariffs, they are otherwise free to compete by offering prices below their maximum tariff rate, as well as competing on other terms of service.

The competitive overlaps between Kinder Morgan and El Paso in pipeline transportation are in the Rocky Mountain gas production areas in and around Wyoming, Colorado, and Utah. Kinder Morgan and El Paso pipelines dominate the transportation options for five production areas in the Rockies: (1) the Denver/Julesburg/Niobrara Production Basin; (2) the Powder River Production Basin; (3) the Wind River Production Basin; (4) the Western Wyoming Production areas including the Green River Production Basin, the Red Desert Production Basin, and the Washakie Production Basins; and (5) the Piceance Production Basin. Each of these production areas is a relevant geographic market for the transportation of natural gas.

Production areas are connected to more than one pipeline and some pipelines connect to more than one production area. Some pipelines do not connect directly to the basins but interconnect

## Analysis to Aid Public Comment

with the pipelines leaving the basins and are necessary to get natural gas from the basins to consuming markets. There are four Kinder Morgan pipelines that serve the basins and interconnections in the Rockies and four El Paso pipelines that serve those same basins and interconnections.

In each of these relevant geographic markets, the pipeline transportation of natural gas is highly concentrated. The Acquisition would significantly increase concentration and eliminate direct competition between the pipelines owned by the two companies, leading to higher prices for pipeline transportation of natural gas to the detriment of producers and consumers of natural gas.

One consumption area in the Rockies is also a relevant geographic market. The Colorado Front Range, which runs from Fort Collins, Colorado in the north to Pueblo, Colorado in the south, contains the major population centers in the Rockies. It overlaps the Denver/

Julesburg/Niobrara Production Basin but requires substantial additional natural gas from the other production areas in the Rockies, particularly in the winter. The pipeline transportation of natural gas into this market from the other production areas is highly concentrated. The Acquisition would significantly increase concentration and eliminate direct and potential competition between the pipelines owned by the two companies, leading to higher prices for pipeline transportation of natural gas to the detriment of consumers of natural gas along the Colorado Front Range.

#### **IV. Other Markets Impacted by the Proposed Acquisition**

Two other markets, the processing of natural gas and the provision of no-notice pipeline transportation services, would also be impacted by the Acquisition. Both services are related to the pipeline transportation of natural gas.

Natural gas must meet certain standards before an interstate pipeline can accept it. In some areas, natural gas contains heavy hydrocarbons, commonly referred to as natural gas liquids or NGLs. Interstate pipelines have a limit on how much NGLs

## Analysis to Aid Public Comment

natural gas can contain and be transported on a pipeline. Gas that contains excessive amounts of NGLs must be treated at a gas processing plant to remove those liquids before it can be transported on interstate pipelines. Currently, the high value of NGLs, relative to the natural gas, would cause the gas to be processed regardless of the specifications of the pipelines. There is no substitute for gas processing to remove the NGLs. The relevant geographic market for processing gas is in the Wind River Production Basin and surrounding areas. For some wells in areas around that basin, only El Paso and Kinder Morgan have processing plants to treat gas before it goes onto interstate pipelines. The Acquisition would eliminate direct competition between the processing plants owned by the two companies, leading to higher prices for gas processing to the detriment of producers of natural gas.

No-notice service is also a relevant market. Interstate pipelines typically require advance notice before a customer transports gas on a pipeline. Some customers' demand for natural gas fluctuates so much that the customers cannot give the required notice to the pipeline and still obtain the natural gas that they need. No-notice service is the term that refers to gas transportation where the customer is not obligated to provide advance notice before shipping gas. Utility customers whose natural gas demand can shift suddenly due to changes in the weather often require no-notice service. No-notice service is provided by pipelines at a premium price. It is not economical for each utility that has need for no-notice service to build sufficient storage to meet all of its peak needs through building its own storage facility. Many utilities are dependent on pipeline companies to provide no-notice service utilizing pipeline owned or third party storage. The relevant geographic market for no-notice service is the Colorado Front Range. Only those pipelines that currently serve this area can offer no-notice service. Currently only El Paso offers no-notice service in that area, but Kinder Morgan is a likely potential entrant into the market. The acquisition by Kinder Morgan of El Paso would eliminate potential competition for no-notice service to the detriment of utility customers.

## Analysis to Aid Public Comment

**V. The Agreement Containing Consent Orders**

Under the Agreement Containing Consent Orders (the “Consent Order”) Kinder Morgan has 180 days from the closing date of its acquisition of El Paso to completely divest three KMI pipelines and two processing plants in the Rockies. The fourth KMI pipeline, the TransColorado, does not raise competitive concerns because its competition with El Paso is limited and there are viable alternatives for transporting natural gas from the San Juan Basin. Accordingly, the TransColorado was not included in the divested assets. These divestitures maintain the competitive status quo ante in the Rockies. Pursuant to the Consent Order, Kinder Morgan may complete its acquisition of El Paso, while the divestiture of pipelines and processing plants already owned by Kinder Morgan will maintain the level of competition that already existed. The Order to Hold Separate and Maintain Assets (discussed in the next section) will protect the competitive status quo until Kinder Morgan successfully finds a buyer for the assets to be divested.

The Consent Order requires Kinder Morgan to provide transitional assistance and support services to the buyer of the divested services. Kinder Morgan must also license any key software and intellectual property to the buyer. The Consent Order allows the buyer to recruit Kinder Morgan employees who work on the divested assets. For a period of two years, Kinder Morgan may not solicit employees that accept employment offers from the buyer to rejoin Kinder Morgan. The Consent Order also limits Kinder Morgan’s access to, and use of, confidential business information pertaining to the divestiture assets.

If Kinder Morgan fails to fully divest the assets within the 180-day time period, the Order grants the Commission power to appoint a divestiture trustee to complete the divestiture. The Consent Order also governs the divestiture trustee’s duties, privileges, and powers.

The Consent Order requires Kinder Morgan, or the divestiture trustee, if appointed, to file periodic reports detailing efforts to divest the assets and the status of that undertaking. Commission representatives may gain reasonable access to Kinder Morgan’s business records related to compliance with the consent

## Analysis to Aid Public Comment

agreement. The Consent Order terminates when all requirements of the divestiture order outlined in Paragraphs II and IV of the Consent Order are satisfied.

**VI. The Order To Hold Separate and Maintain Assets**

The Order to Hold Separate and Maintain Assets (“Hold Separate Order”) requires KMI to separate out the divestiture assets from its remaining businesses and assets. Pursuant to the Hold Separate Order, Kinder Morgan will not exercise any control or influence over the divestiture assets while seeking a buyer. The Hold Separate Order seeks to preserve the divestiture assets as viable, competitive, ongoing businesses, and it assures that Kinder Morgan does not access the confidential business information belonging to those businesses.

The Hold Separate Order also empowers the Commission to appoint a hold separate trustee to monitor the divestiture assets and requires the Respondent to appoint a hold separate manager, subject to approval of the hold separate trustee in concurrence with Commission staff, to manage day-to-day operations. The Hold Separate Order outlines the rights, duties, and responsibilities of both the trustee and the manager, including access to business records, hiring necessary consultants and attorneys, and any other thing reasonably necessary to carry out their duties. The hold separate manager reports to the hold separate trustee and not to Kinder Morgan.

The Hold Separate Order prohibits Kinder Morgan from interfering with the hold separate trustee and requires it to indemnify the trustee. The Hold Separate Order requires Kinder Morgan to provide certain support services and financial assistance to the divestiture assets to ensure they operate as they did before the merger.

The hold separate trustee must submit periodic reports to the Commission concerning compliance with the Hold Separate Order. The Commission may appoint a different hold separate trustee if the original trustee fails to carry out his duties. The hold separate manager has authority to hire staff, maintain the assets, continue on-going capital projects, and ensure employees of the

## Analysis to Aid Public Comment

divestiture assets are not involved in Kinder Morgan's other businesses.

The Hold Separate Order terminates either (1) one day after the divestiture is completed or (2) three business days after the Commission withdraws acceptance of the consent agreement.

**VII. Opportunity For Public Comment**

The proposed Consent Agreement has been placed on the public record for thirty (30) days for receipt of comments by interested persons. The Commission has also issued its Complaint in this matter. Comments received during this comment period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received and will decide whether it should withdraw from the Agreement or make final the Agreement's proposed Order.

By accepting the proposed Consent Agreement subject to final approval, the Commission anticipates that the competitive problems alleged in the Complaint will be resolved. The purpose of this analysis is to invite public comment on the proposed Order to aid the Commission in its determination of whether it should make final the proposed Order contained in the Agreement. This analysis is not intended to constitute an official interpretation of the proposed Order, nor is it intended to modify the terms of the proposed Order in any way.

## Complaint

## IN THE MATTER OF

**PERRIGO COMPANY**  
**AND**  
**PADDOCK LABORATORIES, INC.**

CONSENT ORDER, ETC. IN REGARD TO ALLEGED VIOLATIONS OF  
SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT AND  
SECTION 7 OF THE CLAYTON ACT

*Docket No. C-4329; File No. 111 0083*  
*Complaint, July 22, 2011 – Decision, June 21, 2012*

This consent order addresses the \$540 million acquisition by Perrigo Company of certain assets of Paddock Laboratories, Inc. The complaint alleges that the acquisition, if consummated, would violate Section 7 of the Clayton Act and Section 5 of the FTC Act by substantially lessening competition in the U.S. markets for the manufacture and sale of generic: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the “Products”); and (7) testosterone gel. The consent order requires the companies to divest Paddock’s rights and assets necessary to manufacture and market generic: (1) ammonium lactate external cream 12 percent (“ammonium lactate cream”); (2) ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”); (3) ciclopirox shampoo 1 percent (“ciclopirox shampoo”); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”) to Watson Pharmaceuticals, Inc. The consent order also requires the companies to divest all of Perrigo’s rights and assets necessary to manufacture and market generic clobetasol propionate spray 0.05 percent (“clobetasol spray”) and diclofenac sodium topical solution 1.5 percent (“diclofenac solution”) to Watson.

*Participants*

For the *Commission*: *Christine Palumbo, Susan Huber, and Aylin M. Skroejer.*

For the *Respondents*: *Scott A. Stempel, Morgan, Lewis & Bockius LLP; Garret G. Rasmussen, Orrick, Herrington & Sutcliffe LLP.*

**COMPLAINT**

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade

## Complaint

Commission (“Commission”), having reason to believe that Respondent Perrigo Company (“Perrigo”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire substantially all of the assets of Paddock Laboratories, Inc. (“Paddock”), a corporation subject to the jurisdiction of the Commission, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and it appearing to the Commission that a proceeding in respect thereof would be in the public interest, hereby issues its Complaint, stating its charges as follows:

**I. DEFINITIONS**

1. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Perrigo and Paddock, individually and collectively.

**II. RESPONDENTS**

4. Respondent Perrigo is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Michigan, with its headquarters address at 515 Eastern Avenue, Allegan, Michigan. Perrigo is engaged in the research, development, manufacture, and sale of generic pharmaceuticals.

5. Respondent Paddock is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its headquarters address at 3940 Quebec Avenue North, Minneapolis, Minnesota. Paddock is engaged in the research, development, manufacture, and sale of generic pharmaceuticals.

6. Respondents are, and at all times relevant herein have been, engaged in commerce, as “commerce” is defined in Section 1 of the Clayton Act as amended, 15 U.S.C. § 12, and are corporations whose businesses are in or affect commerce, as

## Complaint

“commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**III. PROPOSED ACQUISITION**

7. On January 20, 2011, Perrigo and Paddock entered into a Purchase Agreement whereby Perrigo proposes to acquire substantially all of the assets of Paddock in a transaction valued at approximately \$540 million (the “Acquisition”).

**IV. RELEVANT MARKETS**

8. For the purposes of this Complaint, the relevant lines of commerce in which to analyze the effects of the Acquisition are the manufacture and sale of the following generic pharmaceuticals:

- a. ammonium lactate external cream 12 percent (“ammonium lactate cream”);
- b. ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”);
- c. ciclopirox shampoo 1 percent (“ciclopirox shampoo”);
- d. promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”);
- e. clobetasol propionate spray 0.05 percent (“clobetasol spray”);
- f. diclofenac sodium topical solution 1.5 percent (“diclofenac solution”); and
- g. testosterone gel 1 percent (“testosterone gel”).

9. For the purposes of this Complaint, the United States is the relevant geographic area in which to analyze the effects of the Acquisition in the relevant lines of commerce.

## Complaint

**V. STRUCTURE OF THE MARKETS**

10. The ammonium lactate cream and lotion products are prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. The same firms compete in both markets – Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. (“Taro”), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo is the leading supplier in the U.S. market for ammonium lactate cream, with 70 percent of the market. In this market, the Acquisition would create a duopoly, with Perrigo accounting for approximately 87 percent. The Herfindahl-Hirschman Index (“HHI”) would increase by 2,380 points, resulting in a post-acquisition HHI of 7,714 points. Perrigo and Paddock are the leading suppliers of ammonium lactate lotion in the United States, with 43 percent and 50 percent of the market, respectively. The Acquisition would increase Perrigo’s market share to 93 percent and increase the HHI concentration by 4,300 points to 8,678 points.

11. Paddock leads the market for ciclopirox shampoo in the United States, with a share of 83 percent. Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Perrigo and E. Fougera & Co. are the only other U.S. suppliers of ciclopirox shampoo. After the Acquisition, Perrigo would control 99 percent of the market, and the HHI concentration would increase by 2,656 points to a post-acquisition HHI of 9,802 points.

12. The market for the manufacture and sale of promethazine suppository is also highly concentrated; Perrigo, Paddock, and G&W Laboratories, Inc. are currently the only U.S. suppliers. Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. The Acquisition would create a duopoly and increase Perrigo’s market share to 34 percent in the 12.5 mg strength, and to 35 percent in the 25 mg strength. The HHI would increase by 570 and 600 for the 12.5 mg and 25 mg strengths, resulting in post-acquisition HHIs of 5,512 and 5,450, respectively.

### Complaint

13. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Perrigo and Paddock are developing clobetasol sprays and are two of a limited number of suppliers capable of entering this future market in a timely manner.

14. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are in the process of entering the diclofenac solution market and are two of a limited number of suppliers capable of entering this future market in a timely manner.

15. Testosterone gel is a prescription gel used to treat adult males who have a deficiency or absence of testosterone. Abbott Laboratories (“Abbott”) currently markets testosterone gel under the Androgel brand name. Perrigo is one of a limited number of suppliers capable of entering this future market in a timely manner. Par Pharmaceutical Companies, Inc. has an agreement with Abbott relating to AndroGel that provides for Abbott to make substantial annual payments to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott’s and Perrigo’s ability to coordinate on delaying the introduction of Perrigo’s product into the market.

## **VI. ENTRY CONDITIONS**

16. Entry into each of the relevant markets described in Paragraph 8 would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and FDA approval requirements take a minimum of two years. Moreover, entry is not likely because the relevant markets are relatively small, limiting sales opportunities for any new potential entrant.

## **VII. EFFECTS OF THE ACQUISITION**

17. The effects of the Acquisition, if consummated, may be to substantially lessen competition and to tend to create a monopoly in the relevant markets in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, in the following ways, among others:

## Complaint

- a. by eliminating actual, direct, and substantial competition between Perrigo and Paddock in the markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository, thereby: (1) increasing the likelihood that Perrigo will be able to unilaterally exercise market power; (2) increasing the likelihood and degree of coordinated interaction between or among the remaining competitors; and (3) increasing the likelihood that customers would be forced to pay higher prices;
- b. by eliminating future competition between Perrigo and Paddock in the markets for clobetasol spray and diclofenac solution, thereby: (1) increasing the likelihood that the combined entity would forego or delay the launch of Perrigo's or Paddock's products in the markets; and (2) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's and Paddock's independent entry into the markets; and
- c. by (1) increasing the likelihood and degree of coordinated interaction between Perrigo and Abbott in the market for testosterone gel; (2) increasing the likelihood that the combined entity would forego or delay the launch of Perrigo's product in the testosterone gel market; and (3) increasing the likelihood that the combined entity would delay or eliminate the substantial additional price competition that would have resulted from Perrigo's independent entry into the testosterone gel market.

**VIII. VIOLATIONS CHARGED**

18. The Acquisition described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

19. The Acquisition described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the

## Order to Maintain Assets

Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

**WHEREFORE, THE PREMISES CONSIDERED**, the Federal Trade Commission on this twenty-second day of July, 2011, issues its Complaint against said Respondents.

By the Commission.

**ORDER TO MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Perrigo Company of substantially all of the assets and substantially all of the liabilities of Respondent Paddock Laboratories, Inc. (collectively “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing: an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint; a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true; and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents

## Order to Maintain Assets

have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having determined to accept the executed Consent Agreement and to place such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its Complaint, makes the following jurisdictional findings and issues this Order to Maintain Assets:

1. Respondent Perrigo Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan with its headquarters located at 515 Eastern Avenue, Allegan, Michigan 49010.
2. Respondent Paddock Laboratories, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota with its headquarters located at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Order to Maintain Assets, the following definitions and the definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), which are incorporated herein by reference and made a part hereof, shall apply:

- A. "Perrigo" means Perrigo Company, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company, and the

## Order to Maintain Assets

respective directors, officers, employees, agents, representatives, successors, and assigns of each.

- B. “Paddock” means Paddock Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Paddock , Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” mean Perrigo and Paddock, collectively and individually.
- D. “Watson” means Watson Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer(s)” means Watson or any other Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to the Decision and Order.
- G. “Acquisition” means the acquisition contemplated by the Purchase Agreement by and among Perrigo Company, Paddock Laboratories, Inc., Paddock Properties Limited Partnership and, solely for purposes of Section 11.15, the person set forth on Exhibit A, Dated as of January 20, 2011.
- H. “Acquisition Date” means the date the Respondents close on the Acquisition.
- I. “Closing Date” means the date on which Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Products Assets and

## Order to Maintain Assets

the Divestiture Products License to an Acquirer(s) pursuant to this Order.

- J. “Confidential Business Information” means information owned by, or in the possession or control of, Respondents that is not in the public domain.
- K. “Decision and Order” means the Decision and Order incorporated into and made a part of the Agreement Containing Consent Orders.
- L. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- M. “Monitor” means any monitor appointed pursuant to this Order or the related Decision and Order.
- N. “Orders” means this Order to Maintain Assets and the Decision and Order.
- O. “Proposed Acquirer” means Watson or any Person proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the Acquirer.

**II.**

**IT IS FURTHER ORDERED** that:

- A. Until Respondents complete the divestitures required by the Decision and Order, including transferring the Divestiture Products Assets and granting the Divestiture Products License(s), Respondents:
  - 1. Shall take such actions as are necessary to:
    - a. maintain the full economic viability and marketability of the Divestiture Products Businesses;

## Order to Maintain Assets

- b. minimize any risk of loss of competitive potential of the Divestiture Products Businesses;
  - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Divestiture Products Businesses;
  - d. ensure the Divestiture Products Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to any Divestiture Product;
  - e. ensure the completeness of the transfer and delivery of the Divestiture Products Manufacturing Technology; and
2. shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in the Orders) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Products Businesses,

*provided* that these obligations shall cease as to any particular Divestiture Product when Respondents have transferred to the Acquirer all assets and materials related to such product and have no further obligations regarding such product under any Contract Manufacturing Agreement.

B. Respondents shall:

1. not directly or indirectly use any Confidential Business Information related exclusively to one or more Divestiture Products other than as necessary to comply with the requirements of this Order, Respondents' obligations to the Acquirer under the terms of any Remedial Agreement, or applicable Law;

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2. not directly or indirectly disclose or convey any Confidential Business Information related exclusively to one or more Divestiture Products to any Person except the Acquirer or other Persons specifically authorized by the Acquirer to receive such information; and
  3. maintain the confidentiality of any Confidential Business Information related to one or more Divestiture Products with the same degree of care and protection as used to protect the Confidential Business Information of Respondents.
- C. The purpose of this Order is to maintain the full economic viability, marketability and competitiveness of the Divestiture Products Businesses through the full transfer and delivery of the Divestiture Products Assets and the Divestiture Products License to an Acquirer, to minimize any risk of loss of competitive potential for the Divestiture Products Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any assets included in the Divestiture Products Assets or Divestiture Products Licenses, except for ordinary wear and tear.

**III.****IT IS FURTHER ORDERED** that

- A. Until the Closing Date, Respondents shall provide all Divestiture Product Employees with reasonable financial incentives to continue in their positions and to continue the Divestiture Products Businesses in a manner consistent with past practices and/or as may be necessary to preserve the existing marketability, viability and competitiveness of the Divestiture Products and to ensure successful execution of the pre-Acquisition plans for such Divestiture Products. Such incentives shall include a continuation of all employee benefits offer by Respondents until the Closing Date, including regularly scheduled raises, bonuses, vesting of pension benefits (as permitted by Law), and

## Order to Maintain Assets

additional incentives as may be necessary to prevent any diminution of the competitiveness of the Divestiture Products.

- B. Until Respondent Perrigo fully transfers and delivers to the Acquirer the Divestiture Products Assets and grants the Divestiture Products License, Respondent Perrigo shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Products' last fiscal year
- C. For a period lasting until six (6) months after the Closing Date, each Respondent shall
  - 1. not later than ten (10) days after written request by the Acquirer or Proposed Acquirer, or staff of the Commission, provide, to the extent permitted by Law, the Acquirer with the following information with respect to Persons employed by such Respondent:
    - a. a complete and accurate list containing the name of each Divestiture Product Employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement); and
    - b. with respect to each such employee,
      - i. the date of hire and effective service date;
      - ii. job title or position held; and
      - iii. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal.

## Order to Maintain Assets

2. not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of any Divestiture Products Employees or make any counteroffer to a Divestiture Products Employee who has received a written offer of employment from an Acquirer or its Manufacturing Designee; and remove any impediments within the control of the Respondent that may deter a Divestiture Products Employee from accepting employment with an Acquirer or its Manufacturing Designee, including, but not limited to, removing non-competition or non-disclosure provisions of employment or other contracts with a Respondent that may affect the ability or incentive of a Divestiture Products Employee to be employed by an Acquirer or its Manufacturing Designee.
  3. if requested by a Divestiture Products Employee, provide such employee with any requested records concerning his or her salary and benefits, including but not limited to, his or her base salary or current wages; his or her most recent bonus paid, aggregate annual compensation for the relevant Respondents' last fiscal year and current target or guaranteed bonus (if any); any material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and copies of all employee benefit plans and summary plan descriptions (if any) applicable to such employee.
- D. For a period lasting until one (1) year after Closing Date, Respondents shall not:
1. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product (ACovered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or

## Order to Maintain Assets

## 2. hire such Covered Employee;

*provided, however,* Respondents may hire any former Covered Employee whose employment has been terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the terms of the Order; and

*provided further,* that Respondents may advertise for employees in newspapers, trade publications or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

**IV.****IT IS FURTHER ORDERED** that:

- A. The Commission may appoint a monitor or monitors (“Monitor”) to assure that Respondents expeditiously comply with all obligations and perform all responsibilities required by the Orders and the Remedial Agreements.
- B. The Commission appoints F. William Rahe as Monitor and approves the Monitor Agreement between F. William Rahe and Respondents, attached as Appendix A.
- C. The Monitor’s duties and responsibilities shall include the following:
  - 1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
  - 2. The Monitor shall have the power and authority to monitor Respondents’ compliance with the Orders, and shall exercise such power and authority and

## Order to Maintain Assets

carry out his or her duties and responsibilities in a manner consistent with the purposes of the Orders and in consultation with the Commission or its staff;

3. The Monitor shall, in his or her sole discretion, consult with Third Parties in the exercise of his or her duties under the Orders or any agreement between the Monitor and Respondents; and
  4. The Monitor shall evaluate the reports submitted to the Commission by Respondents pursuant to the Orders and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning performance by Respondents of its obligations under the Orders.
- D. Respondents shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including but not limited to the following:
1. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders;
  2. Subject to any demonstrated legally recognized privilege, Respondents shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with the Orders;
  3. Respondents shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to the Orders or the Consent Agreement;

## Order to Maintain Assets

4. The Monitor shall serve, without bond or other security, at the expense of Respondent Perrigo, on such reasonable and customary terms and conditions to which the Monitor and Perrigo agree and that the Commission approves;
5. The Monitor shall have authority to use the services of or employ, at the expense of Respondent Perrigo, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Respondents shall indemnify the Monitor and hold the Monitor harmless to the extent set forth in the Monitor Agreement executed on May 13, 2011; and
7. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement,

*provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to Respondents the substance of communications to or from the Commission or the Acquirer.

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.
- F. The Monitor shall serve until Respondents fully and finally transferred Divestiture Products Assets, granted the Divestiture Products License, and fulfilled all obligations under this Order to provide assistance, and

## Order to Maintain Assets

manufacture and supply the Contract Manufacture Products.

- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

**V.****IT IS FURTHER ORDERED** that:

- A. Before the Closing Date, Respondents shall submit to staff of the Commission a verified written report setting forth in detail the procedures Respondents have implemented to:
  - 1. reasonably ensure that all employees and representatives who have or may be exposed to Confidential Business Information understand and are required to comply with the confidentiality obligations contained in Paragraph II.B of this Order and Paragraph II.I of the Decision and Order; and

## Order to Maintain Assets

2. reasonably ensure that all employees and representatives of Respondents, including those hired during the term of the Order, understand and are required to comply with all terms of this Order that are relevant to their job duties.

In further compliance with this provision, Respondents shall provide staff of the Commission with written notice of all changes, additions and modifications to the procedures implemented, and shall include specific information detailing their efforts to comply with this paragraph in all reports of compliance required by this Order.

*provided, however,* that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

- B. Respondents shall submit to the Commission and to the Monitor, a verified written report setting forth in detail the manner and form in which it intends to comply, is complying, and has complied with the Orders, within thirty (30) days after the date this Order becomes final, and every sixty (60) days thereafter until the Decision and Order becomes final, and shall submit at the same time a copy of the report to the Monitor.

Respondents shall include in their compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Orders, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, and shall make available to the Commission and the Monitor all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations.

## Order to Maintain Assets

*provided, however,* that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

**VI.****IT IS FURTHER ORDERED** that:

- A. Each Remedial Agreement shall be incorporated by reference into this Order to Maintain Assets, and made a part hereof. Further, nothing in any Remedial Agreement shall limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of Respondents under a Remedial Agreement. Respondents shall comply with the terms of each Remedial Agreement, and a breach by Respondents of any term of a Remedial Agreement shall constitute a violation of the Orders. To the extent that any term of a Remedial Agreement conflicts with a term of the Orders such that Respondents cannot fully comply with both, Respondents shall comply with the Orders.
- B. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the full scope and breadth of Respondents' obligations to the Acquirer pursuant to the Orders.
- C. Prior to the Closing Date, Respondents shall not modify or amend any material term of any Remedial Agreement without the prior approval of the Commission. Further, any failure to meet any material condition precedent to closing contained in any Remedial Agreement (whether waived or not) shall constitute a violation of the Orders.
- D. After the Closing Date and during the term of each Remedial Agreement, Respondents shall provide written notice to the Commission not more than five

## Order to Maintain Assets

(5) days after any modification (material or otherwise) of the Remedial Agreement. Further, Respondents shall seek Commission approval of such modification (material or otherwise) within ten (10) days of filing such notification. If the Commission denies approval, the Commission will notify Respondents and Respondents shall expeditiously rescind the modification or make such other changes as are required by the Commission.

- E. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of the Orders or the remedial purposes thereof.

**VII.****IT IS FURTHER ORDERED** that

- A. For purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to any Respondents made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address, such Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:
1. access, during business office hours of such Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondents related to compliance with this Order, which copying services shall be provided by such Respondents at the request of the authorized representative(s) of

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the Commission and at the expense of such Respondents; and

2. to interview officers, directors, or employees of such Respondents, who may have counsel present, regarding such matters.

**VIII.**

**IT IS FURTHER ORDERED** that this Order shall terminate

- A. Three (3) days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 2.34, 16 C.F.R. § 2.34; or
- B. The day after the day the related Decision and Order becomes final and effective.

By the Commission.

**DECISION AND ORDER**  
**[Redacted Public Version]**

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Perrigo Company of substantially all of the assets and substantially all of the liabilities of Respondent Paddock Laboratories, Inc. (collectively “Respondents”), and Respondents having been furnished thereafter with a copy of a draft of Complaint that the Bureau of Competition proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge Respondents with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. §18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45; and

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Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing: an admission by Respondents of all the jurisdictional facts set forth in the aforesaid draft of Complaint; a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true; and waivers and other provisions as required by the Commission’s Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that Respondents have violated the said Acts, and that a Complaint should issue stating its charges in that respect, and having thereupon issued its Complaint and an Order to Maintain Assets, and having accepted the executed Consent Agreement and placed such Consent Agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having modified the Decision and Order in certain respects, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. §2.34, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent Perrigo Company is a corporation organized, existing and doing business under and by virtue of the laws of the State of Michigan with its headquarters located at 515 Eastern Avenue, Allegan, Michigan 49010.
2. Respondent Paddock Laboratories, Inc. is a corporation organized, existing and doing business under and by virtue of the laws of the State of Minnesota with its headquarters located at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427.
3. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

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**ORDER****I.**

**IT IS ORDERED** that, as used in the Order, the following definitions shall apply:

- A. “Perrigo” means Perrigo Company, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Perrigo Company, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Paddock” means Paddock Laboratories, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Paddock Laboratories, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” mean Perrigo and Paddock, collectively and individually.
- D. “Watson” means Watson Pharmaceuticals, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Nevada, with its headquarters address at 311 Bonnie Circle, Corona, California 92880.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquirer(s)” means Watson or any other Person approved by the Commission to acquire particular assets or rights that Respondents are required to assign, grant, license, divest, transfer, deliver, or otherwise convey pursuant to this Order.
- G. “Acquisition” means the acquisition contemplated by the Purchase Agreement by and among Perrigo

## Decision and Order

Company, Paddock Laboratories, Inc., Paddock Properties Limited Partnership and, solely for purposes of Section 11.15, the person set forth on Exhibit A, Dated as of January 20, 2011.

- H. “Acquisition Date” means the date the Respondents close on the Acquisition.
- I. “ANDA” means an abbreviated new drug application filed with the United States Food and Drug Administration (“FDA”), together with all revisions, supplements and amendments thereto.
- J. “Androgel Backup Supply Agreement” means the Backup Manufacturing and Supply Agreement, dated September 13, 2006, between Unimed Pharmaceuticals, Inc. and its Affiliates, Laboratoires Besins International S.A. and its Affiliates, and Par Pharmaceutical Companies, Inc. and its Affiliate, Par Pharmaceutical, Inc, including all amendments, exhibits, attachments, agreements, and schedules thereto, including, without limitation, the letter dated September 13, 2006, from Par Pharmaceutical Companies, Inc. to Paddock wherein Par designates Paddock as its Designee.
- K. “cGMP” means current Good Manufacturing Practice as set forth in the United States Federal Food, Drug, and Cosmetic Act, as amended, and includes all rules and regulations promulgated by the FDA thereunder.
- L. “Closing Date” means the date on which Respondents (or a Divestiture Trustee) consummate a transaction to assign, grant, license, divest, transfer, deliver, or otherwise convey the Divestiture Products Assets and the Divestiture Products License to an Acquirer(s) pursuant to this Order.
- M. “Confidential Business Information” means information owned by, or in the possession or control of, Respondents that is not in the public domain.

## Decision and Order

- N. “Contract Manufacture Agreement” means an agreement between Respondents and the Acquirer that has received prior approval of the Commission and by which Respondents shall manufacture or supply the Contract Manufactured Products to the Acquirer.
- O. “Contract Manufactured Products” means the Products manufactured, marketed or sold by Respondents pursuant to the following Product Approvals:
1. ANDA No. A090490 (generic shampoo with the active ingredient ciclopirox at a dosage strength of 1%);
  2. ANDA No. A040479 (generic rectal suppositories with the active ingredient promethazine hydrochloride in dosage strengths of 12.5 and 25 mg); and
  3. ANDA No. A075774 (generic external cream with the active ingredient ammonium lactate at a dosage strength of 12%); and
  4. ANDA No. A075570 (generic topical lotion with the active ingredient ammonium lactate at a dosage strength of 12%).
- P. “Direct Cost” means, with respect to a particular good or service Respondents are required to provide under the terms of this Order, i) the cost reflected or provided in a Remedial Agreement for the relevant good or service or, ii) if no cost is reflected or provided in a Remedial Agreement, the cost of labor, material, travel and other expenditures directly incurred to provide the relevant good or service. As used herein, the cost of labor for the use of the labor of an employee of Respondents shall not exceed the average hourly wage rate for such employee.
- Q. “Divestiture Products” means the Paddock Divestiture Products and the Perrigo ANDA Products.

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- R. “Divestiture Products Assets” means all of the Respondents’ rights, title and interest in all assets related to the Divestiture Products Businesses, to the extent legally transferable, including, without limitation, the following:
1. Product Applications related to one or more Divestiture Products and all Rights of Reference or Use to Drug Master Files related to such Product Applications;
  2. Product Approvals used in the Divestiture Products Businesses;
  3. Divestiture Products Marketing and Business Records;
  4. Divestiture Products Intellectual Property;
  5. Divestiture Products Manufacturing Technology;
  6. Divestiture Products Scientific and Regulatory Material;
  7. NDC Numbers used in the marketing and sale of a Divestiture Product (excluding the manufacturer’s FDA Labeler Code);
  8. At the Acquirer’s option, equipment used to manufacture one or more Divestiture Products to the extent such equipment is not readily available from a Third Party;
  9. At the Acquirer’s option, Divestiture Products Assumed Contracts, *provided, however*, that where a Divestiture Products Assumed Contract also relates to a Retained Product(s), Respondents shall assign the Acquirer all rights under the contract or agreement as are related to one or more Divestiture Products, but concurrently may retain similar rights for purposes related to any Retained Product(s); and

## Decision and Order

## 10. To the extent included in a Remedial Agreement:

- a. inventory in existence as of the Closing Date including, but not limited to, raw materials, packaging materials, work-in-process and finished goods related to any Divestiture Product;
- b. unfilled customer purchase orders (subject to any rights of the customer);

*provided, however,* that “Divestiture Products Assets” shall not include any real estate or the buildings or other permanent structures located on such real estate; or assets used, as of the Acquisition Date, in the Research and Development, manufacture, distribution, sale or marketing of one or more Retained Products.

## S. “Divestiture Products Assumed Contracts” means:

1. All contracts or agreements pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, one or more Divestiture Products from Respondents (unless such contract applies generally to such Respondents’ sales of Products to that Third Party);
2. All contracts or agreements pursuant to which Respondents purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) or component(s) from any Third Party for use in connection with the manufacture of one or more Divestiture Products;
3. All contracts or agreements pursuant to which any Third Party provides any services used in the Research and Development, submitting Product Applications or obtaining Product Approvals for any Divestiture Product; and

## Decision and Order

4. All contracts or agreements transferred, in whole or part, to an Acquirer pursuant to a Remedial Agreement.
- T. “Divestiture Products Businesses” means the Research and Development, manufacture, distribution, marketing and/or sale of the Paddock Divestiture Products and the Perrigo ANDA Products by Respondents.
- U. “Divestiture Products Employee(s)” means salaried employees of Respondents whose duties during the eighteen (18) month period immediately prior to the Closing Date, have related to the following (irrespective of the portion of working time involved and excluding employees whose participation consisted solely of oversight of legal, accounting, tax or financial compliance):
1. Research and Development of one or more Divestiture Products;
  2. The regulatory approval process for one or more Divestiture Products, including submitting Product Applications and obtaining and maintaining Product Approvals; or
  3. Manufacturing one or more Divestiture Products, including planning, design, implementation or operational management of Divestiture Products Manufacturing Technology.
- V. “Divestiture Products Intellectual Property” means all intellectual property owned or used by Respondents relating to one or more Divestiture Products, including Patents, copyrights (including the rights to all original works of authorship of any kind directly relating to the Divestiture Products or the Divestiture Products Businesses and any registration and applications for registrations thereof), Product Trademarks, product trade dress (including the current trade dress of each Divestiture Product including without limitation,

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Product packaging, and the lettering of the Product trade name), trade secrets, know-how, techniques, data, inventions, practices, methods, and other confidential or proprietary technical, business, Research and Development and other information and rights to obtain and file for patents and copyrights and registrations thereof;

*provided, however*, “Divestiture Products Intellectual Property” does not include the corporate names, copyrights or trade dress of “Perrigo” or “Paddock”, or any other corporations or companies owned or controlled by Respondents or the related logos thereof.

- W. “Divestiture Products License” means a perpetual, non-exclusive, fully paid-up and royalty-free license(s) with rights to sublicense to all Divestiture Products Intellectual Property, Divestiture Products Manufacturing Technology and Divestiture Products Marketing and Business Records not included in the Divestiture Products Assets,

*provided however*, that information relating solely to Retained Products shall be included in the Divestiture Products License solely to the extent such information cannot be segregated from information relating to one or more Divestiture Products in a manner that preserves the usefulness of the information relating to the Divestiture Products.

- X. “Divestiture Products Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary data and information (whether patented, patentable or otherwise) related to the manufacture of one or more Divestiture Products including, but not limited to, the following: all product specifications, processes, product designs, plans, trade secrets, ideas, concepts, manufacturing, engineering, and other manuals and drawings, standard operating procedures, flow diagrams, chemical, safety, quality assurance, quality control, research records, clinical data, compositions, annual product reviews, regulatory

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communications and filings or submissions, trending and other metric reports, control history, manufacturing batch records, current and historical information associated cGMP compliance, and labeling and all other information related to the manufacturing process, supplier lists, and other master documents necessary for the manufacture, control and release of a Divestiture Product that is owned or controlled by Respondents or which Respondents have the right to receive.

- Y. “Divestiture Products Marketing and Business Records” means all records, documents, books, files and other information in whatever format stored or used that are related to the Divestiture Products Businesses, including without limitation:
1. All marketing materials used specifically in the marketing or sale of one or more Divestiture Products as of the Closing Date, including, without limitation, all advertising materials, training materials, product data, mailing lists, sales materials (*e.g.*, detailing reports, vendor lists, sales data), marketing information (*e.g.*, competitor information, research data, market intelligence reports, statistical programs (if any) used for marketing and sales research), customer information (including customer net purchase information to be provided on the basis of either dollars and/or units for each month, quarter or year), sales forecasting models, educational materials, and advertising and display materials, speaker lists, promotional and marketing materials, website content and advertising and display materials, artwork for the production of packaging components, television masters and other similar materials related to one or more Divestiture Products; *excluding however*, the pricing of any Divestiture Products to customers;
  2. Website(s) related exclusively to one or more Divestiture Products, including the domain names

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(universal resource locators) and registration(s) thereof issued by any Person or authority that issues and maintains domain name registration for such websites, and copyrights to, and electronic files containing, all content available to or through such websites, *excluding, however*, (i) content not owned by Respondents for which Respondents cannot transfer rights to the Acquirer, (ii) trademarks and service marks other than the Product Trademarks required to be divested; and (iii) content not directly related to one or more Divestiture Products. The electronic files containing the relevant content shall be delivered in a format acceptable to the Acquirer; and

3. Copies of all unfilled customer purchase orders as of the Closing Date,

*provided, however*, that Divestiture Products Marketing and Business Records shall not include (1) documents relating to Respondents' general business strategies or practices, where such documents do not discuss with particularity any Divestiture Product; (2) administrative, financial, and accounting records; or (3) quality control records that are determined by the Monitor or the Acquirer not to be material to the manufacture of any Divestiture Product.

- Z. "Divestiture Products Scientific and Regulatory Material" means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory, and clinical trial materials and information related to one or more Divestiture Products that are owned and controlled by Respondents or which Respondents have a right to receive including, but not limited to:

1. Study reports related to one or more Divestiture Products, including pharmacokinetic study reports, bioavailability study reports (including reference listed drug information), and bioequivalence study reports (including reference listed drug information);

## Decision and Order

2. All communications with the FDA related to one or more Divestiture Products, including correspondence to Respondent(s) from the FDA and all filings, submissions and correspondence from a Respondent to the FDA relating to any Divestiture Product;
3. Annual and periodic reports related to any ANDA used in the Divestiture Products Businesses, including but not limited to, any safety update reports;
4. Product labeling, inserts and other information related to one or more Divestiture Products, including but not limited to,
  - a. FDA approved Product labeling,
  - b. currently used product package inserts (including historical change of control summaries),
  - c. FDA approved patient circulars and information related to one or more Divestiture Products;
5. Product recall reports filed with the FDA related to one or more Divestiture Products, and all reports, studies and other documents related to such recalls;
6. Adverse events/serious adverse event summaries related to one or more Divestiture Products;
7. Summaries of Product complaints
  - a. from physicians related to one or more Divestiture Products, and
  - b. from customers related to one or more Divestiture Products;

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8. Deviation reports, investigation reports and other investigational documents relating to one or more Divestiture Products, including but not limited to,
    - a. Out Of Specification (OOS) and Out Of Trend (OOT) reports,
    - b. Quality Control Data,
    - c. Field Alerts,
    - d. Change control history,
    - e. Information and data trending information, and
    - f. Rejects;
  9. Validation and qualification data and information, including but not limited to studies, protocols and reports;
  10. Reports, documents and information from all consultants or outside contractors engaged to investigate or perform special testing for the purpose of resolving product or process issues such as identification and sources of impurities;
  11. Reports of vendors of active pharmaceutical ingredients (“APIs”), excipients, packaging components and detergents as to specifications, degradation, chemical interactions, testing and historical trends; and
  12. Analytical methods development records.
- AA. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- BB. “Drug Master Files” means the information submitted to the FDA as described in 21 C.F.R. Part 314.420 related to a Product.

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- CC. “FDA” means United States Food and Drug Administration.
- DD. “Government Entity” means any Federal, state, local or non-U.S. government, or any court, legislature, government agency, or government commission, or any judicial or regulatory authority of any government.
- EE. “Holder of the Reference Testosterone Gel Product Approval” means: (1) the person that received FDA approval to market the Reference Testosterone Gel Product, (2) a person owning or controlling the ability to enforce the patent(s) listed in the FDA Publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with any NDA for the Reference Testosterone Gel Product , or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licenses, licensors, successors, and assigns of each of the foregoing.
- FF. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.
- GG. “Manufacturing Designee” means any Person other than Respondents that has been designated by an Acquirer to manufacture a Divestiture Product for that Acquirer.
- HH. “Manufacture” means to manufacture or have manufactured (independent of Respondents) a Product in commercial quantities and in a manner consistent with cGMP; and have secure sources of supply (from sources other than Respondents) of active pharmaceutical ingredients, excipients, other ingredients, and necessary components listed in the Products Application(s) for such Product.

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- II. “Monitor” means any monitor appointed pursuant to this Order or the related Order to Maintain Assets.
- JJ. “NDC Numbers” means the National Drug Code numbers, including both the manufacturer’s FDA labeler code and the additional numbers assigned by an Application holder as a product code for a specific Product.
- KK. “NDA” means a New Drug Application, as defined under 21 U.S.C. §355(b), including all changes or supplements thereto which do not result in the submission of a new NDA.
- LL. “NDA Holder” means: (1) the person that received FDA approval to market a Product pursuant to an NDA, (2) a person owning or controlling the ability to enforce the patent(s) listed in the FDA Publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with the NDA, or (3) the predecessors, subsidiaries, divisions, groups and affiliates controlled by, controlling, or under common control with any of the entities described in subparagraphs (1) and (2) above (such control to be presumed by direct or indirect share ownership of 50% or greater), as well as the licenses, licensors, successors, and assigns of each of the foregoing.
- MM. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.
- NN. “Orders” means this Decision and Order and the Order to Maintain Assets.
- OO. “Paddock Divestiture Products” means all Products in Research and Development, manufactured, marketed or sold by Respondent Paddock pursuant to the following Product Approvals:

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1. ANDA No. A090490 (generic shampoo with the active ingredient ciclopirox at a dosage strength of 1%);
  2. ANDA No. A040479 (generic rectal suppositories with active ingredient promethazine hydrochloride in dosage strengths of 12.5 and 25 mg);
  3. ANDA No. A076829 (generic external cream with the active ingredient ammonium lactate at a dosage strength of 12%); and
  4. ANDA No. A075575 (generic topical lotion with the active ingredient ammonium lactate at a dosage strength of 12%).
- PP. “Par” means Par Pharmaceutical Companies, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its principal executive offices at 300 Tice Boulevard, Woodcliff Lake, NJ 07677. For purposes of this Order, Par shall include any Person who succeeds Par as a party to the Relevant Toll Manufacturing Agreement.
- QQ. “Patents” means all patents, patent applications, including provisional patent applications, invention disclosures, certificates of invention and applications for certificates of invention and statutory invention registrations, in each case existing as of the Closing Date, and includes all reissues, additions, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, and all rights therein provided by international treaties and conventions, related to any Divestiture Product that is owned by Respondents as of the Closing Date.
- RR. “Perrigo ANDA Products” means the following Products in Research and Development by Respondent Perrigo:

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1. Products being developed pursuant to ANDA No. A091167 (generic spray with the active ingredient clobetasol at a dosage strength of .05%); and
  2. Products being developed as a generic equivalent to the brand-name product Pennsaid, a topical solution with the active ingredient diclofenac sodium at a dosage strength of 1.5% that is approved by the FDA under the New Drug Application (NDA) 020947.
- SS. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.
- TT. “Product(s)” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.
- UU. “Product Application(s)” means ANDAs and other submissions to any national, international or local governmental regulatory authority for approvals, registrations, permits, licenses, consents, authorizations, or other approvals to research, develop, manufacture, distribute, finish, package, market, sell, store or transport a Product, together with all supplements, amendments, and revisions to such submissions, all preparatory work, drafts and data necessary for the preparation of such submissions, and all correspondence between Respondents and the relevant national, international or local governmental authority relating to such submissions.
- VV. “Product Approval(s)” means all approvals, registrations, permits, licenses, consents, authorizations, and other approvals by any national, international or local governmental regulatory authority, to research, develop, manufacture,

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distribute, finish, package, market, sell, store or transport a Divestiture Product, including without limitation, any ANDA approved by the FDA.

- WW. “Product Trademark(s)” means all proprietary names or designations, trademarks, service marks, trade names, and brand names, including registrations and applications for registration therefore (and all renewals, modifications, and extensions thereof) and all common law rights, and the goodwill symbolized thereby and associated therewith, for the Divestiture Product(s).
- XX. “Proposed Acquirer” means Watson or any Person proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the Acquirer.
- YY. “Relevant Testosterone Gel Application(s)” means ANDA No. 79015, ANDA No. 91006 and/or NDA No. 203098 (transdermal gel with the active ingredient testosterone at a dosage strength of 1%).
- ZZ. “Relevant Testosterone Gel Products” means all Products in Research and Development, manufactured, marketed or sold by Respondent Paddock pursuant to a Relevant Testosterone Gel Applications.
- AAA. “Reference Testosterone Gel Product” means any Product identified by a Respondent as the Product upon which Respondent bases a Relevant Testosterone Gel Application.
- BBB. “Relevant Toll Manufacturing Agreement” means Amended and Restated Manufacturing and Supply Agreement between Par Pharmaceuticals, Inc. and Paddock Laboratories LLC, dated July \_\_\_\_ 2011 (attached hereto as non-public Appendix B).

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- CCC. “Remedial Agreement(s)” means the following:
1. The Watson Remedial Agreements; or any other agreements between Respondents and an Acquirer (or between the Divestiture Trustee and an Acquirer) that have been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto, and/or
  2. Any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents related to a Divestiture Product for the benefit of an Acquirer that has been approved by the Commission to accomplish the requirements of this Order, including all amendments, exhibits, attachments, agreements, and schedules thereto.
- DDD. “Research and Development” means all preclinical and clinical drug development activities, including formulation, test method development and stability testing, toxicology, pharmacology, process development, manufacturing scale-up, development-stage manufacturing, quality assurance/quality control development, statistical analysis and report writing, conducting clinical trials for the purpose of obtaining any and all Product Approvals necessary for the manufacture, use, storage, import, export, transport, promotion, marketing, and sale of a Product (including any government price or reimbursement approvals); and registration and regulatory affairs related to the foregoing.
- EEE. “Retained Product” means any Product(s) other than a Divestiture Product.
- FFF. “Right of Reference or Use” means the authority to rely upon, and otherwise use, an investigation for the purpose of obtaining a Product Approval, including the ability to make available the underlying raw data from the investigation for FDA audit.

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- GGG. “Third Party(ies)” means any non-governmental Person other than Respondents or an Acquirer of the Divestiture Products Assets.
- HHH. “Watson Remedial Agreements” means all of the following agreements (attached hereto as non-public Appendix C):
1. “Asset Purchase Agreement” by and among Watson Pharmaceuticals, Inc. and Perrigo Company, dated as of May 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto; and
  2. “Manufacturing and Supply Agreement” Watson Pharmaceuticals, Inc. and Perrigo Company, dated as of May 16, 2011, and all amendments, exhibits, attachments, agreements, and schedules thereto.

**II.****IT IS FURTHER ORDERED** that:

- A. Not later than ten (10) days after the Acquisition Date, Respondents shall divest the Divestiture Products Assets and grant the Divestiture Products License, absolutely and in good faith, to Watson pursuant to, and in accordance with, the Watson Remedial Agreements;

*provided, however,* that if Respondents have divested the Divestiture Products Assets and granted the Divestiture Products License to Watson prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that Watson is not an acceptable purchaser of the Divestiture Products Assets, then Respondents shall immediately rescind the transaction with Watson, in whole or in part, as directed by the Commission, and shall divest the Divestiture Products Assets and grant the Divestiture Products License within one hundred eighty (180)

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days from the date this Order becomes final, absolutely and in good faith, at no minimum price, to an Acquirer or Acquirers that receive(s) the prior approval of the Commission, and only in a manner that receives the prior approval of the Commission;

*provided further*, that if Respondents have divested the Divestiture Products Assets and granted the Divestiture Products License to Watson prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Products Assets or grant of the Divestiture Products License, as applicable, to Watson (including, but not limited to, entering into additional agreements or arrangements) as the Commission may determine are necessary to satisfy the requirements of this Order.

- B. Prior to the Closing Date, Respondents shall secure all consents and waivers from all Third Parties that are necessary to permit Respondents to divest the Divestiture Products Assets and grant the Divestiture Products License to the Acquirer, and to permit the Acquirer to continue the Research and Development, manufacture, sale, marketing or distribution of the Divestiture Products;

*provided, however*, Respondents may satisfy this requirement by certifying that the Acquirer has executed all such agreements directly with each of the relevant Third Parties.

- C. Respondents shall deliver the materials to be divested and licensed pursuant to this Order to the Acquirer (or at the option of the Acquirer, the Acquirer's Manufacturing Designee) in an organized, comprehensive, complete, useful, timely (*i.e.*, ensuring

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no unreasonable delays in transmission), and meaningful manner.

D. Until Respondents complete the divestitures required by this Paragraph, including transferring the Divestiture Products Assets and granting the Divestiture Products License(s), Respondents:

1. shall take such actions as are necessary to:
  - a. maintain the full economic viability and marketability of the Divestiture Products Businesses;
  - b. minimize any risk of loss of competitive potential of the Divestiture Products Businesses;
  - c. prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets related to the Divestiture Products Businesses;
  - d. ensure the Divestiture Products Assets are provided to the Acquirer in a manner without disruption, delay, or impairment of the regulatory approval processes related to any Divestiture Product;
  - e. ensure the completeness of the transfer and delivery of the Divestiture Products Manufacturing Technology; and
2. shall not sell, transfer, encumber or otherwise impair the assets required to be divested (other than in the manner prescribed in this Order) nor take any action that lessens the full economic viability, marketability, or competitiveness of the Divestiture Products Businesses,

*provided* that these obligations shall cease as to any particular Divestiture Product when Respondents have

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transferred to the Acquirer all assets and materials related to such product and have no further obligations regarding such product under any Contract Manufacturing Agreement.

- E. Respondents shall provide the Acquirer(s) with the assistance and advice reasonably necessary to enable the Acquirer(s) to engage in the Divestiture Products Businesses in a manner at least consistent with the past practice and expertise of Respondents. The advice and assistance required by this provision shall be provided at no greater than Direct Cost and shall include, without limitation, the following:
1. Designating employees knowledgeable about the Divestiture Products Manufacturing Technology used to manufacture each Divestiture Product who will be responsible for communicating directly with the Acquirer or its Manufacturing Designee (if applicable) and the Monitor for the purpose of effectuating the terms of this Order, including but not limited to, assisting in the transfer of the Divestiture Products and resolving any issues related to Respondents' obligations under the Order;
  2. Preparing technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to each of the Divestiture Products that are acceptable to the Acquirer;
  3. Preparing and implementing a detailed technological transfer plan that contains, *inter alia*, the transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all Divestiture Products Manufacturing Technology (including all related intellectual property) to the Acquirer or its Manufacturing Designee;

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4. Making available to the Acquirer employees with knowledge of the Research and Development, manufacture, Product Applications and Product Approvals for the Divestiture Products; and
  5. Providing, in a timely manner, such other assistance and advice as is needed to enable the Acquirer or its Manufacturing Designee to:
    - a. manufacture each Divestiture Product in the quality and quantities achieved by the Respondents;
    - b. obtain any Product Approvals necessary for the Acquirer or its Manufacturing Designee, to manufacture, distribute, market, and sell each Paddock Divestiture Product in commercial quantities and to obtain all Product Approvals for each such Divestiture Product; and
    - c. receive, integrate, and use all Divestiture Products Manufacturing Technology and all Divestiture Products Intellectual Property.
- F. At the option of the Acquirer, Respondent Perrigo shall manufacture and supply the Contract Manufactured Products to the Acquirer pursuant to a Contract Manufacturing Agreement that is entered into on or before the Closing Date. This agreement shall be subject to the following:
1. Respondent Perrigo shall give priority to manufacturing and supplying the Contract Manufactured Products to the Acquirer over manufacturing and supplying Products for Respondents' own use or sale;
  2. Each Respondent shall represent and warrant to the Acquirer that it shall hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by that Respondent to perform the duties required of it under this Order,

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including, in the case of Respondent Perrigo, any failure to deliver the Contract Manufactured Products in a timely manner as required by the Contract Manufacture Agreement unless the Respondent can demonstrate that such failure was entirely beyond the control of the Respondent and in no part the result of negligence or willful misconduct by the Respondent;

*provided, however,* that the Contract Manufacture Agreement may contain limits on each Respondent's aggregate liability for such a breach;

3. With respect to any Contract Manufactured Products to be marketed or sold in the United States of America, Respondent Perrigo shall indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure of the Contract Manufactured Products to meet cGMP. Paddock shall indemnify, defend and hold the Acquirer harmless from any and all suits, claims, actions, demands, liabilities, expenses or losses alleged to result from the failure any of the Contract Manufactured Products, if any, that it manufactured to meet cGMP. This obligation may be made contingent upon the Acquirer giving Respondents prompt written notice of such claim and cooperating fully in the defense of such claim;

*provided,* that Respondents may reserve the right to control the defense of any such litigation, including the right to settle the litigation, so long as such settlement is consistent with Respondents' responsibilities to supply the ingredients and/or components in the manner required by this Order;

*provided, further,* that this obligation shall not require Respondents to be liable for any negligent act or omission of the Acquirer or for any representations and warranties, express or implied, made by the

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Acquirer that exceed the representations and warranties made by Respondents to the Acquirer;

*provided further* that the Contract Manufacture Agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Contract Manufactured Products to meet cGMP;

4. During the term of the Contract Manufacture Agreement, upon written request of the Acquirer or the Monitor (if any has been appointed), Respondents shall make available all data, information and records that relate to the manufacture of the Contract Manufactured Products generated or created after the Closing Date;
5. Respondent Perrigo shall maintain manufacturing facilities necessary to manufacture each Contract Manufactured Product in finished form, i.e., suitable for sale to the ultimate consumer/patient, until Respondent Perrigo has no further obligation to continue manufacture and supply of such product under the terms of this Order.
6. Respondent Perrigo shall continue to supply and manufacture a given Contract Manufactured Product until the earliest of the following:
  - a. Acquirer obtains all necessary Product Approvals to market and sell such Product in the United States and has the capability to Manufacture such Product using the same active pharmaceutical ingredients in all dosage strengths and presentations marketed and sold by Respondents, including without limitation, having all facilities, equipment, methods and processes qualified and validated for the Manufacture of such product; or
  - b. Acquirer notifies the Commission and Respondents of its intention to abandon its

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efforts to manufacture such Divestiture Product; or

- c. Staff of the Commission provides written notification to Respondents that the Monitor, in consultation with staff of the Commission, has determined that the Acquirer has abandoned its efforts to manufacture such Divestiture Product; or
- d. Eighteen (18) months after the Closing Date, *provided, however,* that the Monitor, in consultation with staff of the Commission, may, as necessary to fulfill the remedial purposes of this Order, authorize up to three six (6) month extensions of Respondents' obligation to manufacture and supply a Contract Manufactured Product.

G. With respect to all NDC Numbers (including FDA Labeler Codes) used in the Divestiture Products Businesses ("Former NDC Number(s)") Respondents shall:

1. not seek to have any customer cross-reference a Former NDC Number with an NDC Number for a Retained Product, and shall inform the Acquirer of any such cross-referencing that is discovered by Respondents;
2. not interfere with efforts by the Acquirer to have a customer cease cross-referencing a Former NDC Number with the NDC Number of a Retained Product;
3. not interfere with efforts by the Acquirer to have a customer cross-reference a Former NDC Number with the NDC Number used by the Acquirer for a Divestiture Product; and
4. pursuant to the manner and timing reflected in the Remedial Agreements,

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- a. discontinue the use of the Former NDC Numbers in the sale or marketing of the Divestiture Products except for returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Acquisition Date and except as may be required by applicable Law; and
  - b. obtain approval from the Acquirer for any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of the Former NDC Numbers by Respondents prior to such notification(s) being disseminated to the customer(s).
- H. Respondents shall include in a Remedial Agreement a representation from the Acquirer that such Acquirer shall use commercially reasonable efforts to secure the FDA approval(s) necessary to manufacture, or to have manufactured by a Third Party, in commercial quantities, each Divestiture Product and to have any such manufacture to be independent of Respondents, all as soon as reasonably practicable.
- I. Respondents shall:
1. not directly or indirectly use any Confidential Business Information related exclusively to one or more Divestiture Products other than as necessary to comply with the requirements of this Order, Respondents' obligations to the Acquirer under the terms of any Remedial Agreement, or applicable Law;
  2. not directly or indirectly disclose or convey any Confidential Business Information related exclusively to one or more Divestiture Products to any Person except the Acquirer or other Persons specifically authorized by the Acquirer to receive such information; and

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3. maintain the confidentiality of any Confidential Business Information related to one or more Divestiture Products with the same degree of care and protection as used to protect the Confidential Business Information of Respondents.
- J. Respondents shall not enforce any agreement against a Third Party or the Acquirer to the extent that such agreement may limit or otherwise impair the ability of the Acquirer to acquire or use any Divestiture Products Manufacturing Technology. Such agreements include, but are not limited to, agreements with respect to the disclosure of Confidential Business Information related to the Divestiture Products Manufacturing Technology. Further, not later than ten (10) days after the Closing Date, Respondents shall grant a release to each Third Party that is subject to an agreement as described in this paragraph, which release shall allow the Third Party to provide the relevant Divestiture Products Manufacturing Technology to the Acquirer. Within five (5) days of the execution of each such release, Respondents shall provide a copy of the release to such Acquirer.
- K. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the Acquirer for the Research and Development, manufacture, use, import, export, distribution, or sale of any Divestiture Product under any patents that
1. are owned or licensed by Respondents as of the day after the Acquisition Date that claim a method of making, using, or administering, or a composition of matter, relating to one or more Divestiture Products, or that claim a device relating to the use thereof; or
  2. are owned or licensed at any time after the Acquisition Date by Respondents that claim any aspect of Research and Development, manufacture, use, import, export, distribution, or sale of one or more Divestiture Products, other than such patents

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that claim inventions conceived by and reduced to practice after the Acquisition Date;

if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

Respondents shall also covenant to the Acquirer that as a condition of any assignment, transfer, or license to a Third Party of the Patents described in the immediately preceding paragraph, the Third Party shall agree to provide a covenant whereby the Third Party covenants not to sue the Acquirer under such patents, if such suit would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

- L. Upon reasonable written notice and request from an Acquirer to Respondent Perrigo, Respondent Perrigo shall provide, at no greater than Direct Cost, in a timely manner, assistance of knowledgeable employees of Respondent Perrigo to assist the Acquirer to defend against, respond to, or otherwise participate in any litigation related to the Divestiture Products Intellectual Property, if such litigation would have the potential to interfere with the Acquirer's freedom to practice the following: (1) Research and Development, or manufacture of one or more Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America.

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- M. For any patent infringement suit in which either Respondent is alleged to have infringed a Patent of a Third Party prior to the Closing Date where such a suit would have the potential to interfere with the Acquirer's freedom to practice the Research and Development, or manufacture of one or more Divestiture Products anywhere in the world; or the use, import, export, supply, distribution, or sale of one or more Divestiture Products within the territory of the United States of America, Respondents shall:
1. cooperate with the Acquirer and provide any and all necessary technical and legal assistance, documentation and witnesses from Respondents in connection with obtaining resolution of any pending patent litigation involving such Divestiture Product;
  2. waive conflicts of interest, if any, to allow the Respondents' outside legal counsel to represent the relevant Acquirer in any ongoing patent litigation involving such Divestiture Product; and
  3. permit the transfer to the Acquirer of all of the litigation files and any related attorney work-product in the possession of Respondents' outside counsel relating to such Divestiture Product.
- N. Respondents shall not, in the territory of the United States of America,
1. use the Product Trademarks contained in the Divestiture Products Intellectual Property or any mark confusingly similar to such Product Trademarks, as a trademark, trade name, or service mark;
  2. attempt to register such Product Trademarks;
  3. attempt to register any mark confusingly similar to such Product Trademarks;

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4. challenge or interfere with the Acquirer's use and registration of such Product Trademarks; or
5. challenge or interfere with the Acquirer's efforts to enforce its trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

*provided however*, that this paragraph shall not preclude Respondents from continuing to use all trademarks, trade names, or service marks that have been used in commerce on a Retained Product at any time prior to the Acquisition Date.

- O. The purpose of this Order is:
1. To ensure the continued use of Divestiture Products in the Divestiture Products Business independent of Respondents;
  2. To create a viable and effective competitor in the Divestiture Products Business that is independent of the Respondents; and
  3. To remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

**III.****IT IS FURTHER ORDERED** that

- A. Until the Closing Date, Respondents shall provide all Divestiture Product Employees with reasonable financial incentives to continue in their positions and to continue the Divestiture Products Businesses in a manner consistent with past practices and/or as may be necessary to preserve the existing marketability, viability and competitiveness of the Divestiture Products and to ensure successful execution of the pre-Acquisition plans for such Divestiture Products.

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- B. Until Respondent Perrigo fully transfers and delivers to the Acquirer the Divestiture Products Assets and grants the Divestiture Products License, Respondent Perrigo shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Products for the relevant Divestiture Products' last fiscal year.
- C. For a period lasting until six (6) months after the Closing Date, each Respondent shall
1. not later than ten (10) days after written request by the Acquirer or Proposed Acquirer, or staff of the Commission, provide, to the extent permitted by Law, the Acquirer with the following information with respect to Persons employed by such Respondent:
    - a. a complete and accurate list containing the name of each Divestiture Product Employee (including former employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement); and
    - b. with respect to each such employee,
      - i. the date of hire and effective service date;
      - ii. job title or position held; and
      - iii. a specific description of the employee's responsibilities related to the relevant Divestiture Product; *provided, however*, in lieu of this description, Respondents may provide the employee's most recent performance appraisal.
  2. not interfere with the hiring or employing by the Acquirer or its Manufacturing Designee of any Divestiture Products Employees or make any counteroffer to a Divestiture Products Employee

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who has received a written offer of employment from an Acquirer or its Manufacturing Designee; and remove any impediments within the control of the Respondent that may deter a Divestiture Products Employee from accepting employment with an Acquirer or its Manufacturing Designee, including, but not limited to, removing non-competition or non-disclosure provisions of employment or other contracts with a Respondent that may affect the ability or incentive of a Divestiture Products Employee to be employed by an Acquirer or its Manufacturing Designee.

3. if requested by a Divestiture Products Employee, provide such employee with any requested records concerning his or her salary and benefits, including but not limited to, his or her base salary or current wages; his or her most recent bonus paid, aggregate annual compensation for the relevant Respondents' last fiscal year and current target or guaranteed bonus (if any); any material terms and conditions of employment in regard to such employee that are not otherwise generally available to similarly situated employees; and copies of all employee benefit plans and summary plan descriptions (if any) applicable to such employee.

D. For a period lasting until one (1) year after Closing Date, Respondents shall not:

1. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer or its Manufacturing Designee with any amount of responsibility related to a Divestiture Product ("Covered Employee") to terminate his or her employment relationship with the Acquirer or its Manufacturing Designee; or
2. hire such Covered Employee;

*provided, however*, Respondents may hire any former Covered Employee whose employment has been

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terminated by the Acquirer or its Manufacturing Designee or who independently applies for employment with Respondents, as long as such employee was not solicited in violation of the terms of the Order; and

*provided further*, that Respondents may advertise for employees in newspapers, trade publications or other media not targeted specifically at Covered Employees; or hire a Covered Employee who contacts Respondents on his or her own initiative without any direct or indirect solicitation or encouragement from Respondents.

**IV.****IT IS FURTHER ORDERED** that:

- A. Respondents shall relinquish, at the Acquisition Date, all rights to receive, and shall not receive, the payment of any Service Fee (as that term is defined in the Androgel Backup Supply Agreement) that may accrue after the initial term of the Androgel Backup Supply Agreement, which ends September 30, 2012. Not later than ten (10) days after the Acquisition Date, Respondents shall provide written notice to Par that it relinquishes all rights to receive the payment of a Service Fee pursuant to this paragraph, and shall provide a copy of such written notice to the Commission and to the Monitor.
- B. For so long as an agreement for the actual or potential production by Perrigo of AndroGel remains in force under the Androgel Backup Supply Agreement, any extension of that agreement, or any new agreement, Respondents shall, after the Acquisition Date, not enter into any agreement with a Holder of the Reference Testosterone Gel Product Approval pursuant to which Respondents receive anything of value in exchange for their agreement to refrain from researching, developing, manufacturing, marketing or selling any Relevant Testosterone Gel Product, or

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taking any other action that otherwise deters, prevents, or inhibits Respondents' ability to manufacture, market or sell any Relevant Testosterone Gel Product immediately on or after the date Respondents receive Product Approval for such Relevant Testosterone Gel Product from the FDA; provided, however, that nothing in this paragraph shall prohibit a resolution or settlement of a patent infringement claim in which the consideration provided by the Holder of the Reference Testosterone Gel Product Approval to Respondents as part of the resolution or settlement includes only one or more of the following: (1) the right to market the Relevant Testosterone Gel Product in the United States prior to the expiration of (a) any patent that is the basis for the patent infringement claim, or (b) any patent right or other statutory exclusivity that would prevent the marketing of the Relevant Testosterone Gel Product; (2) a payment for reasonable litigation expenses not to exceed \$2,000,000; (3) a covenant not to sue on any claim that the Relevant Testosterone Gel Product infringes a United States patent.

- C. Respondents shall not modify or amend the Relevant Toll Manufacturing Agreement without the prior approval of the Commission.

**V.****IT IS FURTHER ORDERED** that:

- A. The Commission may appoint a monitor or monitors ("Monitor") to assure that Respondents expeditiously comply with all obligations and perform all responsibilities required by the Orders and the Remedial Agreements.
- B. The Commission appoints F. William Rahe as Monitor and approves the Monitor Agreement between F. William Rahe and Respondents, attached as Appendix A.

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- C. The Monitor's duties and responsibilities shall include the following:
1. The Monitor shall act in a fiduciary capacity for the benefit of the Commission;
  2. The Monitor shall have the power and authority to monitor Respondents' compliance with the Orders, and shall exercise such power and authority and carry out his or her duties and responsibilities in a manner consistent with the purposes of the Orders and in consultation with the Commission or its staff;
  3. The Monitor shall, in his or her sole discretion, consult with Third Parties in the exercise of his or her duties under the Orders or any agreement between the Monitor and Respondents; and
  4. The Monitor shall evaluate the reports submitted to the Commission by Respondents pursuant to the Orders and the Consent Agreement, and within thirty (30) days from the date the Monitor receives a report, report in writing to the Commission concerning performance by Respondents of its obligations under the Orders.
- D. Respondents shall grant and transfer to the Monitor, and such Monitor shall have, all rights, powers, and authority necessary to carry out the Monitor's duties and responsibilities, including but not limited to the following:
1. Respondents shall cooperate with any reasonable request of the Monitor and shall take no action to interfere with or impede the Monitor's ability to monitor Respondents' compliance with the Orders;
  2. Subject to any demonstrated legally recognized privilege, Respondents shall provide the Monitor full and complete access to personnel, books, documents, records kept in the ordinary course of

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business, facilities and technical information, and such other relevant information as the Monitor may reasonably request, related to Respondents' compliance with the Orders;

3. Respondents shall deliver to the Monitor a copy of each report submitted to the Commission pursuant to the Orders or the Consent Agreement;
4. The Monitor shall serve, without bond or other security, at the expense of Respondent Perrigo, on such reasonable and customary terms and conditions to which the Monitor and Respondent Perrigo agree and that the Commission approves;
5. The Monitor shall have authority to use the services of or employ, at the expense of Respondent Perrigo, such consultants, accountants, attorneys and other representatives and assistants as are reasonably necessary to carry out the Monitor's duties and responsibilities;
6. Respondents shall indemnify the Monitor and hold the Monitor harmless to the extent set forth in the Monitor Agreement executed on May 13, 2011; and
7. Respondents may require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement,

*provided, however,* that such agreement shall not restrict the Monitor from providing any information to the Commission or require the Monitor to report to Respondents the substance of communications to or from the Commission or the Acquirer.

- E. The Commission may, among other things, require the Monitor and each of the Monitor's consultants, accountants, attorneys and other representatives and assistants to sign an appropriate confidentiality

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agreement related to Commission materials and information received in connection with the performance of the Monitor's duties.

- F. The Monitor shall serve until Respondents fully and finally transferred Divestiture Products Assets, granted the Divestiture Products License, and fulfilled all obligations under this Order to provide assistance, and manufacture and supply the Contract Manufacture Products.
- G. If the Commission determines that the Monitor has ceased to act or failed to act diligently, the Commission may appoint a substitute Monitor. The Commission shall select the substitute Monitor, subject to the consent of Respondents, which consent shall not be unreasonably withheld. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed substitute Monitor within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed substitute Monitor, Respondents shall be deemed to have consented to the selection of the proposed substitute Monitor.
- H. The Commission may on its own initiative, or at the request of the Monitor, issue such additional orders or directions as may be necessary or appropriate to assure compliance with the requirements of the Order.
- I. The Monitor appointed pursuant to this Order may be the same Person appointed as a Divestiture Trustee pursuant to the relevant provisions of this Order.

**VI.****IT IS FURTHER ORDERED** that:

- A. If Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Products Assets and Divestiture Products License as required by

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this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey these assets in a manner that satisfies the requirements of this Order. In the event that the Commission or the Attorney General brings an action pursuant to §5(l) of the Federal Trade Commission Act, 15 U.S.C. §45(l), or any other statute enforced by the Commission, Respondents shall consent to the appointment of a Divestiture Trustee in such action to assign, grant, license, divest, transfer, deliver or otherwise convey these assets. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph shall preclude the Commission or the Attorney General from seeking civil penalties or any other relief available to it, including a court-appointed Divestiture Trustee, pursuant to §5(l) of the Federal Trade Commission Act, or any other statute enforced by the Commission, for any failure by Respondents to comply with this Order.

- B. The Commission shall select the Divestiture Trustee, subject to the consent of Respondents which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a Person with experience and expertise in acquisitions and divestitures. If Respondents have not opposed, in writing, including the reasons for opposing, the selection of any proposed Divestiture Trustee within ten (10) days after notice by the staff of the Commission to Respondents of the identity of any proposed Divestiture Trustee, Respondents shall be deemed to have consented to the selection of the proposed Divestiture Trustee.
- C. Not later than ten (10) days after the appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture required by this Order.

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- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph, Respondents shall consent to the following terms and conditions regarding the Divestiture Trustee's powers, duties, authority, and responsibilities:
1. Subject to the prior approval of the Commission, the Divestiture Trustee shall have the exclusive power and authority to assign, grant, license, divest, transfer, deliver or otherwise convey the assets that are required by this Order to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed.
  2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to accomplish the divestiture, which shall be subject to the prior approval of the Commission. If, however, at the end of the one (1) year period, the Divestiture Trustee has submitted a plan of divestiture or the Commission believes that the divestiture can be achieved within a reasonable time, the divestiture period may be extended by the Commission; *provided, however*, the Commission may extend the divestiture period only two (2) times.
  3. Subject to any demonstrated legally recognized privilege, the Divestiture Trustee shall have full and complete access to the personnel, books, records and facilities related to the relevant assets that are required to be assigned, granted, licensed, divested, delivered or otherwise conveyed by this Order and to any other relevant information, as the Divestiture Trustee may request. Respondents shall develop such financial or other information as the Divestiture Trustee may request and shall cooperate with the Divestiture Trustee. Respondents shall take no action to interfere with or impede the Divestiture Trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the

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time for divestiture under this Paragraph in an amount equal to the delay, as determined by the Commission or, for a court-appointed Divestiture Trustee, by the court.

4. The Divestiture Trustee shall use commercially reasonable efforts to negotiate the most favorable price and terms available in each contract that is submitted to the Commission, subject to Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to an Acquirer as required by this Order; *provided, however*, if the Divestiture Trustee receives bona fide offers from more than one acquiring Person, and if the Commission determines to approve more than one such acquiring Person, the Divestiture Trustee shall divest to the acquiring Person selected by Respondents from among those approved by the Commission; *provided further*, that Respondents shall select such Person within five (5) days after receiving notification of the Commission's approval.
5. The Divestiture Trustee shall serve, without bond or other security, at the cost and expense of Respondent Perrigo, on such reasonable and customary terms and conditions as the Commission or a court may set. The Divestiture Trustee shall have the authority to employ, at the cost and expense of Respondent Perrigo, such consultants, accountants, attorneys, investment bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. The Divestiture Trustee shall account for all monies derived from the divestiture and all expenses incurred. After approval by the Commission of the account of the Divestiture Trustee, including fees for the Divestiture

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Trustee's services, all remaining monies shall be paid at the direction of Respondent Perrigo, and the Divestiture Trustee's power shall be terminated. The compensation of the Divestiture Trustee shall be based at least in significant part on a commission arrangement contingent on the divestiture of all of the relevant assets that are required to be divested by this Order.

6. Respondent Perrigo shall indemnify the Divestiture Trustee and hold the Divestiture Trustee harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Divestiture Trustee's duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of, any claim, whether or not resulting in any liability, except to the extent that such losses, claims, damages, liabilities, or expenses result from gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.
7. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be divested by this Order; *provided, however,* that the Divestiture Trustee appointed pursuant to this Paragraph may be the same Person appointed as Monitor pursuant to the relevant provisions of the Order to Maintain Assets in this matter.
8. The Divestiture Trustee shall report in writing to Respondent Perrigo and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.
9. Respondents may require the Divestiture Trustee and each of the Divestiture Trustee's consultants, accountants, attorneys and other representatives and assistants to sign a customary confidentiality agreement; *provided, however,* such agreement

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shall not restrict the Divestiture Trustee from providing any information to the Commission.

- E. If the Commission determines that a Divestiture Trustee has ceased to act or failed to act diligently, the Commission may appoint a substitute Divestiture Trustee in the same manner as provided in this Paragraph.
- F. The Commission or, in the case of a court-appointed Divestiture Trustee, the court, may on its own initiative or at the request of the Divestiture Trustee issue such additional orders or directions as may be necessary or appropriate to accomplish the divestiture required by this Order.

**VII.****IT IS FURTHER ORDERED** that:

- A. Each Remedial Agreement shall be incorporated by reference into this Order, made a part hereof. Further, nothing in any Remedial Agreement shall limit or contradict, or be construed to limit or contradict, the terms of this Order, it being understood that nothing in this Order shall be construed to reduce any rights or benefits of an Acquirer or to reduce any obligations of Respondents under a Remedial Agreement. Respondents shall comply with the terms of each Remedial Agreement, and a breach by Respondents of any term of a Remedial Agreement shall constitute a violation of this Order. To the extent that any term of a Remedial Agreement conflicts with a term of this Order or the Order to Maintain Assets such that Respondents cannot fully comply with both, Respondents shall comply with the Order or the Order to Maintain Assets.
- B. Respondents shall include in each Remedial Agreement a specific reference to this Order, the remedial purposes thereof, and provisions to reflect the

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full scope and breadth of Respondents' obligations to the Acquirer pursuant to this Order.

- C. Prior to the Closing Date, Respondents shall not modify or amend any material term of any Remedial Agreement without the prior approval of the Commission. Further, any failure to meet any material condition precedent to closing contained in any Remedial Agreement (whether waived or not) shall constitute a violation of this Order.
- D. After the Closing Date and during the term of each Remedial Agreement, Respondents shall provide written notice to the Commission not more than five (5) days after any modification (material or otherwise) of the Remedial Agreement. Further, Respondents shall seek Commission approval of such modification (material or otherwise) within ten (10) days of filing such notification. If the Commission denies approval, the Commission will notify Respondents and Respondents shall expeditiously rescind the modification or make such other changes as are required by the Commission.
- E. Respondents shall not seek, directly or indirectly, pursuant to any dispute resolution mechanism incorporated in any Remedial Agreement, or in any agreement related to any of the Divestiture Products a decision the result of which would be inconsistent with the terms of the Orders or the remedial purposes thereof.

**VIII.****IT IS FURTHER ORDERED** that:

- A. Within five (5) days of the Acquisition, Respondent Perrigo shall submit to the Commission a letter certifying the date on which the Acquisition occurred.
- B. Before the Closing Date, Respondents shall submit to staff of the Commission a verified written report

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setting forth in detail the procedures Respondent Perrigo has implemented to:

1. reasonably ensure that all employees and representatives who have or may be exposed to Confidential Business Information understand and are required to comply with the confidentiality obligations contained in Paragraph II.I; and
2. reasonably ensure that all employees and representatives of Respondents, including those hired during the term of the Order, understand and are required to comply with all terms of this Order that are relevant to their job duties.

In further compliance with this provision, Respondents shall provide staff of the Commission with written notice of all changes, additions and modifications to the procedures implemented, and shall include specific information detailing their efforts to comply with this paragraph in all reports of compliance required by this Order;

*provided, however,* that Respondent Paddock shall have further no obligations under this paragraph after the Acquisition Date.

- C. Respondents shall submit to the Commission a verified written report setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with this Order,
1. within sixty days after submitting the last report required by the Order to Maintain Assets, and every sixty (60) days thereafter until Respondents have fully complied with their obligations under Paragraphs II.A – II.F of the Order, and shall submit at the same time a copy of the report to the Monitor; and
  2. one (1) year after the date this Order becomes final, annually for the next nine years on the

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anniversary of the date this Order becomes final, and at other times as the Commission may require (Respondents are not required to submit these reports to the Monitor).

Respondents shall include in the compliance reports, among other things that are required from time to time, a full description of the efforts being made to comply with the Orders, including a full description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all Persons contacted, and shall make available to the Commission and the Monitor all written communications to and from such Persons, all internal memoranda, and all reports and recommendations concerning completing the obligations;

*provided, however,* that Respondent Paddock shall have no further obligations under this paragraph after the Acquisition Date.

**IX.****IT IS FURTHER ORDERED** that

- A. For purposes of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request and upon five (5) days notice to Respondents, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:
  1. access, during business office hours of Respondents and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda and all other records and documents in the possession or under the control of such Respondents related to compliance with this Order, which copying services shall be provided by such Respondents at the request of the authorized representative(s) of

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the Commission and at the expense of such Respondents; and

2. to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

**X.**

**IT IS FURTHER ORDERED** that Respondents shall notify the Commission at least thirty (30) days prior to any proposed:

A. dissolution of Respondents;

B. acquisition, merger or consolidation of Respondents; or

C. any other change in Respondents including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**XI,**

**IT IS FURTHER ORDERED** that this Order shall terminate on June 21, 2022.

By the Commission, Commissioner Ohlhausen not participating.

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**APPENDIX A****MONITOR AGREEMENT (WITHOUT NON-PUBLIC  
EXHIBIT)****MONITOR AGREEMENT**

This Monitor Agreement ("Monitor Agreement") entered into among Quantic Regulatory Services, LLC ("Monitoring Firm" or "Quantic"), Perrigo Company (together with its affiliates and/or subsidiaries, "Perrigo"), Paddock Laboratories, Inc. ("Paddock" and, together with Perrigo, the "Respondents"), F. William Rahe, as an individual Monitor (as defined below) and R. Owen Richards, provides as follows:

WHEREAS, the United States Federal Trade Commission (the "Commission"), is evaluating whether to accept for Public Comment an *Agreement Containing Consent Orders*, incorporating a Decision and Order ("Decision and Order") and an Order to Maintain Assets, with Perrigo and Paddock (collectively, the "Orders"), which, among other things, require Perrigo to divest or transfer certain defined assets and Respondents to maintain those assets pending such divestiture or transfer, and provide for the appointment of one or more Monitors to ensure that Respondents comply with their respective obligations under the Orders;

WHEREAS, the Commission may appoint Mr. Rahe of Quantic as Monitor, and provide that he may seek assistance as needed, including the assistance of Mr. Richards of Quantic, pursuant to the Orders to monitor Respondents' compliance with the terms of the Consent Agreement and Orders and with the Remedial Agreement referenced in the Orders, and to monitor the efforts of the Commission-approved Acquirers (as defined in the Orders) to obtain all necessary FDA approvals and to complete the technology

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transfers of all Divested Products, as applicable, and Mr. Richards and Mr. Rahe, each pursuant to his Consulting Agreement with the Monitoring Firm, consented to such appointment and agrees to serve pursuant to the terms of his Consulting Agreement with the Monitoring Firm and this Agreement;

WHEREAS, the Orders further provide or will provide that Respondents shall execute a Monitor Agreement, subject to the prior approval of the Commission, conferring all the rights, powers and authority necessary to permit the Monitor to carry out such duties and responsibilities pursuant to the Orders;

WHEREAS, this Monitor Agreement conforms or will conform with the requirements of the Orders and does not contradict the Orders;

WHEREAS, this Monitor Agreement, although subject to Commission approval, is effective for any purpose, including but not limited to imposing rights and responsibilities on Respondents, the Monitoring Firm or the Monitor under the Orders, upon execution by the parties; and

WHEREAS, the parties to this Monitor Agreement intend to be legally bound;

NOW, THEREFORE, the parties agree as follows:

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1. Capitalized terms used herein and not specifically defined herein shall have the respective definitions given to them in the Consent Agreement and the Orders. The term "Divestiture Products" means the Divestiture Products as defined in the Consent Agreement.
2. The Monitor and the Monitoring Firm shall have all of the powers, responsibilities and protections conferred upon the Monitor by the Orders, including but not limited to:
  - a. monitoring the transfer of the Divestiture Products Assets to the Commission-approved Acquirers;
  - b. monitoring any redaction and use of Confidential Business Information retained by Respondents as required by the Orders; and
  - c. monitoring the performance of any transition services, including Contract Manufacture, required by the Orders.
3. Respondents hereby agree that, upon execution by all parties of this Monitor Agreement, Respondents will comply fully with all terms of the Orders requiring them to confer all rights, powers, authority and privileges upon the Monitor and the Monitoring Firm, or to impose upon themselves any duties or

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obligations with respect to the Monitor, to enable the Monitor to perform the duties and responsibilities of the Monitor thereunder.

4. Respondents, individually or together (as applicable) further agree with the Monitoring Firm and the Monitor that:
  - a. they will use their best efforts to ensure that any Commission-approved Acquirer works with the Monitor starting at or about the Closing Date to facilitate the Monitor's fulfillment of his duties under the Orders and the exchange of information between the Commission-approved Acquirer and the Monitor;
  - b. no later than ten (10) business days after the Commission approves this Monitor Agreement, Respondents will provide the Monitor with the following, as applicable:
    - (1) a complete inventory and description of the Divestiture Products, identifying, in particular, those Divestiture Products which may require actions to maintain their viability and marketability, and the person(s) responsible for taking those actions;
    - (2) a complete inventory of all existing FDA approvals and pending FDA approvals for the Products included in the Divestiture

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Products identifying actions required to maintain or complete such approvals and identifying the person(s) responsible for taking such actions;

- (3) a complete inventory of all activities or operations worldwide that relate to the manufacture of the Divestiture Products, and which relate to Respondents' compliance with the Orders, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities and giving an inventory of materials and records relating to such manufacture;
- (4) a complete inventory of all activities or operations worldwide that relate to the Research and Development of the Perrigo ANDA Products, and which relate to Respondents' compliance with the Orders, including processes and process validations which are under development, identifying the person(s) responsible for maintaining or pursuing such activities, and giving an inventory of materials and records relating to such manufacture;
- (5) full and complete details of all dealings with any future Commission-approved Acquirer of the Divestiture Products, including copies of all correspondence and written reports of all

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contacts and discussions with any such future Commission-approved Acquirer and any draft and/or executed complete agreements, including any attached exhibits, schedules and appendices; and

- (6) a complete inventory of all Divestiture Products Intellectual Property included in the Divestiture Products Assets related to the manufacture or sale of the Divestiture Products in the United States, identifying actions needed to maintain such applicable intellectual property and the person(s) responsible for such actions;
- c. they will each designate a senior individual as a primary contact for the Monitor, provide a written list of the principal individuals to be involved in the transitioning of the Divestiture Products to the Commission-approved Acquirers, together with their locations, telephone numbers, electronic mail addresses (if available), and responsibilities, and provide the Monitor with written notice of any changes in such personnel occurring thereafter;
  - d. they will, in consultation with the Monitor, identify employees who possess know-how, trade secrets and other business information used in the manufacture of the Divestiture Products and will ensure that those employees are reasonably available as needed to provide assistance to the Acquirer as required under the Orders;

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- e. they will provide the Monitor with prompt notification of significant meetings, including date, time and venue, scheduled after the execution of this Monitor Agreement, relating to the development, manufacture, registration, regulatory approvals, marketing, sale and divestiture of the Divestiture Products, and such meetings may be attended by the Monitor or his representative, at the Monitor's option or at the request of the Commission or staff of the Commission;
- f. they will provide the Monitor with the minutes, if any, of the above-referenced meetings as soon as practicable and, in any event, not later than those minutes are available to any employee of the Respondents;
- g. they will provide the Monitor with all correspondence, meeting minutes, telephone summaries, or reports sent to or received from the FDA relating to the Divestiture Products;
- h. they will provide the Monitor with electronic or hard copies, as may be appropriate, of all reports submitted to the Commission pursuant to the Consent Agreement and the Orders, simultaneous with the submission of such reports to the Commission;
- i. to the extent not reflected in the reports submitted to the Commission pursuant to the Consent Agreement and the Orders, they will provide

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every (3) months commencing one (1) month after the Consent Agreement is accepted by the Commission for public comment, or as reasonably requested by the Monitor, electronic or hard copy reports to the Monitor reasonably describing Respondents' activities and obligations under the Orders concerning the Divestiture Products including, without limitation, to the extent applicable:

- (1) all significant activities concerned with the manufacture, supply and technology transfer of the relevant Products that are identified in the Divestiture Products, including, without limitation, negotiation and operation of supply agreements, actual supply, and inventory; and
- (2) all minutes and records of significant meetings, action plans, and follow-ups to action plans and meetings with the Commission-approved Acquirers related to the manufacture, supply, and technology transfer of the Products identified in the Divestiture Products; and
- (3) all significant activities concerning the assistance, advice and consultation provided to any Commission-approved Acquirer generally as provided in the Orders;

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*provided, however,* that, at the time the Orders become final, the reports described in this paragraph shall be due to the Monitor either as requested by the Monitor or within five (5) business days of the date that Respondents file Respondents' reports with the Commission as required pursuant to the Orders;

- j. on request, they will provide the Monitor with any and all records that relate to the manufacture of the Products identified in the Divestiture Products with the right to use them to achieve the purposes of the Orders;
- k. they will comply with the Monitor's requests for onsite visits and audits of Respondents' facilities (or any contract manufacturer's facility) used to manufacture the Products identified in the Divestiture Products;
- l. they will comply with the Monitor's reasonable requests for follow-up discussions or supplementary information concerning any reports provided to or requested by the Monitor pursuant to this Agreement or in connection with any matters the Monitor deems reasonably necessary to perform its responsibilities under the Orders, including, without limitation, as applicable, meetings and discussions with the principal staff involved in any activities relating to the research, development, manufacture, sale and/or divestiture of the Divestiture Products or any Product comprised therein and, further including, actions necessary to maintain all necessary

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FDA approvals to manufacture and sell any of the Divestiture Products, to maintain the viability and marketability of the Divestiture Products, as well as the tangible assets of the facilities used to manufacture and sell all of the Divestiture Products, and to prevent the destruction, removal, wasting, deterioration or impairment of the Divestiture Products, and they will provide the Monitor with access to and hard and electronic copies of all other data, records, or other information that the Monitor believes are necessary to the proper discharge of its responsibilities under the Orders;

- m. they will provide prompt notice of any meetings, activities or events affecting or likely to affect the maintenance of the Divestiture Products, including, but not limited to, any and all meetings or communications with the FDA; and
- n. they will provide the Monitor with such other information, documents, and the like requested by the Monitor in order to carry out Monitor's responsibilities under this Monitoring Agreement and the Orders.

- 5. Respondents shall promptly notify the Monitor of any significant written or oral communication that occurs after the date of this Monitor Agreement between the Commission and Respondents related to the Orders or this Monitor Agreement, together with electronic or hard copies (or, in the case of

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oral communications, summaries), as may be requested by the Monitor, of such communications.

6. Respondents agree that to the extent authorized by the Orders, the Monitoring Firm and the Monitor shall have the authority to consult with and employ, at the expense of Perrigo, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Monitoring Firm and the Monitor's duties and responsibilities, including but not limited to supervising the transfer of Confidential Business Information.
  
7. Respondents and the Monitor understand and agree that the Commission or its staff may request, pursuant to and consistent with the Orders, that the Monitor investigates and/or audits Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders, and submits such additional written or oral reports, under applicable confidentiality restrictions, to the Commission as the Commission or its staff may at any time request concerning Respondents' compliance with Respondents' obligations to maintain assets pursuant to the Orders. Respondents and the Monitor further understand and agree that the Commission or its staff may request assistance from the Monitor with respect to the content of the Orders prior to such Orders becoming final.

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8. The Monitoring Firm and the Monitor shall maintain the confidentiality of all information provided to the Monitor by Respondents. Such information shall be used by the Monitoring Firm and the Monitor only in connection with the performance of the Monitor's duties pursuant to this Agreement. Such information shall not be disclosed by the Monitoring Firm and the Monitor to any third party other than:
  - a. persons engaged, employed by, or working with, the Monitor under this Agreement;
  - b. any Commission-approved Acquirer to the extent that the information is of a non-privileged nature; or
  - c. persons employed at, or engaged by, the Commission and working on this matter.
  
9. Upon termination of the Monitor's duties under this Monitor Agreement, the Monitor and the Monitoring Firm each shall promptly return to Respondents all material provided to the Monitor by Respondents that is confidential to Respondents and that Respondents are entitled to have returned to Respondent under the Orders, and shall destroy any material prepared by the Monitor that contains or reflects any confidential information of Respondents provided that the Commission staff does not require the Monitor to maintain the materials,

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and provided, that, notwithstanding the foregoing, the Monitoring Firm shall be entitled to keep one copy of all such information and materials in its confidential files. Nothing herein shall abrogate the Monitor's and the Monitoring Firm's duty of confidentiality.

10. In addition, the Monitoring Firm and the Monitor shall keep confidential for a period of five (5) years all other aspects of the performance of its duties under this Monitor Agreement. To the extent that the Monitoring Firm or the Monitor wishes to retain any employee, agent, consultant or any other third party to assist the Monitor in accordance with the Orders, the Monitoring Firm and the Monitor shall ensure that such persons execute an appropriate confidentiality agreement.

For the purposes of this Section and Sections 8, 9 and 10, information shall not be considered confidential or proprietary to the extent that it is or becomes part of the public domain (other than as the result of any action by the Monitoring Firm or the Monitor or by any employee, agent, affiliate or consultant of the Monitor), or to the extent that the recipient of such information can demonstrate that such information was already known to the recipient at the time of receipt or becomes known to the recipient from a source other than Respondents, or any director, officer, employee, agent, consultant or affiliate of Respondents, when such source is entitled to make such disclosure to such

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recipient or such information was independently developed by the Monitor as evidenced by written records.

11. Nothing in this Monitor Agreement shall require Respondents to disclose any material or information that is subject to a legally recognized privilege or that Respondents are prohibited from disclosing by reason of law or an agreement with a third party.
12. Neither the Monitor nor the Monitoring Firm shall have a fiduciary responsibility to the Respondents, but shall have fiduciary duties to the Commission.
13. Each party shall be reasonably available to the other to discuss any questions or issues that either party may have concerning compliance with the Orders as it relates to Respondents.
14. Perrigo will pay the Monitoring Firm in accordance with the fee schedule attached hereto as Confidential Exhibit A for all time spent in the performance of the Monitor's duties, including all monitoring activities related to the efforts of the Commission-approved Acquirers of the Divestiture Products (including any and all such activities performed prior to the date of this Agreement), all work in connection with the negotiation and preparation of this Monitor Agreement, and all reasonable and necessary travel time. Every six months

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such hourly rates should be reviewed and may be adjusted by agreement with Perrigo.

- a. In addition, Perrigo will pay all out-of-pocket expenses incurred by the Monitor in the performance of the Monitor's duties, including any auto, train, or air travel and all telecommunication charges incurred in the performance of the Monitor's duties.
- b. Any expense charged to a credit card incurred in a currency other than U.S. dollars shall be converted into dollars for expense reimbursement purposes at the exchange rate used for said credit card transaction and any ancillary cash expenses for which a credit card is not possible shall be converted at the exchange rate for which said currency was purchased.
- c. The Monitoring Firm and the Monitor shall have full and direct responsibility for compliance with all applicable laws, regulations and requirements pertaining to work permits, income and social security taxes, unemployment insurance, worker's compensation, disability insurance, and the like.

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15. Perrigo agrees to pay all fees, costs and expenses set forth under paragraph 14 within thirty (30) days of receipt of an invoice therefore.

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16. Perrigo hereby confirms its obligation to indemnify the Monitoring Firm and the Monitor and hold each of them harmless in accordance with the discharge of their duties under the Orders (and, upon direction by the Commission to the Monitor to divest any Divestiture Products).

Without in any way limiting the generality of the foregoing, Perrigo shall indemnify the Monitoring Firm and each of the Monitor and any subcontractor and their respective consultants, agents, partners, principals, directors, officers, members, managers and employees (the "Indemnified Parties") and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or expenses, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, arising out of or in connection with the performance of the Monitor's duties and obligations, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the willful misconduct or gross negligence of the Monitor. This section shall survive the expiration or termination of this Agreement.

Paddock shall indemnify the Indemnified Parties and hold the Indemnified Parties harmless (regardless of form of action, whether in contract, statutory law, tort or otherwise) against any losses, claims, damages, liabilities or

## Decision and Order

expenses, including all reasonable fees of counsel and other reasonable expenses incurred in connection with the preparations for, or defense of, any claim, whether or not resulting in any liability, arising out of or in connection with the performance of the Monitor's duties and obligations prior to the closing of Perrigo's acquisition of Paddock, except to the extent that such losses, claims, damages, liabilities, or expenses are finally judicially determined to result from the willful misconduct or gross negligence of the Monitor. This section shall survive the expiration or termination of this Agreement.

17. The Monitor's and the Monitoring Firm's maximum liability to the Respondents relating to services pursuant to this Agreement (regardless of the form of the action, whether in contract, statutory law, tort, or otherwise) shall be limited to the total sum of the fees paid to the Monitoring Firm by Perrigo, not to exceed \$250,000. In no circumstances whatsoever shall Monitor or Monitoring Firm be liable for any special, incidental, consequential, or punitive damages, unless they engage in willful misconduct. The Monitor is not responsible for evaluating the legal or technical sufficiency of any documents, materials or actions of Respondents or any Commission-approved Acquirers under the Orders. The Monitor or the Monitoring Firm shall not incur any liability of any nature for the failure of Respondents, the Commission-approved Acquirer, or the Commission to perform any acts, or not perform any acts. This section shall survive the termination or expiration o

## Decision and Order

this Agreement. Each Respondent agrees that its obligations to indemnify the Monitoring Firm and the Monitor extend to (i) any agreement that is entered between the Monitor or the Monitoring Firm and any Commission-approved Acquirer and any action under this Monitor Agreement and the Orders related to the Commission-approved Acquirer(s) and (ii) any and all Monitor's and Monitoring Firm's responsibilities under this Monitor Agreement or the Orders. This section shall survive the termination or expiration of this Agreement.

18. Upon this Monitor Agreement becoming effective, the Monitor shall be permitted, and Respondents shall be required, to notify all current Commission-approved Acquirers and potential future Acquirers with respect to its appointment as Monitor.
19. In the event that a disagreement or dispute between Respondents and the Monitor or the Monitoring Firm cannot be resolved by the parties, any party may seek the assistance of the individual in charge of the Commission's Compliance Division to resolve this issue. In the event that such disagreement or dispute cannot be resolved by the parties, the parties shall submit the matter to binding arbitration before the American Arbitration Association under its Commercial Arbitration Rules, but only if the individual in charge of the Commission's Compliance Division determines within the Commission's reasonable discretion that such a matter is appropriate for submission to the

## Decision and Order

American Arbitration Association. Binding arbitration shall not be available, however, to resolve any disagreement or dispute concerning the Respondents' obligations pursuant to the Orders.

20. This agreement shall be subject to the substantive law of the State of New York (regardless of any other jurisdiction's choice of law principles).
21. This Monitor Agreement shall terminate when the Monitor has discharged his obligations under the Order. The FTC will consult with the Monitor to determine when the Respondents' obligations under the Order have terminated. The Commission may extend this Monitor Agreement as may be necessary or appropriate to accomplish the purposes of the Orders. The confidentiality and indemnity obligations of this Monitor Agreement shall survive its termination.
22. It is understood that the Monitor will be serving under this Monitor Agreement as an independent contractor of the Monitoring Firm and that the relationship of employer and employee shall not exist between Monitor and Respondents.
23. This Agreement is for the sole benefit of the parties hereto and their permitted assigns and the Commission, and nothing herein express or implied shall give or be construed to give any other person any legal or equitable rights hereunder.

## Decision and Order

24. This Agreement contains the entire agreement between the parties hereto with respect to the matters described herein and replaces any and all prior agreements or understandings, whether written or oral.
25. Any notices or other communication required to be given hereunder shall be deemed to have been properly given if sent by mail, reputable overnight courier or fax (with acknowledgment of receipt of such fax having been received), to the applicable party at its address below (or to such other address as to which such party shall hereafter notify the other party):

If to the Monitoring Firm, to:

Mr. R. Owen Richards  
Quantic Regulatory Services, LLC  
5N Regent Street, Suite 502  
Livingston, NJ 07039  
Telephone: 973-992-0505  
Email: orichards@quanticgroup.com

If to the Monitor, to:

Mr. F. William Rahe  
Quantic Regulatory Services, LLC  
5N Regent Street, Suite 502  
Livingston, NJ 07039

## Decision and Order

Telephone: 317-331-3890

Email: [wrahe@quanticgroup.com](mailto:wrahe@quanticgroup.com)

If to Perrigo, to:

Mr. Andrew M. Solomon

Assistant General Counsel

Perrigo Company

515 Eastern Avenue

Allegan, MI 49010

Telephone: 269-686-7294

Email: [Andrew.Solomon@perrigo.com](mailto:Andrew.Solomon@perrigo.com)

If to Paddock, to:

Mr. Phil Thompson

Vice President, General Counsel

Paddock Laboratories, Inc.

3940 Quebec Avenue North

Minneapolis, MN 55427

Telephone: 763-732-0214

Email: [pthompson@paddocklabs.com](mailto:pthompson@paddocklabs.com)

If to the Commission:

Federal Trade Commission

Decision and Order

601 New Jersey Avenue, NW

Washington, DC 20001

Attn: Ms. Susan Huber

Telephone: 202-326-3331

Email: shuber@ftc.gov

26. This Monitor Agreement shall become binding upon execution, although it will be subject to approval by the Commission.
  
27. This Monitor Agreement may be signed in counterparts.

## Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 13 of May, 2011.

Quantic Regulatory Services, LLC:

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R. Owen Richards, President

Quantic Regulatory Services, LLC

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F. William Rahe, Monitor

Perrigo Company:



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Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

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Phil Thompson, Vice President and General Counsel

Decision and Order

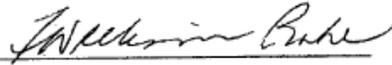
IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 13<sup>th</sup> of May, 2011.

Quantic Regulatory Services, LLC:

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R. Owen Richards, President

Quantic Regulatory Services, LLC



F. William Rahe, Monitor

Perrigo Company:

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Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

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Phil Thompson, Vice President and General Counsel

## Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 12<sup>th</sup> of May, 2011.

Quantic Regulatory Services, LLC:

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R. Owen Richards, President

Quantic Regulatory Services, LLC

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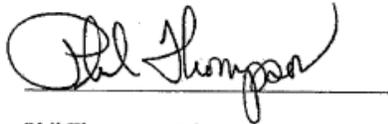
F. William Rahe, Monitor

Perrigo Company:

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Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.



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Phil Thompson, Vice President and General Counsel

Decision and Order

IN WITNESS WHEREOF, the parties hereto have executed this Monitor Agreement as of the 17<sup>th</sup> of May, 2011.

Quantic Regulatory Services, LLC:



R. Owen Richards, President

Quantic Regulatory Services, LLC

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F. William Rahe, Monitor

Perrigo Company:

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Raymond Canole, Vice President, Corporate Development

Paddock Laboratories, Inc.

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Phil Thompson, Vice President and General Counsel

Decision and Order

**NON-PUBLIC APPENDIX A-1**

**EXHIBIT TO THE MONITOR AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX B**

**RELEVANT TOLL MANUFACTURING AGREEMENT**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

**NON-PUBLIC APPENDIX C**

**WATSON REMEDIAL AGREEMENTS**

**[Redacted From the Public Record Version, But Incorporated  
By Reference]**

## Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDER TO AID PUBLIC COMMENT****I. Introduction**

The Federal Trade Commission (“Commission”) has accepted, subject to final approval, an Agreement Containing Consent Orders (“Consent Agreement”) from Perrigo Company (“Perrigo”) and Paddock Laboratories, Inc. (“Paddock”) that is designed to remedy the anticompetitive effects resulting from Perrigo’s acquisition of Paddock. Under the terms of the proposed Consent Agreement, the companies would be required to divest to Watson Pharmaceuticals, Inc. (“Watson”) Paddock’s rights and assets necessary to manufacture and market generic: (1) ammonium lactate external cream 12 percent (“ammonium lactate cream”); (2) ammonium lactate topical lotion 12 percent (“ammonium lactate lotion”); (3) ciclopirox shampoo 1 percent (“ciclopirox shampoo”); and (4) promethazine hydrochloride rectal suppository 12.5 mg and 25 mg (“promethazine suppository”). The proposed Consent Agreement also requires the companies to divest to Watson all of Perrigo’s rights and assets necessary to manufacture and market generic clobetasol propionate spray 0.05 percent (“clobetasol spray”) and diclofenac sodium topical solution 1.5 percent (“diclofenac solution”). Further, the proposed Consent Agreement prohibits the companies from accepting certain payments under a backup supply agreement between Paddock and Abbott Laboratories (“Abbott”) for Androgel, the branded version of testosterone gel 1 percent (“testosterone gel”), and entering into any “pay-for-delay” arrangements with Abbott.

The proposed Consent Agreement has been placed on the public record for thirty days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty days, the Commission will again review the proposed Consent Agreement and the comments received, and will decide whether it should withdraw from the proposed Consent Agreement, modify it, or make final the Decision and Order (“Order”).

Pursuant to a Purchase Agreement dated January 20, 2011, Perrigo plans to acquire substantially all of Paddock’s assets for

## Analysis to Aid Public Comment

\$540 million. The Commission's Complaint alleges that the proposed acquisition, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the FTC Act, as amended, 15 U.S.C. § 45, by substantially lessening competition in the U.S. markets for the manufacture and sale of the following generic pharmaceuticals: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; (4) promethazine suppository; (5) clobetasol spray; (6) diclofenac solution (collectively, the "Products"); and (7) testosterone gel. The proposed Consent Agreement will remedy the alleged violations in each of these markets.

## II. The Products and Structure of the Markets

The proposed acquisition would reduce the number of generic suppliers in six generic drug markets. The number of generic suppliers has a direct and substantial impact on generic pricing, as each additional generic supplier can have a competitive impact on the market. Because there are multiple generic equivalents for each of the products at issue here and the branded products are substantially more expensive than the generic versions, the branded versions no longer significantly constrain the generics' pricing.

The proposed acquisition would reduce the number of competitors from three to two in four markets: (1) ammonium lactate cream; (2) ammonium lactate lotion; (3) ciclopirox shampoo; and (4) promethazine suppository. The structure of each of these markets is as follows:

- The ammonium lactate cream and lotion products are both prescription moisturizers used to treat dry, scaly skin conditions, and help relieve itching. In 2010, annual sales of ammonium lactate cream were approximately \$9.7 million, while sales of the ammonium lactate lotion totaled \$19 million. The same firms compete in both markets – Perrigo, Paddock, and Taro Pharmaceutical Industries Ltd. ("Taro"), although Paddock has temporarily withdrawn its products from the U.S. market. Perrigo leads the market for ammonium lactate cream with a 70 percent share in the United States. Paddock has 17 percent of the market and Taro has 12 percent. In the market for ammonium lactate

## Analysis to Aid Public Comment

cream, the combined firm would account for 87 percent after the proposed acquisition. Perrigo and Paddock are the leading U.S. suppliers of ammonium lactate lotion, with 43 percent and 50 percent of the market, respectively. Taro has only captured a 5 percent market share to date. Post-acquisition, Perrigo's share would increase to 93 percent of the market.

- Ciclopirox shampoo is a prescription shampoo used to treat seborrheic dermatitis, an inflammatory condition that causes flaky scales and patches on the scalp. Paddock is the leading supplier in the \$14.5 million market for ciclopirox shampoo, with a share of approximately 83 percent. Perrigo, with a share of 16 percent, and E. Fougera & Co., with a 1 percent share, are the only other U.S. suppliers of the product. The proposed acquisition, therefore, would result in a combined market share of 99 percent.
- Promethazine suppository is indicated for a variety of uses, including to treat allergic reactions, to prevent and control motion sickness, and to relieve nausea and vomiting associated with surgery. Sales of the 12.5 mg and 25 mg strengths were approximately \$7.9 million and \$36.1 million in 2010, respectively. Perrigo, Paddock, and G&W Laboratories, Inc. ("G&W") are the only U.S. suppliers of both strengths. For the 12.5 mg strength, Perrigo has 15 percent of the market, Paddock has 19 percent, and G&W has 66 percent. For the 25 mg strength, Perrigo has 15 percent of the market, Paddock has 20 percent, and G&W has 65 percent. A combined Perrigo and Paddock would possess 34 percent of the 12.5 mg market and 35 percent of the 25 mg market.

Both Perrigo and Paddock also are developing products for two future generic drug markets: (1) clobetasol spray and (2) diclofenac solution. Clobetasol spray is a topical steroid used to treat moderate to severe psoriasis in adults. Diclofenac solution is a non-steroidal anti-inflammatory drug used to treat osteoarthritis of the knee. Perrigo and Paddock are among a limited number of suppliers that are capable of, and interested in, entering these

## Analysis to Aid Public Comment

markets in a timely manner. Accordingly, the proposed acquisition would eliminate important future competition in these markets.

Finally, the proposed acquisition also could inhibit important future competition in the testosterone gel market. Testosterone gel, marketed by Abbott under the brand name Androgel, is a prescription gel used to treat adult males with a testosterone deficiency. Perrigo is one of a limited number of suppliers capable of entering this future generic market in a timely manner. Pursuant to an agreement between Par Pharmaceutical Companies, Inc. ("Par"), Paddock, and Solvay Pharmaceuticals, the former owner of Androgel, Par agreed to delay introducing a generic version of Androgel in exchange for, among other things, payments under a backup supply agreement. That agreement has since been transferred to Paddock. The proposed acquisition would make Perrigo a party to that agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product.

### **III. Entry**

Entry into the markets for the manufacture and sale of the products would not be timely, likely, or sufficient in its magnitude, character, and scope to deter or counteract the anticompetitive effects of the acquisition. Entry would not take place in a timely manner because the combination of generic drug development times and U.S. Food and Drug Administration ("FDA") drug approval requirements take a minimum of two years. Furthermore, entry would not be likely because many of the relevant markets are small, so the limited sales opportunities available to a new entrant would likely be insufficient to warrant the time and investment necessary to enter.

### **IV. Effects of the Acquisition**

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for ammonium lactate cream, ammonium lactate lotion, ciclopirox shampoo, and promethazine suppository. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. The

#### Analysis to Aid Public Comment

evidence shows that with the entry of each additional competitor, the prices of the generic products at issue have decreased. Customers consistently state that the price of a generic drug decreases with the entry of the second, third, and even fourth competitor. In these markets, the proposed acquisition would eliminate one of only three competitors. The evidence indicates that anticompetitive effects – both unilateral and coordinated – are likely to result from a decrease in the number of independent competitors in these markets, thereby increasing the likelihood that customers will pay higher prices.

The proposed acquisition also eliminates or delays important future competition between Perrigo and Paddock in the U.S. markets for clobetasol spray and diclofenac solution. Perrigo's and Paddock's independent entry into these markets likely would have resulted in lower prices for customers. The proposed acquisition would deprive customers of the expected price decrease that would occur upon the parties' entry into these markets.

Similarly, the proposed acquisition increases the likelihood and degree of coordinated interaction between Perrigo and Abbott in the U.S. testosterone gel market. Perrigo would become a party to the Par/Paddock backup supply agreement, thereby enhancing Abbott's and Perrigo's ability to coordinate to delay the introduction of Perrigo's product. Perrigo's independent entry into the market likely would result in lower prices for customers. The proposed acquisition could therefore deprive customers of the expected price decrease that would ensue upon Perrigo's timely entry into the market.

#### **V. The Consent Agreement**

The proposed Consent Agreement effectively remedies the acquisition's anticompetitive effects in the relevant product markets by requiring a divestiture of the Products to a Commission-approved acquirer no later than ten days after the acquisition. The acquirer of the divested assets must receive the prior approval of the Commission. The Commission's goal in evaluating a possible purchaser of divested assets is to maintain the competitive environment that existed prior to the acquisition.

## Analysis to Aid Public Comment

The Consent Agreement requires that the parties divest rights and assets related to the Products to Watson. Watson is the third largest generic drug manufacturer in the United States, and well-situated to manufacture and market the acquired products. Watson has extensive experience in the development, manufacturing, and distribution of generic pharmaceuticals, as well as experience transferring assets from other pharmaceutical companies. Watson has approximately 325 active products and an active product development pipeline. Moreover, Watson's acquisition of the divested assets does not in itself present competitive concerns because Watson does not compete, nor does it have plans to independently enter, any of the markets affected by the proposed transaction. With its resources, capabilities, strong reputation, and experience manufacturing and marketing generic products, Watson is well-positioned to replicate the competition that would be lost with the acquisition.

If the Commission ultimately determines that Watson is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Watson is not acceptable, the parties must unwind the sale and divest the Products within six months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six months, the Commission may appoint a trustee to divest the Product assets.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Perrigo and Paddock to provide transitional services to enable Watson to obtain all of the necessary approvals from the FDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Perrigo and Paddock. In addition, the parties must supply Watson with the Products pursuant to a supply agreement while they transfer the manufacturing technology to a third-party manufacturer of Watson's choice.

The Consent Agreement also preserves competition in the market for testosterone gel by prohibiting the parties from: (1) receiving any payments that accrue after the initial term of the backup supply agreement aside from those for manufacturing the

*Analysis to Aid Public Comment*

product; and (2) entering into any anticompetitive pay-for-delay arrangements with Abbott regarding the testosterone gel product.

The Commission has appointed F. William Rahe of Quantic Regulatory Services, LLC (“Quantic”) as the Interim Monitor to oversee the asset transfer and to ensure Perrigo and Paddock’s compliance with the provisions of the proposed Consent Agreement. Mr. Rahe is a senior consultant at Quantic and has several years of experience in the pharmaceutical industry. He is a highly-qualified expert on FDA regulatory matters and currently advises Quantic clients on achieving satisfactory regulatory compliance and interfacing with the FDA. In order to ensure that the Commission remains informed about the status of the proposed divestitures and the transfers of assets, the proposed Consent Agreement requires the parties to file reports with the Commission periodically until the divestitures and transfers are accomplished.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement, and it is not intended to constitute an official interpretation of the proposed Order or to modify its terms in any way.

INTERLOCUTORY, MODIFYING,  
VACATING, AND MISCELLANEOUS  
ORDERS

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IN THE MATTER OF

**TOPS MARKETS LLC,  
MORGAN STANLEY CAPITAL PARTNERS V  
U.S. HOLDCO LLC,  
AND  
THE PENN TRAFFIC COMPANY**

*Docket No. C-4295. Order, January 4, 2012*

Letter approving the divestiture of the Penn Traffic Supermarket Business Assets to Moran Foods, Inc.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

Matthew S. Morris  
The Food Partners, LLC

Re: *In the Matter of Tops Markets LLC, Morgan Stanley  
Capital Partners V U.S. Holdco LLC, and The Penn  
Traffic Company; File No. 101-0074, Docket No. C-4295*

Dear Mr. Morris:

This letter responds to the *Petition of Divestiture Trustee for Approval of Proposed Divestiture to Moran Foods, Inc.* (“Petition”) filed by you as the Divestiture Trustee, on November 7, 2011, pursuant to the Decision and Order in this matter. In the Petition, you request that the Commission approve your proposed divestiture to Moran Foods, Inc. of the Penn Traffic Supermarket Business Assets at the following location: No. 3115, 404 West Morris Street in Bath, New York. The Petition was placed on the public record for comments until December 19, 2011, and no comments were received.

After consideration of the proposed divestiture as set forth in the Petition and supplemental documents, as well as other

## Interlocutory Orders, Etc.

available information, the Commission has determined to approve the proposed divestiture. In according its approval, the Commission has relied upon the information submitted and representations made in connection with the Petition, and has assumed them to be accurate and complete.

By direction of the Commission.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**PROMEDICA HEALTH SYSTEM, INC.**

*Docket No. 9346. Order, January 11, 2012*

Order granting a Joint Motion for Scheduling of Oral Argument.

**ORDER SCHEDULING ORAL ARGUMENT**

Both the Respondent and Counsel for the Complaint have filed Appeal Briefs perfecting appeals from the Initial Decision in this matter, and on January 9, 2012, they filed a Joint Motion for Scheduling of Oral Argument. Consistent with both the Commission Rules and the request in the Joint Motion, the Commission has determined to conduct the Oral Argument in this matter on Monday, February 6, 2012, at 2 p.m. in Hearing Room 532-H of the Headquarters Building of the Federal Trade Commission, located at 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

Each side will be allotted thirty minutes to present its argument. Respondent will have the opportunity to open and close the argument, and will be permitted to reserve up to five minutes for rebuttal. If either side wishes to provide the Commission with a short written or electronic compilation of material to facilitate its presentation during the Oral Argument, any such compilation may contain only public information that is already in the record of the proceeding, and copies must be filed with the Secretary of the Commission and provided to opposing counsel no later than Thursday, February 2, 2012, at 5 p.m.

By the Commission.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**ALAN B. MILLER,  
UNIVERSAL HEALTH SERVICES, INC.,  
AND  
PSYCHIATRIC SOLUTIONS, INC.**

*Docket No. C-4309. Order, January 19, 2012*

Letter approving the divestiture of the Puerto Rico Divestiture Assets to Donald R. Dizney and David A. Dizney through two companies, Capestrano Realty Company, Inc., and San Juan CP Hospital, Inc.

**LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS**

Peter T. Barbur, Esquire  
Christopher D. Belelieu, Esquire  
Cravath, Swaine & Moore LLP

Re: *In the Matter of Universal Health Services, Inc.,  
Docket No. C-4309*

Dear Mr. Barbur and Mr. Belelieu:

This letter responds to the Application for Approval of Divestiture of the Puerto Rico Divestiture Assets filed by Universal Health Services, Inc., on October 13, 2011. The Application requests that the Commission approve, pursuant to the order in this matter, Universal's proposed divestiture of the Puerto Rico Divestiture Assets to Donald R. Dizney and David A. Dizney through two companies, Capestrano Realty Company, Inc., and San Juan CP Hospital, Inc. The application was placed on the public record for comments until November 14, 2011, and no comments were received.

After consideration of the proposed divestiture as set forth in Universal's Application and supplemental documents, as well as other available information, the Commission has determined to approve the proposed divestiture. In according its approval, the Commission has relied upon the information submitted and

Interlocutory Orders, Etc.

representations made in connection with Universal's Application and has assumed them to be accurate and complete.

By direction of the Commission.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**THE NORTH CAROLINA BOARD OF DENTAL  
EXAMINERS**

*Docket No. 9343. Order, February 10, 2012*

Order granting respondent's motion for Stay of Order Pending Review by the U.S. Court of Appeals.

**ORDER ON RESPONDENT'S APPLICATION FOR STAY OF ORDER  
PENDING REVIEW BY U.S. COURT OF APPEALS**

On January 13, 2012, Respondent North Carolina State Board of Dental Examiners filed an Application for Stay of Order Pending Review by the U.S. Court of Appeals. Complaint Counsel opposes the motion. For the reasons described below, the Commission grants Respondent's motion and stays the Final Order entered on December 2, 2011 until disposition of Respondent's appeal.

On December 2, 2011, the Commission issued an Opinion and Final Order against Respondent. The Commission held that Respondent excluded non-dentist providers from the market for teeth whitening services, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. The Commission's Final Order prohibited the Board from directing non-dentist teeth whitening providers to cease providing teeth whitening products or services. In its Application, Respondent asserts that it intends to seek review of the Commission's Opinion and Final Order in the Court of Appeals for the Fourth Circuit. (Petition at 1, 2.)

Section 5(g) of the Federal Trade Commission Act provides that Commission cease and desist orders (except divestiture orders) take effect "upon the sixtieth day after such order is served," unless "stayed, in whole or in part and subject to such conditions as may be appropriate, by ... the Commission" or "an appropriate court of appeals of the United States." 15 U.S.C. § 45(g)(2); *see also* 16 C.F.R. § 3.56(a). A party seeking a stay must first apply for such relief to the Commission, as Respondent has done here. *See* 15 U.S.C. § 45(g)(2); *see also* 16 C.F.R. § 3.56(b); Fed. R. App. P. 18(a)(1). If, "within the 30-day period

## Interlocutory Orders, Etc.

beginning on the date the application was received by the Commission,” the Commission either denies the application or does not act on the application, the petitioner may seek a stay in the court of appeals where a petition for review of the final order is pending. 15 U.S.C. § 45(g)(2)(B); *see also* 16 C.F.R. § 3.56(b).

Pursuant to Rule 3.56(c) of the Commission’s Rules of Practice, an application for a stay is evaluated on four factors: (1) the likelihood of the applicant’s success on appeal; (2) whether the applicant will suffer irreparable harm if a stay is not granted; (3) the degree of injury to other parties if a stay is granted; and (4) whether the stay is in the public interest. 16 C.F.R. § 3.56(c); *Toys “R” Us, Inc.*, 126 F.T.C. 695, 696 (1998). If the balance of the equities (i.e., the last three factors) is not heavily tilted in the petitioner’s favor, the petitioner must make a more substantial showing of likelihood of success on the merits in order to obtain a stay pending appeal. *California Dental Ass’n*, No. 9259, 1996 FTC LEXIS 277, at \*10 (May 22, 1996); *see also North Texas Specialty Physicians*, 141 F.T.C. 456, 457-58 & n.2 (2006) (the required likelihood of success “is inversely proportional to the amount of irreparable injury suffered absent the stay”).

*Likelihood of Respondent’s Success on Appeal* – Respondent asserts that it is likely to succeed in its appeal because the Commission’s decisions contravene the U.S. Constitution, federal law, and state law. (Petition at 2-5.) Respondent’s argument focuses on the Commission’s February 8, 2011 decision, which held that financially-interested governmental bodies must meet the active supervision prong of *Midcal* to be exempted from antitrust scrutiny under the state action doctrine. Respondent asserts that the Commission’s holding conflicts with *Midcal* itself, as well as several decisions of the Court of Appeals. (*Id.* at 3-4 (listing cases).)

The Commission harbors no doubts about its February 8, 2011 decision. As we noted in that decision, there is “ample” judicial precedent supporting the Commission’s Opinion—including from the Fourth Circuit—as well as leading antitrust commentary and the policies underlying the state action doctrine. *North Carolina Board of Dental Examiners*, 151 F.T.C. 607, 617-28 (2011)

## Interlocutory Orders, Etc.

(citing *Asheville Tobacco Bd. of Trade, Inc. v. FTC*, 263 F.2d 502, 509 (4th Cir. 1959)).

Nevertheless, the Supreme Court has yet to rule on the applicability of the active supervision prong to regulatory bodies controlled by private market participants. In addition, we have acknowledged that “the courts of appeals have been less than consistent on this issue.” *Id.* at 620. Given that a difficult legal question can be sufficient to establish a substantial showing of a likelihood of success on the merits, *North Texas Specialty Physicians*, 141 F.T.C. at 457; *California Dental*, 1996 FTC LEXIS 277 at \*10, we conclude that Respondent has made a sufficient showing to warrant consideration of the equities. *Cf. Florida v. HHS*, 780 F. Supp. 2d 1307, 1317-20 (N.D. Fla. 2011) (granting stay pending appeal in part because of split in authority); *Pokorny v. Quixtar Inc.*, No. 07-00201, 2008 U.S. Dist. LEXIS 91951, at \*4 (N.D. Cal. Apr. 17, 2008) (finding that a serious question was raised due to an apparent split among the federal courts); *In re Westwood Plaza Apts.*, 150 B.R. 163, 168 (Bankr. E.D. Tex. 1993) (granting stay pending appeal because the “Fifth Circuit has yet to address this question and the circuits which have are split”).

*Irreparable Injury to Respondent Absent a Stay* – Respondent bears the burden of demonstrating that denial of a stay will cause irreparable harm. Simple assertions of harm or conclusory statements based on unsupported assumptions will not suffice. *See Toys “R” Us*, 126 F.T.C. at 698; *California Dental*, 1996 FTC LEXIS 277, at \*7. A party seeking a stay must show, with particularity, that the alleged injury is substantial and likely to occur absent a stay. *See Toys “R” Us*, 126 F.T.C. at 698; *California Dental*, 1996 FTC LEXIS 277, at \*7.

In a declaration submitted in support of its Application, the Dental Board’s Chief Operating Officer asserts that the Commission’s Final Order will cause “significant irreparable harm to the State Board and the consuming public.” (White Declaration ¶ 3.) Specifically, he asserts that the Final Order will prevent the Board from enforcing the Dental Practice Act (*id.* ¶ 6), will limit the Board’s remedies for violations of the Dental Practice Act to seeking judicial relief (*id.* ¶ 5), will force the

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Board to adopt a particular interpretation of the Dental Practice Act (*id.* ¶ 4), and will force the Board to provide administrative hearings to non-licensees (*id.* ¶ 8). As explained in Section VII of the Commission's December 2, 2011 Opinion, each of these assertions is without merit and reflects a serious misreading of the Commission's Final Order.

Nevertheless, it does appear that at least certain portions of the Final Order, when implemented, may cause harm to the Board and have the potential to cause confusion if reversed by the Court of Appeals. In particular, Section III of the Final Order requires the Board to send corrective disclosures to each person to whom the Board previously sent a cease and desist letter or similar communication. If the Commission's decision were overturned on appeal, these persons could once again be subject to the Board's cease and desist letters. This repeated change in policy could create significant confusion about the law—not only for recipients of the notifications, but also for dentists, non-dentist teeth whiteners, and consumers. The Commission has held that where compliance with an order could cause confusion or require costly notification if reversed on appeal, a party may be irreparably injured. *See, e.g., Novartis Corp.*, 128 F.T.C. 233, 235-36 (1999); *California Dental*, 1996 FTC LEXIS 277, at \*7. Accordingly, this factor weighs in favor of a stay, at least with respect to Section III of the Final Order.

*Harm to Others and the Public Interest* – The final remaining questions are whether a stay would harm other parties and whether it is in the public interest. *California Dental*, 1996 FTC LEXIS 277, at \*7-8. These two factors are stated separately, but the FTC considers them together because Complaint Counsel is responsible for representing the public interest by enforcing the law. *See id.* at \*8.

Respondent argues that a stay would not harm any party because it has stopped the challenged conduct: “Over the past two years, the State Board has sent no letters stating North Carolina law to non-dentist providers or to their commercial real estate landlords.” (Petition at 8; *see also* Reply at 13 (“The State Board has sent no communications to non-licensees regarding

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stain removal in the past two years.”)) Even if true,<sup>1</sup> this would not eliminate the potential for ongoing harm to consumers during the pendency of the appeal. For example, many non-dentist teeth whitening providers that had received cease and desist letters would continue to remain off the market, and potential entrants could be deterred from entering by the Board’s past conduct. Nevertheless, the Board’s apparent cessation of the conduct that led to this action substantially diminishes the potential for ongoing consumer harm during the appeal.

*Conclusion* – Although this motion presents a close call, we conclude that Respondent has satisfied the requirements for a stay pending appeal. On the one hand, there is some potential for ongoing harm to consumers in North Carolina during the pendency of the appeal. On the other hand, this case presents an important unresolved legal question, Respondent has represented that it has stopped the challenged conduct, and there is a potential for consumer confusion if the Commission’s Opinion and Final Order were overturned. We reiterate that the grant of stay pending appeal neither states nor implies doubt on our part as to the soundness of the Commission’s resolution of this matter. *See Novartis*, 128 F.T.C. at 234-35; *California Dental*, 1996 LEXIS 227, at \*10.

Accordingly,

**IT IS ORDERED THAT** enforcement of the Commission’s Final Order of December 2, 2011 be stayed upon the filing of a timely petition for review of the Commission’s order in an appropriate Court of Appeals until issuance of the Court of Appeals’ mandate.

By the Commission, Commissioner Ramirez dissenting and Commissioner Brill recused.

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<sup>1</sup> This assertion in Respondent’s brief is not supported by “affidavits or other sworn statements,” as required by Commission Rule 3.56(c), 16 C.F.R. § 3.56(c). Nevertheless, this assertion is consistent with the ALJ’s findings (IDF 208-218), and is not challenged by Complaint Counsel (Opposition at 7).

## Dissenting Statement

**Dissenting Statement of Commissioner Edith Ramirez**

I respectfully dissent from the Commission's decision to grant Respondent North Carolina State Board of Dental Examiners' Application for a Stay of Order Pending Review by the U.S. Court of Appeals. In my view, the Board has not shown that it is likely to succeed on appeal or that, absent a stay, it will suffer irreparable harm. This, together with the harm to competition the Commission has identified and sought to remedy, leads me to conclude that the public interest would be best served by immediate enforcement of our order.

The Board's request for a stay centers on the claim that the Commission's order improperly interferes with the Board's legitimate enforcement activities, resulting in irreparable harm to the Board and the citizens of North Carolina. The claim does not withstand scrutiny. In addressing the first factor of the applicable test, likelihood of success on appeal, the Board relies on arguments the Commission has already twice considered and rejected, as reflected in our February 8, 2011 decision denying the Board's motion to dismiss the complaint on state action grounds and December 2, 2011 ruling that the Board violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. As the majority makes clear, none of the Board's renewed arguments gives us pause about our decision.

Whether a case is especially complex or poses a difficult legal question is, however, relevant to the likelihood of success factor. See *North Texas Specialty Physicians* ("NTSP"), 141 F.T.C. 456, 457 (2006). According to the Board, with its decision, the Commission "has constructed a novel legal argument unfounded in case law . . . to prevent a state agency from enforcing a state law." Respondent's Reply at 4. While it is certainly true that the Supreme Court has yet to address the applicability of the active supervision prong to financially-interested regulatory boards and that the courts of appeals have not adopted a uniform approach to this issue, the Board's characterization is far from accurate. The Commission's determination that the Board's exclusionary acts are not immune from the antitrust laws as conduct of the state is well supported by judicial precedent, including that in the Fourth Circuit where the Board's appeal will be heard, and fully

## Dissenting Statement

consistent with the policies underlying the state action doctrine. In light of the balance of equities discussed below, the absence of direct Supreme Court precedent and lack of unity in the courts of appeals on the core issue the Commission decided are not enough to justify a stay. See *In re California Dental Ass'n*, No. 9259, 1996 FTC LEXIS 277, at \*10 (May 22, 1996) (noting that “the probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury suffered absent the stay”).

Turning to the equities, the Board must show that its alleged irreparable injury “is both substantial and likely to occur absent a stay” in order to satisfy its burden. *NTSP*, 141 F.T.C. at 460. But rather than address the impact of the Commission’s order as it actually reads, the Board instead maintains that the order contains “conflicting statements” and “would have the effect of prohibiting the State Board from fulfilling its state-mandated responsibility to prevent the unlicensed practice of dentistry.” Respondent’s Reply at 7. In fact, the relief fashioned by the Commission, carefully and narrowly tailored as it is to forbid only the Board’s exclusionary conduct, would do no such thing. By its express terms, the order permits the Board to enforce the North Carolina Dental Practice Act in the manner specified by the North Carolina legislature. The Board may investigate suspected violations of the Act, institute court actions for alleged violations, and pursue available administrative remedies. Final Order at 4. The order even makes clear that the Board may notify third parties of its “belief or opinion” regarding suspected violations. *Id.* The Board is only prohibited from conduct it claims it has not engaged in for at least the last two years: “directing” non-dentists to stop providing teeth whitening services and conveying to potential entrants or lessors of commercial property that non-dentist teeth whitening is illegal. *Id.* § 2; Respondent’s Application at 8.

The majority acknowledges that the Board’s assertion of irreparable injury is “without merit” and based on “a serious misreading of the Commission’s Final Order.” Order on Respondent’s Application at 3. The majority nonetheless makes a finding of irreparable injury citing a concern the Board never even raised: the potential for confusion arising from the remedial portion of the Commission’s order if the ruling were overturned.

## Dissenting Statement

While the potential for confusion may suffice to show irreparable injury in some circumstances, I do not agree that this case rises to that level.

For instance, in *California Dental*, on which the majority relies, the association sought a narrow stay of the portion of the Commission's order requiring, among other things, the dissemination of information about the Commission's decision to all 19,000 of the association's members, the review of past disciplinary actions, and reinstatement of members who had been improperly expelled. 1996 FTC LEXIS 277, at \*7-8. Recognizing that a reversal would require re-notification to all association members and could subject reinstated members to renewed expulsion, thereby inflicting significant costs on the association and creating a significant potential for confusion about the law, the Commission granted a limited stay. *Id.* In *Novartis*, also cited by the majority, the Commission granted a partial stay after respondent showed it would needlessly incur substantial financial costs and reputational harm if there were a reversal of the re-labeling of product and corrective advertising ordered by the Commission. *In re Novartis Corp.*, 233 F.T.C. 235, 235-36 (1999). There is no comparable cost or potential for harm here. Not only is the number of affected persons who received the Board's unlawful cease and desist letters and would be due a corrective disclosure dramatically smaller (approximately 60), but the corrective disclosure ordered by the Commission merely clarifies that the Board's prior communications did not constitute a "legal determination," a fact that is undisputed. *See* Final Order, Section III and Appendices A-C; *NTSP*, 141 F.T.C. at 465-66 (rejecting argument that notifying 400 member physicians and a limited number of payors of the Commission's decision would cause irreparable injury).

On the other hand, a stay will cause substantial harm to competition and consumers. The harm resulting from the Board's exclusionary conduct will continue if the order is not enforced. The non-dentist providers who exited the market after receiving cease and desist letters from the Board will likely remain out of the market unless corrective action is taken, thereby depriving consumers of access to less expensive services. I also believe that delaying enforcement of the order until the Board's appeal is

Dissenting Statement

resolved, a process that could take years, will undermine the effectiveness of the corrective notices the Commission has ordered. Finally, in the absence of an enforceable order, there is nothing to prevent the Board from resuming its anticompetitive campaign of sending cease and desist letters to potential new entrants or returning firms.

The Board therefore has not shown that the equities weigh in its favor or that a stay is otherwise warranted. In my view, the public interest calls for enforcement of the order without delay.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**THE DOW CHEMICAL COMPANY**

*Docket No. C-4243. Order, February 23, 2012*

Letter approving the divestiture of the real property related to the Torrance Facility to Hager Pacific Properties.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

George S. Cary, Esq.  
Cleary Gottlieb Steen & Hamilton LLP

*Re: In the Matter of The Dow Chemical Company, Docket No.  
C-4243*

Dear Mr. Cary:

Pursuant to Rule 2.41(f) of the Commission's Rules of Practice, the Commission has determined to approve the Petition of The Dow Chemical Company For Approval of the Proposed Divestiture of the Real Property Related to the Torrance Facility to Hager Pacific.

In according its approval to Dow's Petition, the Commission has relied upon the information submitted by Dow and the acquiring entities, and the representations made by Dow, in the course of the Commission staff's review of Dow's Petition. The Commission has assumed the information and representations to be accurate and complete. The manner of divestiture considered by the Commission is that set forth in the Real Estate Purchase and Sale Agreement filed with the Petition.

By direction of the Commission.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**MCWANE, INC.,  
AND  
STAR PIPE PRODUCTS, LTD.**

*Docket No. 9351. Order, February 23, 2012*

Order granting the joint motion of Complaint Counsel and Respondent Star Pipe Products, Ltd. to withdraw this matter from adjudication in order to enable the Commission to consider a proposed Consent Agreement

**ORDER WITHDRAWING MATTER FROM ADJUDICATION AS TO  
RESPONDENT STAR PIPE PRODUCTS, LTD. FOR THE PURPOSE OF  
CONSIDERING A CONSENT AGREEMENT**

Complaint Counsel and Respondent Star Pipe Products, Ltd. (“Respondent Star”) having jointly moved for Respondent Star to be withdrawn from adjudication in this matter in order to enable the Commission to consider a proposed Consent Agreement; and

Complaint Counsel and Respondent Star having submitted a proposed Consent Agreement containing a proposed Decision and Order, executed by Respondent Star and by Complaint Counsel and approved by the Director of the Bureau of Competition that, if accepted by the Commission, would resolve the claims against Respondent Star in their entirety;

**IT IS ORDERED**, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c), that all claims against Respondent Star, as set forth in the First Violation Alleged and the Second Violation Alleged in the Complaint, be, and they hereby are, withdrawn in their entirety from adjudication until 12:01 a.m. on March 31, 2012, and that all proceedings against Respondent Star before the Administrative Law Judge be, and they hereby are, stayed pending a determination by the Commission with respect to the proposed Consent Agreement, pursuant to Rule 3.25(f), 16 C.F.R. § 3.25(f); and

**IT IS FURTHER ORDERED**, pursuant to Rule 3.25(b) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b), that the

## Interlocutory Orders, Etc.

proposed Consent Agreement shall not be placed on the public record unless and until it is accepted by the Commission; and

**IT IS FURTHER ORDERED**, pursuant to Rule 3.25(e) of the Commission Rules of Practice, 16 C.F.R. § 3.25(e), that this matter shall remain in an adjudicative status as to Respondent McWane, Inc. (“Respondent McWane”), and all claims against Respondent McWane in the Complaint, including but not limited to those set forth in the First, Second, Third, Fourth, Fifth, Sixth, and Seventh Violations Alleged in the Complaint, shall remain in an adjudicative status.

By the Commission.

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**IN THE MATTER OF**

**GRACO INC.,  
ILLINOIS TOOL WORKS INC.,  
AND  
ITW FINISHING LLC**

*Docket No. 9350. Order, March 13, 2012*

Order granting a joint motion to withdraw this matter from adjudication to enable the Commission to consider a proposed Consent Agreement.

**ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THE  
PURPOSE OF CONSIDERING A PROPOSED CONSENT AGREEMENT**

Complaint Counsel and Counsel for the Respondents having filed a joint motion to withdraw this matter from adjudication to enable the Commission to consider a proposed Consent Agreement; and

Complaint Counsel and Counsel for the Respondents having submitted a proposed Consent Agreement containing a proposed Decision and Order, executed by the Respondents and by Complaint Counsel and approved by the Director of the Bureau of Competition which, if accepted by the Commission, would resolve this matter in its entirety;

**IT IS ORDERED**, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c), that this matter in its entirety be, and it hereby is, withdrawn from adjudication, and that all proceedings before the Administrative Law Judge are hereby stayed as the Commission evaluates the proposed Consent Agreement, pursuant to Rule 3.25(f), 16 C.F.R. § 3.25(f); and

**IT IS FURTHER ORDERED**, pursuant to Rule 3.25(b) of the Commission Rules of Practice, 16 C.F.R. § 3.25(b), that the proposed Consent Agreement shall not be placed on the public record unless and until it is accepted by the Commission.

By the Commission.

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IN THE MATTER OF

**HEALTHCARE TECHNOLOGY HOLDINGS,  
INC.**

*Docket No. C-4340. Order, March 15, 2012*

Letter approving the divestiture of the SDI Audits Business to inVentiv Health, Inc.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

David I. Gelfand, Esquire  
Cleary, Gottlieb, Steen & Hamilton

*Re: In the Matter of Healthcare Technology Holdings, Inc.  
FTC File No. 111-0097, Docket No. C-4340*

Dear Mr. Gelfand:

This letter responds to the *Petition of Healthcare Technology, Inc. for Approval of Proposed Divestiture* (“Petition”) filed by Healthcare Technology, Inc. (“Healthcare Technology”) on January 12, 2012, requesting that the Commission approve Healthcare Technology Inc.’s proposed divestiture of the SDI Audits Business to inVentiv Health, Inc. (“inVentiv”) pursuant to the Decision and Order in this matter. The Petition was placed on the public record for comments until February 27, 2012 and no comments were received.

After consideration of the proposed divestiture as set forth in the Petition and supplemental documents, as well as other available information, the Commission has determined to approve the proposed divestiture. In according its approval, the Commission has relied upon the information submitted and representations made in connection with the Petition, and has assumed them to be accurate and complete.

By direction of the Commission.

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**IN THE MATTER OF**

**GRACO INC.,  
ILLINOIS TOOL WORKS INC.,  
AND  
ITW FINISHING LLC**

*Docket No. 9350. Order, March 26, 2012*

Order to Hold Separate and Maintain Assets while the Commission considers a proposed Consent Agreement.

**ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS**

The Federal Trade Commission (“Commission”), having heretofore issued its administrative Complaint charging Respondents Graco Inc. (“Graco”), Illinois Tool Works Inc., and ITW Finishing LLC (“ITW”), hereinafter referred to as Respondents, with violations of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and Respondents having been served with a copy of the Complaint, together with a notice of contemplated relief, and the Respondents having answered the Complaint denying said charges; and

Respondents, their attorneys, and counsel for the Commission having thereafter executed an Agreement Containing Consent Orders (“Consent Agreement”), containing an admission by Respondents of all the jurisdictional facts set forth in the aforesaid Complaint, a statement that the signing of said Consent Agreement is for settlement purposes only and does not constitute an admission by Respondents that the law has been violated as alleged in such Complaint, or that the facts as alleged in such Complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission’s Rules; and

The Secretary of the Commission having thereafter withdrawn the matter from adjudication in accordance with § 3.25(c) of its Rules; and

The Commission having thereafter considered the matter and the executed Consent Agreement, now in further conformity with

## Interlocutory Orders, Etc.

the procedure described in § 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and issues this Order to Hold Separate and Maintain Assets (“Hold Separate”):

1. Respondent Graco Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Minnesota, with its office and principal place of business located at 88-11th Avenue Northeast, Minneapolis, Minnesota 55413.
2. Respondent Illinois Tool Works Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 3600 West Lake Avenue, Glenview, Illinois 60026.
3. Respondent ITW Finishing LLC is a limited liability company organized, existing, and doing business under and by virtue of the laws of the State of Delaware, with its office and principal place of business located at 3600 West Lake Avenue, Glenview, Illinois 60026. ITW Finishing LLC is indirectly wholly-owned by Illinois Tool Works Inc.
4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

**ORDER****I.**

**IT IS ORDERED** that, as used in this Hold Separate, the following definitions, and all other definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), shall apply:

- A. “Acquisition” means the proposed acquisition described in the Asset Purchase Agreement by and among Graco Inc., Graco Holdings Inc., Graco Minnesota Inc., Illinois Tool Works Inc., and ITW

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Finishing LLC, dated April 14, 2011 (the “Asset Purchase Agreement”).

- B. “Acquisition Date” means the date the Acquisition is consummated.
- C. “Commission-approved Acquirer” means any Person that receives the prior approval of the Commission to acquire the Liquid Finishing Business Assets pursuant to the Decision and Order.
- D. “Confidential Business Information” means competitively sensitive, proprietary and all other business information of any kind, except for any information that Respondents demonstrate (i) was or becomes generally available to the public other than as a result of a disclosure by Respondents, or (ii) was available, or becomes available, to Respondents on a non-confidential basis, but only if, to the knowledge of Respondents, the source of such information is not in breach of a contractual, legal, fiduciary, or other obligation to maintain the confidentiality of the information.
- E. “Decision and Order” means (i) the proposed Decision and Order contained in the Consent Agreement in this matter until the issuance and service of a final Decision and Order by the Commission; and (ii) the final Decision and Order issued by the Commission following the issuance and service of a final Decision and Order by the Commission.
- F. “Divestiture Date” means the date on which Respondent Graco (or the Divestiture Trustee) and a Commission-approved Acquirer consummate a transaction to divest, license, assign, grant, transfer, deliver and otherwise convey the Liquid Finishing Business Assets completely and as required by Paragraph II. (or Paragraph V.) of Decision and Order.
- G. “Gema Powder Finishing Business” means the worldwide business of developing, assembling,

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manufacturing, distributing, selling, or servicing powder finishing systems and products conducted prior to the Acquisition by Respondent ITW, including all business activities relating to the development, manufacture, and sale of products under the brand name Gema. “Gema Powder Finishing Business” does not include the Liquid Finishing Business.

- H. “Hold Separate” means this Order to Hold Separate and Maintain Assets.
- I. “Hold Separate Business” means the (i) Liquid Finishing Business Assets and (ii) Liquid Finishing Business.
- J. “Hold Separate Business Employees” means the Liquid Finishing Business Employees, the Hold Separate Gema Employees, and the Hold Separate Gema Shared Employees.
- K. “Hold Separate Gema Employees” means employees located in the United Kingdom, Germany, France, Italy, Australia, Japan, and Mexico in facilities shared with the Liquid Finishing Business or Liquid Finishing Business Assets whose job responsibilities relate exclusively to Gema powder finishing products.
- L. “Hold Separate Gema Shared Employees” means employees located in the United Kingdom, Germany, France, Italy, Australia, Japan, and Mexico in facilities shared with the Liquid Finishing Business or Liquid Finishing Business Assets whose job responsibilities relate to both the liquid finishing and powder finishing businesses.
- M. “Hold Separate Period” means the time period during which the Hold Separate is in effect, which shall begin on the date this Hold Separate becomes a final and effective order, which shall occur on or prior to the Acquisition Date, and terminate pursuant to Paragraph V. of this Hold Separate.

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- N. “Hold Separate Manager(s)” means the Person(s) appointed pursuant to Paragraph II.C.2. of this Hold Separate.
- O. “Hold Separate Trustee” means the Person appointed pursuant to Paragraph II.C.1. of this Hold Separate.
- P. “Liquid Finishing Business” means the worldwide business of developing, assembling, manufacturing, distributing, selling, or servicing liquid finishing systems and products conducted prior to the Acquisition by Respondent ITW, including all business activities relating to the development, manufacture, and sale of products under the brand names Binks, DeVilbiss, Ransburg, and BGK. “Liquid Finishing Business” does not include the Gema Powder Finishing Business.
- Q. “Liquid Finishing Business Assets” means all rights, title, and interest in and to all property and assets, tangible and intangible, of every kind and description, wherever located, and any improvements or additions thereto, relating to the Liquid Finishing Business.
- R. “Liquid Finishing Business Employees” means any full-time, part-time, or contract employee(s) of the Liquid Finishing Business, including the Hold Separate Gema Shared Employees, immediately prior to the Acquisition.
- S. “Orders” means the Decision and Order and this Hold Separate.
- T. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other business entity.
- U. “Prospective Acquirer” means a Person that Graco (or a Divestiture Trustee appointed under the Decision and Order) intends to submit as a Commission-approved Acquirer to the Commission for its prior approval pursuant to the Decision and Order.

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**II.**

**IT IS FURTHER ORDERED** that:

- A. During the Hold Separate Period, Respondent Graco shall:
1. Hold the Hold Separate Business separate, apart, and independent as required by this Hold Separate and shall vest the Hold Separate Business with all rights, powers, and authority necessary to conduct its business.
  2. Not exercise direction or control over, or influence directly or indirectly, the Hold Separate Business or any of its operations, the Hold Separate Trustee, or the Hold Separate Managers, except to the extent that Respondent Graco must exercise direction and control over the Hold Separate Business as is necessary to assure compliance with this Hold Separate, the Consent Agreement, the Decision and Order, and all applicable laws. Nothing herein shall limit taking such action as may be required to ensure compliance with financial reporting requirements, with all applicable laws, regulations, and other legal requirements, or with policies and standards concerning health, safety, and environmental aspects of the Hold Separate Business or with the integrity of the Hold Separate Business financial controls.
  3. Take such actions as are necessary to maintain and assure the continued viability, marketability, and competitiveness of the Hold Separate Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear, and shall not sell, transfer, encumber, or otherwise impair the Hold Separate Business (except as required by the Decision and Order).

## Interlocutory Orders, Etc.

- B. From the time Respondents execute the Consent Agreement until the Acquisition Date, Respondent ITW shall take such actions as are necessary to maintain and assure the continued maintenance of the full economic viability, marketability, and competitiveness of the Hold Separate Business, and prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets, except for ordinary wear and tear.
- C. Respondent Graco shall hold the Hold Separate Business separate, apart, and independent of Respondent Graco on the following terms and conditions:
  - 1. At any time after the Respondents sign the Consent Agreement, the Commission may appoint a Hold Separate Trustee to monitor the operations of the Hold Separate Business and to ensure that the Respondents comply with their obligations as required by this Hold Separate and the Decision and Order. The Hold Separate Trustee shall serve as Hold Separate Trustee pursuant to the agreement executed by the Hold Separate Trustee and Respondent Graco (“Hold Separate Trustee Agreement”).
    - a. The Commission shall select the Hold Separate Trustee, subject to the consent of Respondent Graco, which consent shall not be unreasonably withheld. If Respondent Graco has not opposed, in writing, including the reasons for opposing, the selection of the proposed Hold Separate Trustee within ten (10) days after notice by the staff of the Commission to Respondent Graco of the identity of the proposed Hold Separate Trustee, Respondent Graco shall be deemed to have consented to the selection of the proposed Hold Separate Trustee.

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- b. The Hold Separate Trustee shall have the responsibility for monitoring the organization of the Hold Separate Business; supervising the management of the Hold Separate Business by the Hold Separate Managers; maintaining the independence of the Hold Separate Business; and monitoring Respondents' compliance with their respective obligations pursuant to the Orders, including, without limitation, maintaining the viability, marketability, and competitiveness of the Hold Separate Business pending divestiture.
- c. No later than one (1) day after the appointment of the Hold Separate Trustee, Respondent Graco shall enter into an agreement ("Hold Separate Trustee Agreement") that, subject to the prior approval of the Commission, transfers to and confers upon the Hold Separate Trustee all rights, powers, and authority necessary to permit the Hold Separate Trustee to perform his or her duties and responsibilities pursuant to this Hold Separate, in a manner consistent with the purposes of the Orders and in consultation with Commission staff, and shall require that the Hold Separate Trustee shall act in a fiduciary capacity for the benefit of the Commission.
- d. Subject to all applicable laws and regulations, the Hold Separate Trustee shall have full and complete access to all personnel, books, records, documents, and facilities of the Hold Separate Business, and to any other relevant information as the Hold Separate Trustee may reasonably request including, but not limited to, all documents and records kept by Respondents in the ordinary course of business that relate to the Hold Separate Business. Respondents shall develop such financial or other information as the Hold Separate Trustee

## Interlocutory Orders, Etc.

may reasonably request and shall cooperate with the Hold Separate Trustee.

- e. Respondents shall take no action to interfere with or impede the Hold Separate Trustee's ability to monitor Respondents' compliance with this Hold Separate, the Consent Agreement, or the Decision and Order, or otherwise to perform his or her duties and responsibilities consistent with the terms of this Hold Separate.
- f. The Hold Separate Trustee shall have the authority to employ, at the cost and expense of Respondent Graco, such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to carry out the Hold Separate Trustee's duties and responsibilities.
- g. The Commission may require the Hold Separate Trustee and each of the Hold Separate Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement relating to materials and information received from the Commission in connection with performance of the Hold Separate Trustee's duties.
- h. Respondents may require the Hold Separate Trustee and each of the Hold Separate Trustee's consultants, accountants, attorneys, and other representatives and assistants to sign an appropriate confidentiality agreement; *provided, however*, such agreement shall not restrict the Hold Separate Trustee from providing any information to the Commission.
- i. Thirty (30) days after the Acquisition Date, and every thirty (30) days thereafter until the Hold Separate terminates, the Hold Separate Trustee

## Interlocutory Orders, Etc.

shall report in writing to the Commission concerning the efforts to accomplish the purposes of this Hold Separate and Respondents' compliance with their obligations under the Hold Separate and the Decision and Order. Included within that report shall be the Hold Separate Trustee's assessment of the extent to which the businesses comprising the Hold Separate Business are meeting (or exceeding) their projected goals as are reflected in operating plans, budgets, projections, or any other regularly prepared financial statements.

- j. If the Hold Separate Trustee ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Commission may appoint a substitute Hold Separate Trustee consistent with the terms of this Hold Separate, subject to the consent of Respondent Graco, which consent shall not be unreasonably withheld. If Respondent Graco has not opposed, in writing, including the reasons for opposing, the selection of the substitute Hold Separate Trustee within ten (10) days after notice by the staff of the Commission to Respondent Graco of the identity of any substitute Hold Separate Trustee, Respondent Graco shall be deemed to have consented to the selection of the proposed substitute Hold Separate Trustee. Respondent Graco and the substitute Hold Separate Trustee shall execute a Hold Separate Trustee Agreement, subject to the approval of the Commission, consistent with this paragraph.
- k. The Hold Separate Trustee shall serve until the day after the Divestiture Date; *provided, however,* that the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders.

## Interlocutory Orders, Etc.

2. No later than five (5) days after the Acquisition Date, Respondent Graco shall appoint one or more Hold Separate Managers (collectively the “Hold Separate Managers”), subject to the approval of the Hold Separate Trustee in consultation with Commission staff, to manage and maintain the Hold Separate Business in the regular and ordinary course of business and in accordance with past practice.
  - a. The Hold Separate Managers shall be responsible for the operation of the Hold Separate Business and shall report directly and exclusively to the Hold Separate Trustee, and shall manage the Hold Separate Business independently of the management of Respondent Graco. The Hold Separate Managers shall not be involved, in any way, in the operations of the other businesses of Respondent Graco during the term of this Hold Separate.
  - b. No later than three (3) days after appointment of the Hold Separate Manager(s), Respondent Graco shall enter into a management agreement with each such manager that, subject to the prior approval of the Hold Separate Trustee, in consultation with the Commission staff, transfers all rights, powers, and authority necessary to permit each such Hold Separate Manager to perform his or her duties and responsibilities pursuant to this Hold Separate, in a manner consistent with the purposes of the Orders.
  - c. Respondents shall provide the Hold Separate Managers with reasonable financial incentives to undertake this position. Such incentives shall include employee benefits, including regularly scheduled raises, bonuses, vesting of retirement benefits (as permitted by law) on the same basis as provided for under the Asset

## Interlocutory Orders, Etc.

Purchase Agreement for other employees hired by Respondent Graco, and additional incentives as may be necessary to assure the continuation and prevent any diminution of the Hold Separate Business's viability, marketability, and competitiveness until the end of the Hold Separate Period, and as may otherwise be necessary to achieve the purposes of this Hold Separate.

- d. The Hold Separate Managers shall make no material changes in the ongoing operations of the Hold Separate Business except with the approval of the Hold Separate Trustee, in consultation with the Commission staff.
- e. The Hold Separate Managers shall have the authority, with the approval of the Hold Separate Trustee, to remove Hold Separate Business Employees and replace them with others of similar experience or skills. If any Person ceases to act or fails to act diligently and consistent with the purposes of this Hold Separate, the Hold Separate Managers, in consultation with the Hold Separate Trustee, may request Respondent Graco to, and Respondent Graco shall, appoint a substitute Person, which Person the respective manager shall have the right to approve.
- f. In addition to Hold Separate Business Employees, the Hold Separate Managers may, with the approval of the Hold Separate Trustee and at the cost and expense of Respondent Graco, employ such consultants, accountants, attorneys, and other representatives and assistants as are reasonably necessary to assist the respective manager in managing the Hold Separate Business and in carrying out the manager's duties and responsibilities. Nothing contained herein shall preclude a Hold Separate Manager from contacting or communicating

## Interlocutory Orders, Etc.

directly with the staff of the Commission, either at the request of the staff of the Commission or in the discretion of the manager.

- g. The Hold Separate Trustee shall be permitted, in consultation with the Commission staff, to remove any Hold Separate Manager for cause. Within three (3) days after such removal, Respondent Graco shall appoint a replacement manager, subject to the approval of the Hold Separate Trustee in consultation with Commission staff, on the same terms and conditions as provided in this paragraph.
3. The Hold Separate Trustee and the Hold Separate Managers shall serve, without bond or other security, at the cost and expense of Respondent Graco, on reasonable and customary terms commensurate with the person's experience and responsibilities.
4. Respondent Graco shall indemnify the Hold Separate Trustee and Hold Separate Managers and hold each harmless against any losses, claims, damages, liabilities, or expenses arising out of, or in connection with, the performance of the Hold Separate Trustee's or the Hold Separate Managers' duties, including all reasonable fees of counsel and other expenses incurred in connection with the preparation for, or defense of any claim, whether or not resulting in any liability, except to the extent that such liabilities, losses, damages, claims, or expenses result from gross negligence or willful misconduct by the Hold Separate Trustee or the Hold Separate Managers.
5. The Hold Separate Business shall be staffed with sufficient employees (including any full-time, part-time, or contract employee of the Hold Separate Business) to maintain the viability and competitiveness of the Hold Separate Business. To

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the extent that such employees leave or have left the Hold Separate Business prior to the Divestiture Date, the Hold Separate Managers, with the approval of the Hold Separate Trustee, may replace departing or departed employees with persons who have similar experience and expertise or determine not to replace such departing or departed employees.

6. In connection with support services or products not included within the Hold Separate Business, Respondent Graco shall continue to provide, or offer to provide, the same support services to the Hold Separate Business as customarily have been or were being provided to such businesses by ITW prior to the Acquisition Date. For any services or products that Respondents may provide to the Hold Separate Business, Respondents may charge no more than the same price they charge others for the same services or products (or a commercially reasonable rate if ITW had not previously charged for such services). Respondents' personnel providing such services or products must retain and maintain all Confidential Business Information of or pertaining to the Hold Separate Business on a confidential basis, and, except as is permitted by this Hold Separate, such persons shall be prohibited from disclosing, providing, discussing, exchanging, circulating, or otherwise furnishing any such information to or with any person whose employment involves any of Respondents' businesses, other than the Hold Separate Business. Such personnel shall also execute confidentiality agreements prohibiting the disclosure of any Confidential Business Information of the Hold Separate Business.
  - a. Respondent Graco shall offer to the Hold Separate Business, directly or through Respondent ITW, any services and products that Respondent ITW provided, in the ordinary course of business directly or through third

## Interlocutory Orders, Etc.

party contracts to the business constituting the Hold Separate Business at any time since December 31, 2011, or such services that Respondent ITW is obligated to provide under Schedule 1.2 of the Asset Purchase Agreement. Respondent ITW shall treat the Hold Separate Business as a Graco Subsidiary, as that term is defined in the Asset Purchase Agreement. Subject to the foregoing, the services and products that Respondent Graco shall offer the Hold Separate Business shall include, but shall not be limited to, the following:

- i. human resources and administrative services, including but not limited to payroll processing, labor relations support, retirement administration, and procurement and administration of employee benefits, including health benefits;
- ii. federal and state regulatory compliance and policy development services;
- iii. environmental health and safety services, which are used to develop corporate policies and insure compliance with federal and state regulations and corporate policies;
- iv. financial accounting services;
- v. preparation of tax returns;
- vi. audit services;
- vii. information technology support services;
- viii. processing of accounts payable and accounts receivable;
- ix. technical support;
- x. procurement of supplies;

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- xi. maintenance and repair of facilities;
  - xii. procurement of goods and services utilized in the ordinary course of business by the Hold Separate Business;
  - xiii. legal services; and
  - xiv. cash management services in the ordinary course of business, including cash sweeps, consistent with the cash management services provided by Respondent ITW prior to the Acquisition Date.
- b. The Hold Separate Business shall have, at the option of the Hold Separate Managers with the approval of the Hold Separate Trustee, the ability to acquire services and products from third parties (including Respondent ITW) unaffiliated with Respondent Graco.
7. Respondent Graco shall provide the Hold Separate Business with sufficient financial and other resources:
- a. as are appropriate in the judgment of the Hold Separate Trustee to operate the Hold Separate Business as it is currently operated (including efforts to generate new business) consistent with the practices of the Hold Separate Business in place prior to the Acquisition;
  - b. to perform all maintenance to, and replacements of, the assets of the Hold Separate Business in the ordinary course of business and in accordance with past practice and current plans;
  - c. to carry on during the Hold Separate Period such capital projects, physical plant improvements, and business plans as are already underway for which all necessary

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regulatory and legal approvals have been obtained, including but not limited to existing or planned renovation or expansion projects; and

- d. to maintain the viability, competitiveness, and marketability of the Hold Separate Business.

Such financial resources to be provided to the Hold Separate Business shall include, but shall not be limited to, (i) general funds, (ii) capital, (iii) working capital, and (iv) reimbursement for any operating losses, capital losses, or other losses; *provided, however,* that, consistent with the purposes of the Decision and Order and in consultation with the Hold Separate Trustee: (i) the Hold Separate Managers may reduce in scale or pace any capital or research and development project, or substitute any capital or research and development project for another of the same cost; and (ii) to the extent that the Hold Separate Business generates financial funds in excess of financial resource needs, Respondent Graco shall have availability to such excess funds consistent with practices in place for the Hold Separate Business prior to the Acquisition.

8. Respondent Graco shall cause the following individuals that have access to Confidential Business Information of or pertaining to the Hold Separate Business to submit to the Hold Separate Trustee, or Commission staff as appropriate, a signed statement that the individual will maintain the confidentiality required by the terms and conditions of this Hold Separate: (i) the Hold Separate Trustee, (ii) the Hold Separate Managers, (iii) each of Respondent Graco's employees not subject to the Hold Separate, (iv) the Hold Separate Gema Employees, (v) the Hold Separate Gema Shared Employees, and (vi) such additional Persons that the Hold Separate Trustee, in consultation with Commission staff, may identify. These individuals must retain and maintain all

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Confidential Business Information of, or pertaining to, the Hold Separate Business on a confidential basis and, except as is permitted by this Hold Separate, such Persons shall be prohibited from disclosing, providing, discussing; exchanging, circulating, or otherwise furnishing any such information to or with any other Person whose employment involves any of Respondents' businesses or activities other than the Hold Separate Business.

9. Except for the Hold Separate Managers, Hold Separate Business Employees, and support services employees involved in providing services to the Hold Separate Business pursuant to this Hold Separate, and except to the extent provided in this Hold Separate, Respondent Graco shall not permit any other of its employees, officers, or directors to be involved in the operations of the Hold Separate Business.
10. Respondents' employees (other than the Liquid Finishing Business Employees, the Hold Separate Gema Shared Employees, and Graco employees involved in providing support services to the Hold Separate Business pursuant to Paragraph II.C.6.) shall not receive, or have access to, or use or continue to use any Confidential Business Information of the Hold Separate Business except:
  - a. as required by law; and
  - b. to the extent that necessary information is exchanged:
    - i. in the course of consummating the Acquisition in compliance with the terms of the Asset Purchase Agreement;
    - ii. as necessary to effect the divestiture of the Hold Separate Business, including in connection with the marketing of the

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divested assets pursuant to the Consent Agreement, in negotiating agreements to divest assets pursuant to the Consent Agreement and engaging in related due diligence;

- iii. in complying with this Hold Separate or the Consent Agreement;
- iv. in overseeing compliance with policies and standards concerning the safety, health, and environmental aspects of the operations of the Hold Separate Business and the integrity of the financial controls of the Hold Separate Business;
- v. in defending legal claims, investigations, or enforcement actions threatened or brought against or related to the Hold Separate Business;
- vi. to lenders and auditors; or
- vii. in obtaining legal advice.

Nor shall the Hold Separate Managers or any Hold Separate Business Employees receive or have access to, or use or continue to use, any Confidential Business Information about Respondents and relating to Respondents' businesses, except such information as is necessary to maintain and operate the Hold Separate Business.

In addition to the foregoing, Respondent Graco may receive aggregate financial and operational information relating to the Hold Separate Business to the extent necessary to allow Respondent Graco to comply with the requirements and obligations of the laws of the United States and other countries, to prepare consolidated financial reports, tax returns, reports required by securities laws, payroll and benefits information, and personnel reports, and to

## Interlocutory Orders, Etc.

comply with this Hold Separate. Any such information that is obtained pursuant to this subparagraph shall be used only for the purposes set forth in this subparagraph.

11. Subject to all other provisions in this Hold Separate, the:

- a. Hold Separate Gema Employees (i) may receive or have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the Gema Powder Finishing Business; (ii) shall not seek, receive, have access to, or disclose any Confidential Business Information pertaining to the Liquid Finishing Business; and (iii) shall provide the signed confidentiality statement required by Paragraph II.C.8. of this Hold Separate.
- b. Hold Separate Gema Shared Employees (i) may receive or have access to, use or continue to use, or disclose any Confidential Business Information pertaining to the Gema Powder Finishing Business and to the Liquid Finishing Business; (ii) shall not disclose, provide, discuss, exchange, circulate, or otherwise furnish any such information pertaining to the Liquid Finishing Business to or with any other Person whose employment involves any of Respondent Graco's competing liquid finishing businesses; and (iii) shall provide the signed confidentiality statement required by Paragraph II.C.8. of this Hold Separate.

12. Respondent Graco and the Hold Separate Business shall jointly implement, and at all times during the Hold Separate Period maintain in operation, a system, as approved by the Hold Separate Trustee, of access and data controls to prevent unauthorized access to or dissemination of Confidential Business Information of the Hold Separate Business, including, but not limited to, the opportunity by the

## Interlocutory Orders, Etc.

Hold Separate Trustee, on terms and conditions agreed to with Respondents, to audit Respondents' networks and systems to verify compliance with this Hold Separate.

13. No later than five (5) days after the Acquisition Date, Respondent Graco shall establish written procedures, subject to the approval of the Hold Separate Trustee, covering the management, maintenance, and independence of the Hold Separate Business consistent with the provisions of this Hold Separate.
  14. No later than five (5) days after the date this Hold Separate becomes final, Respondent Graco shall circulate to persons who are employed in Respondent Graco's businesses that compete with the Hold Separate Business, and shall circulate on the Acquisition Date to employees of the Hold Separate Business, a notice of this Hold Separate, in a form approved by the Hold Separate Trustee in consultation with Commission staff.
- D. Until the Divestiture Date, Respondent Graco shall provide each Hold Separate Employee with reasonable financial incentives to continue in his or her position consistent with past practices and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Liquid Finishing Business and the Liquid Finishing Business Assets pending divestiture. Such incentives shall include employee benefits, including regularly scheduled raises, bonuses, vesting of retirement benefits (as permitted by law) on the same basis as provided for under the Asset Purchase Agreement for other employees hired by Respondent Graco, and additional incentives as may be necessary to assure the continuation and prevent any diminution of the viability, marketability, and competitiveness of the Liquid Finishing Business Assets until the Divestiture Date, and as may otherwise be necessary to achieve the purposes of this Hold Separate.

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- E. From the date the Respondents execute the Consent Agreement until this Hold Separate terminates, Respondent Graco shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Hold Separate Employee for a position of employment with Respondent Graco. A Prospective Acquirer or the Commission-approved Acquirer shall have the option of offering employment to any Hold Separate Employee. Respondent Graco shall not interfere with the employment by a Prospective Acquirer or the Commission-approved Acquirer of such employee; shall not offer any incentive to such employee to decline employment with a Prospective Acquirer or the Commission-Acquirer or to accept other employment with the Respondent Graco; and shall remove any impediments that may deter such employee from accepting employment with a Prospective Acquirer or the Commission-approved Acquirer including, but not limited to, any non-compete or confidentiality provisions of employment or other contracts that would affect the ability of such employee to be employed by a Prospective Acquirer or the Commission-approved Acquirer.
- F. Respondent Graco shall not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Hold Separate Employee who has accepted an offer of employment with a Prospective Acquirer or the Commission-approved Acquirer to terminate his or her employment relationship with such Person; *provided, however,* Respondent Graco may:
1. advertise for employees in newspapers, trade publications, or other media, or engage recruiters to conduct general employee search activities, so long as these actions are not targeted specifically at any Hold Separate Business Employees; and
  2. hire Hold Separate Business Employees who apply for employment with Respondent Graco, so long as such individuals were not solicited by the Respondent Graco in violation of this paragraph;

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*provided further*, that this sub-Paragraph shall not prohibit Respondent Graco from making offers of employment to or employing any Hold Separate Business Employees if a Prospective Acquirer or the Commission-approved Acquirer has notified Respondent Graco in writing that a Prospective Acquirer or the Commission-approved Acquirer does not intend to make an offer of employment to that employee, or where such an offer has been made and the employee has declined the offer, or where the individual's employment has been terminated by a Prospective Acquirer or the Commission-approved Acquirer.

- G. The purpose of this Hold Separate is to: (1) preserve the assets and businesses within the Hold Separate Business as viable, competitive, and ongoing businesses independent of Respondent Graco until the divestiture required by the Decision and Order is achieved; (2) assure that no Confidential Business Information is exchanged between the Respondents and the Hold Separate Business, except in accordance with the provisions of this Hold Separate; (3) prevent interim harm to competition pending the relevant divestitures and other relief; and (4) maintain the full economic viability, marketability, and competitiveness of the Hold Separate Business, and prevent the destruction, removal, wasting, deterioration, or impairment of any of the assets or businesses within the Hold Separate Business except for ordinary wear and tear.

**III.**

**IT IS FURTHER ORDERED** that Respondent Graco shall notify the Commission at least thirty (30) days prior to:

- A. Any proposed dissolution of Respondent Graco;
- B. Any proposed acquisition, merger, or consolidation of Respondent Graco; or

## Interlocutory Orders, Etc.

- C. Any other change in Respondent Graco, including, but not limited to, assignment and the creation or dissolution of subsidiaries, if such change might affect compliance obligations arising out of this Order.

**IV.**

**IT IS FURTHER ORDERED** that, for the purpose of determining or securing compliance with this Hold Separate, and subject to any legally recognized privilege, and upon written request and upon five (5) days' notice to the relevant Respondent, relating to compliance with this Hold Separate, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during business office hours of the relevant Respondent(s) and in the presence of counsel, to all facilities and access to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and all other records and documents in the possession or under the control of the relevant Respondent(s) related to compliance with the Consent Agreement and/or the Orders, which copying services shall be provided by such Respondent(s) at the request of the authorized representative(s) of the Commission and at the expense of such Respondent(s); and
- B. Without restraint or interference from such Respondent(s), to interview officers, directors, or employees of such Respondent(s), who may have counsel present.

**V.**

**IT IS FURTHER ORDERED** that this Hold Separate shall terminate at the earlier of:

- A. Three (3) business days after the Commission withdraws its acceptance of the Consent Agreement pursuant to the provisions of Commission Rule 3.25(f), 16 C.F.R. § 3.25(f); or

## Statement of the Commission

- B. The day after the Divestiture Date of the Hold Separate Assets required to be divested pursuant to the Decision and Order.

By the Commission.

**Statement of the Federal Trade Commission**

On December 15, 2011, the Commission issued an administrative complaint challenging Graco Inc.'s ("Graco") proposed acquisition of the industrial finishing equipment businesses of ITW Finishing LLC and Illinois Tool Works Inc. (collectively "ITW"). The Commission also authorized its staff to file a separate complaint seeking a temporary restraining order and preliminary injunction in federal district court. That federal court proceeding is pending in the United States District Court for the District of Minnesota.

The matter has now been withdrawn from administrative adjudication, and the Commission has voted unanimously to issue an Order to Hold Separate and Maintain Assets ("Hold Separate") to Respondents Graco and ITW, pending consideration of a proposed Agreement Containing Consent Orders ("Consent Agreement") that has been entered into by and among the Respondents and Complaint Counsel supporting the administrative complaint. This will allow Graco to complete the challenged acquisition, subject to and in compliance with the requirements of the Hold Separate issued today.

The Hold Separate applies to all ITW liquid finishing businesses and assets worldwide that Graco is acquiring in the acquisition (collectively, the "Liquid Finishing Business Assets"), including business activities related to the development, manufacture, and sale of products under the Binks, DeVilbiss, Ransburg, and BGK brand names.

## Statement of the Commission

The purpose of the Hold Separate is to allow the Commission staff sufficient time fully to review and consider the appropriate scope of divestiture and other relief needed to remedy the anticompetitive effects of Graco's acquisition of the Liquid Finishing Business Assets as alleged in the administrative complaint. During the hold separate period, Graco and ITW have committed to cooperate fully and in good faith with staff's review.

The Commission is not voting to accept or reject the proposed Consent Agreement for public comment at this time. After staff completes its review and submits to the Commission any additional recommendations regarding the proposed Consent Agreement, the Commission may take such action as it deems appropriate, including accepting the Consent Agreement, either as proposed or with modifications, for public comment.

The Commission is able to accept the Hold Separate under conditions that will allow the parties to complete their planned acquisition because both sides appear to be moving closer to a solution that will benefit consumers.

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**IN THE MATTER OF**

**MCWANE, INC.,  
AND  
STAR PIPE PRODUCTS, LTD.**

*Docket No. 9351. Order, March 29, 2012*

Order extending the withdrawal of Respondent Star Pipe Products from adjudication in this matter to facilitate further consideration of a proposed consent agreement.

**ORDER**

On February 23, 2012, all claims in this matter against Respondent Star Pipe Products, Ltd. (“Respondent Star”) were by order withdrawn from adjudication for the purpose of considering a proposed consent agreement. Under the February 23, 2012 Order, all proceedings in this matter as they pertain to Respondent Star are scheduled to revert to Part 3 adjudicative status at 12:01 a.m. on Saturday, March 31, 2012. To facilitate further consideration of a proposed consent agreement, the Commission has decided to further extend the withdrawal of Respondent Star from adjudication in this matter. Accordingly,

**IT IS ORDERED**, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c), that all claims against Respondent Star, as set forth in the First Violation Alleged and the Second Violation Alleged in the Complaint will remain withdrawn in their entirety from adjudication until 12:01 a.m. on June 1, 2012, at which time Respondent Star will return to adjudicative status under Part 3 of the Commission Rules of Practice.

By the Commission.

Interlocutory Orders, Etc.

IN THE MATTER OF

**PROMEDICA HEALTH SYSTEM, INC.***Docket No. 9346. Order, April 17, 2012*

Order giving notice of the Commission's intent to disclose *in camera* information served on Complaint Counsel, Counsel for the Defendant, and eight non-party participants. This Notice was served via ten individual Orders, which were identical except for the identity of the individual participant.

## NOTICE OF INTENT TO DISCLOSE IN CAMERA INFORMATION

This notice advises counsel for the parties and [ ] in this matter that, consistent with Section 21(d)(2) of the Federal Trade Commission (FTC) Act, 15 U.S.C. § 57b-2(d)(2), and FTC Rule of Practice 3.45, 16 C.F.R. § 3.45, the Commission intends to place on the public record the information described in the attachment to this notice as part of the Commission's Opinion and Final Order in the above-captioned matter. (Except for notice to Complaint Counsel and to Counsel for Respondent, the attachment to this notice describes only information submitted by the recipient of this notice, and does not describe information submitted by others, who are being served with their own notices and attachments.)

In determining to release information for which [ ] has requested *in camera* treatment in the course of an adjudicative proceeding, the Commission balances the potential harm [ ] of disclosure against the substantial interest in making publicly available the key facts and background underlying a Commission decision. *Orkin Exterminating Co.*, 108 F.T.C. 147 (1986). Public knowledge of such information both permits improved evaluation of the fairness and wisdom of a given Commission decision and provides clearer guidance to affected parties. *Id.* See also *RSR Corp.*, 88 F.T.C. 206 (1976); *id.*, 88 F.T.C. 734, 735 (1976). Accordingly, the *in camera* standard requires that there be a "clearly defined, serious injury" [ ] sufficient to outweigh the public interest in disclosure. See *H.P. Hood & Sons, Inc.*, 58 F.T.C. 1184, 1188 (1961); *General Foods Corp.*, 95 F.T.C. 352, 355 (1980). As noted in its *in camera* rule, the Commission reserves the authority to disclose *in camera* material to the extent

## Interlocutory Orders, Etc.

necessary for the proper disposition of the proceeding. 16 C.F.R. § 3.45(a).

The Commission does not believe that public disclosure of the information in question will clearly cause Aetna the kind of substantial competitive harm that would be sufficient to meet the high *in camera* standard. The information to be disclosed is either so minimal in amount, piecemeal in nature, or dated that it would appear to be of little, if any, meaningful, current use to a competitor. Moreover, some of the disclosures constitute general references or statements based on the content of confidential materials, rather than any direct disclosure of such material, which the *in camera* procedures expressly permit. See 16 C.F.R. § 3.45(d). Additionally, some of the information is already disclosed in other publicly available materials. The Commission believes that the potential harm resulting from the limited disclosures described above is outweighed by the value of making public to the greatest extent possible the factual evidence underlying the Commission's Opinion and Order. Such disclosures are directly relevant and material to an understanding of the factual basis for the decision reached in this matter. 15 U.S.C. § 57b-2(d)(2); *Orkin Exterminating*, 108 F.T.C. at 147.

For these reasons, the Commission does not believe that the disclosure of the information at issue would provide sufficient knowledge to competitors so that its release would impose any clearly defined, serious injury [ ] that would outweigh the public interest in such disclosure. See *Orkin Exterminating Co.*, 108 F.T.C. at 147; *General Foods Corp.*, 95 F.T.C. at 355. The Commission further notes that these disclosures will not affect the ongoing *in camera* status, if any, of the underlying *in camera* exhibits or other protected filings that may be cited in the Commission's Opinion and Order, except for the portions of exhibits or filings disclosed therein. Accordingly, the Commission intends to place its Opinion and Order on the public record, including information described in the attachment to this notice, no sooner than ten days following service of this notice.

By direction of the Commission, Commissioner Ohlhausen not participating.

Interlocutory Orders, Etc.

IN THE MATTER OF

**CARDINAL HEALTH, INC.**

*Docket No. C-4339. Order, April 18, 2012*

Letter approving the divestiture of three former Cardinal nuclear pharmacies to Patient Care Infusion, LLC.

LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

David P. Wales, Esquire  
Jones Day

Re: *In the Matter of Cardinal Health, Inc.*,  
*FTC File No. 091-0136; Docket No. C-4339*

Dear Mr. Wales:

This letter responds to the *Petition of Cardinal Health, Inc. for Approval of Proposed Divestiture* (“Petition”) filed by Cardinal Health, Inc. (“Cardinal”) on February 17, 2012, requesting that the Commission approve Cardinal’s proposed divestiture of three former Cardinal nuclear pharmacies to Patient Care Infusion, LLC (“PCI”) pursuant to the Decision and Order in this matter. The Petition was placed on the public record for comments until March 26, 2012 and one comment was received.

After consideration of the proposed divestiture as set forth in the Petition and supplemental documents, as well as other available information, the Commission has determined to approve the proposed divestiture. In according its approval, the Commission has relied upon the information submitted and representations made in connection with the Petition, and has assumed them to be accurate and complete.

By direction of the Commission, Commissioner Ohlhausen not participating.

Interlocutory Orders, Etc.

**IN THE MATTER OF**

**MCWANE, INC.,  
AND  
STAR PIPE PRODUCTS, LTD.**

*Docket No. 9351. Order, May 21, 2012*

Order permanently withdrawing Respondent Star Pipe Products from adjudication in this matter because the Commission has accorded final approval to the Decision and Order against Respondent Star Pipe Products.

**ORDER WITHDRAWING RESPONDENT STAR PIPE PRODUCTS, LTD.  
FROM ADJUDICATION**

On February 23, 2012, all claims in this matter against Respondent Star Pipe Products, Ltd. (“Respondent Star”) were by Commission Order withdrawn from adjudication for the purpose of considering a proposed consent agreement, and that withdrawal was extended until June 1, 2012, by Commission Order dated March 29, 2012. The Commission has now accorded final approval to the Decision and Order against Respondent Star, and has therefore determined to permanently withdraw from adjudication the proceedings in this matter as they pertain to Respondent Star. Accordingly,

**IT IS ORDERED**, pursuant to Rule 3.25(c) of the Commission Rules of Practice, 16 C.F.R. § 3.25(c), that all claims against Respondent Star, as set forth in the First Violation Alleged and the Second Violation Alleged in the Complaint be, and they hereby are, permanently withdrawn from adjudication; and

**IT IS FURTHER ORDERED**, pursuant to Rule 3.25(e) of the Commission Rules of Practice, 16 C.F.R. § 3.25(e), that all claims against Respondent McWane, Inc. in this matter will remain in an adjudicative status.

By the Commission, Commissioner Ohlhausen not participating.

Interlocutory Orders, Etc.

IN THE MATTER OF

**AMERIGAS PROPANE, L.P.,  
AMERIGAS PROPANE, INC.,  
ENERGY TRANSFER PARTNERS, L.P.,  
AND  
ENERGY TRANSFER PARTNERS GP, L.P.**

*Docket No. C-4346. Order, May 31, 2012*

Letter approving the divestiture of Heritage Propane Express to JP Energy Partners, LP.

## LETTER ORDER APPROVING DIVESTITURE OF CERTAIN ASSETS

Dionne C. Lomax  
Vinson & Elkins LLP

*Re: AmeriGas Partners, L.P./Energy Transfer Partners L.P.,  
Docket No. C-4346*

Dear Ms. Lomax:

This is in reference to the Petition of Energy Transfer Partners, L.P. and Energy Transfer Partners, GP, L.P. for Approval of the Proposed Divestiture of Heritage Propane Express to JP Energy Partners, LP (“the Petition”). Pursuant to the Decision and Order in Docket No. C-4346, Energy Transfer Partners requests prior Commission approval of its proposal to sell its Heritage Propane Express business and related assets to JP Energy Partners.

After consideration of Energy Transfer Partner’s Petition and other available information, the Commission has determined to approve the proposed sale as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by Energy Transfer Partners and JP Energy Partners in connection with Energy Transfer Partner’s Application and has assumed them to be accurate and complete.

Interlocutory Orders, Etc.

By direction of the Commission, Commissioner Ohlhausen  
not participating.

RESPONSES TO PETITIONS TO QUASH OR  
LIMIT COMPULSORY PROCESS

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**WYNDHAM WORLDWIDE CORPORATION,  
WYNDHAM HOTEL GROUP, LLC,  
WYNDHAM HOTELS & RESORTS, LLC,  
AND  
WYNDHAM HOTEL MANAGEMENT, INC.**

*FTC File No. 102 3142 – Decision, April 11, 2012*

RESPONSE TO WYNDHAM HOTELS AND RESORTS, LLC AND  
WYNDHAM WORLDWIDE CORPORATION’S PETITION TO QUASH OR  
LIMIT CIVIL INVESTIGATIVE DEMAND DATED DECEMBER 8, 2011

Dear Messrs. Silber and Meal:

On January 20, 2012, the Federal Trade Commission (“FTC” or “Commission”) received the petition filed by Wyndham Hotels and Resorts (“WHR”) and its parent company Wyndham Worldwide Corporation (“WWC,” and collectively with WHR, “Wyndham,” or “Petitioners”). This letter advises you of the Commission’s disposition of the petition, effected through this ruling by Commissioner Julie Brill, acting as the Commission’s delegate.<sup>1</sup>

For the reasons explained below, the petition is granted as to modifying the definition of personal information and one CID Instruction and denied in all other respects. The documents and information required by the CID must now be produced on or before April 23, 2012, consistent with modifications to the CID definitions and instructions described below. You have the right to request review of this ruling by the full Commission.<sup>2</sup> Any such request must be filed with the Secretary of the Commission

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<sup>1</sup> See 16 C.F.R. § 2.7(d)(4).

<sup>2</sup> 16 C.F.R. § 2.7(f).

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within three days after service of this letter ruling.<sup>3</sup> The timely filing of a request for review of this ruling by the full Commission does not stay the return dates established by this ruling.<sup>4</sup>

## I. INTRODUCTION

In early 2010, WHR disclosed that an intruder or intruders had gained access to its computer networks and to networks belonging to independently-owned Wyndham-branded hotels. Later press reports indicated that breaches of its computer network occurred on three occasions between July 2008 and January 2010.<sup>5</sup> Among the information compromised in these repeated breaches were payment cards for more than 619,000 people.<sup>6</sup> The exposure of this information can result in harms including identity theft, financial fraud, and the basic inconvenience of replacing stolen card numbers.<sup>7</sup>

In response, on April 8, 2010, FTC staff commenced an investigation and delivered to WHR a voluntary request for information (“Access Letter”) that included both interrogatories and document requests. Though the letter was addressed to an official at WHR, the letter defined “Wyndham” to include not only WHR but also “its parents, subsidiaries, affiliates, franchisees, hotels managed by franchisees that use the Wyndham trade name, and agents.”<sup>8</sup> After discussions, staff and WHR agreed to limit an initial production to two custodians, although

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<sup>3</sup> *Id.* This letter ruling is being delivered by e-mail and courier delivery. The e-mail copy is provided as a courtesy, and the deadline by which an appeal to the full Commission would have to be filed should be calculated from the date on which you receive the original letter by courier delivery.

<sup>4</sup> *Id.*

<sup>5</sup> Pet., Exh. 3, at 1 n.1.

<sup>6</sup> See, e.g., Pet. Exh. 5, at 4 (proposed complaint).

<sup>7</sup> See, e.g., *Data Breaches and Identity Theft: Hearing Before the S. Comm. on Commerce, Science, and Transportation*, 109th Cong. 3-4, 10 (2005) (statement of Deborah Platt Majoras, Chairman of the Federal Trade Commission).

<sup>8</sup> Pet., Exh. 3, at 2.

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staff reserved the right to identify additional custodians based on the materials produced. The letter called for a response by May 10, 2010, but WHR did not respond to the interrogatories until July 19, 2010, and did not complete production of documents until October 2010.

Upon review, staff identified deficiencies in the production, most notably that WHR produced a large number of completely irrelevant and nonresponsive materials. WHR also failed to produce information that was obviously relevant to the investigation, such as supporting documents and information referenced in forensic reports that the company did provide.

In November 2010, Commission staff informed WHR of these deficiencies and the need to obtain documents from additional custodians. During these negotiations, WHR expressed an interest in pursuing settlement. The company stated, however, that it could not respond to the Access Letter and negotiate settlement simultaneously, and it asked staff to suspend the document collection. In January 2011, staff agreed to do so, but informed WHR that it reserved the right to demand resumption of document collection and to pursue additional custodians should settlement discussions fail.

Staff pursued settlement discussions with WHR over the next nine months. Staff and WHR were unable to reach settlement terms, and on September 19, 2011, WHR informed staff it would not enter into a settlement on the terms staff proposed.

Accordingly, in September 2011, staff informed WHR that it would resume the investigation. Soon thereafter, WHR agreed to provide a certification as to the completeness of the materials it had produced to date in response to the Access Letter. WHR provided this certification on December 1, 2011.

The FTC issued a CID to WHR on December 8, 2011 pursuant to Resolution P954807, a “blanket resolution” issued by the Commission on January 3, 2008. This Resolution authorizes FTC staff to use compulsory process in investigations

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[t]o determine whether unnamed persons, partnerships, corporations, or others are engaged in, or may have engaged in, deceptive or unfair acts or practices related to consumer privacy and/or data security, in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended. Such investigation shall, in addition, determine whether Commission action to obtain redress of injury to consumers or others would be in the public interest.<sup>9</sup>

## II. ANALYSIS

### A. The CID was lawfully issued and Petitioners have sufficient notice of the nature and scope of the investigation.

Petitioners' principal objection, which they restate in various ways, is that the CID and its authorizing resolution are deficient for failing to inform them sufficiently of the nature and scope of the investigation. We find this complaint not credible, coming as it does nearly two years after the investigation commenced. As the petition acknowledges, there have been substantial ongoing communications since FTC staff first contacted Petitioners in April 2010. As Petitioners readily admit, they have already reviewed and produced over one million pages of documents at significant expense; presumably, Petitioners did not do so without some understanding of why those documents had been requested.<sup>10</sup> Moreover, Petitioners admit that the "CID did not come as a surprise[.]" because they undertook to certify their prior productions in anticipation.<sup>11</sup> Indeed, staff presented Petitioners with a draft complaint, Petitioners responded with a 60-page "white paper," and both parties have engaged in detailed and lengthy settlement negotiations.<sup>12</sup> In light of these facts, we find

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<sup>9</sup> Pet., Exh. 1.

<sup>10</sup> Pet., at 35.

<sup>11</sup> *Id.*, at 10.

<sup>12</sup> *Id.*, at 7-9 and Exh. 7.

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that the nature and scope of the investigation are quite clear to Petitioners and consequently that their claim of insufficient notice is specious.<sup>13</sup>

More important, it is well-established that a CID is proper if it “state[s] the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation.”<sup>14</sup> In the present matter, we find that the authorizing resolution adequately delineates the purpose and scope of the investigation: “[t]o determine whether unnamed persons, partnerships; corporations, or others are engaged in, or may have engaged in, deceptive or unfair acts or practices *related to consumer privacy and/or data security*, in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended” (emphasis added). The description of the subject matter of the investigation, coupled with a citation to the statutory prohibition on “unfair or deceptive acts or practices” satisfies that requirement.<sup>15</sup> This has put WHR on notice as to the purpose, scope, and legal basis for the Commission’s investigation. There is no need to either state the

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<sup>13</sup> Cf. *Assocs. First Capital Corp.*, 127 F.T.C. 910, 915 (1999) (“In sum, the notice provided in the compulsory process resolutions, CIDs, and other communications with Petitioners more than meets the Commission’s obligation of providing notice of the conduct and the potential statutory violations under investigation.”).

<sup>14</sup> 15 U.S.C. § 57b-1(c)(2). See also 16 C.F.R. § 2.6.

<sup>15</sup> *FTC v. O’Connell Assoc.*, 828 F. Supp. 165, 170-71 (E.D.N.Y. 1993) (quoting *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1090 (D.C. Cir. 1992)); see also *FTC v. Carter*, 636 F.2d 781, 788 (D.C. Cir. 1980). Petitioners attempt to distinguish *O’Connell* on the grounds that the resolution in that case was an omnibus resolution, not a blanket one, and it was used on the basis of a tip to authorize compulsory process to a new recipient as part of an ongoing investigation. The issue of whether a resolution is blanket or omnibus is not relevant because either is an acceptable form of resolution. Furthermore, the resolution upheld in *O’Connell* stated only that the nature and scope of that investigation involved Section 5 and the Fair Credit Reporting Act. *O’Connell*, 828 F. Supp. at 167 & n.1. This description is at least as specific as “consumer privacy and/or data security,” the description at issue here. Finally, just as in *O’Connell*, the CID here was issued as part of a pre-existing, ongoing investigation. In fact, considering the history of the investigation before the CID was issued, Petitioners here had far greater information about what staff was investigating than did *O’Connell Associates*.

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purpose of an investigation with greater specificity, or tie the conduct under investigation to any particular theory of violation.<sup>16</sup>

Moreover, contrary to Petitioners' contention, the resolution is not invalid because it is a so-called "blanket resolution." According to Petitioners, Sections 2.4 and 2.7 of the Commission's Rules of Practice, 16 C.F.R. §§ 2.4, 2.7, require resolutions to be tailored to the facts of each investigation.<sup>17</sup> But no such requirement arises under the Commission's Rules. Rule 2.4 states that the Commission "may, in any matter under investigation adopt a resolution authorizing the use of any or all of the compulsory processes provided for by law."<sup>18</sup> That provision does not require a separate investigational resolution for each investigation, as Petitioners seem to suggest.<sup>19</sup> Likewise, Rule 2.7 simply states that the Commission may, pursuant to a resolution, issue compulsory process for documents or testimony.<sup>20</sup> This rule does not address the contents or form of

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<sup>16</sup> *Invention Submission*, 965 F.2d at 1090; *FTC v. National Claims Serv., Inc.*, No. S 98-283 FCD DAD, 1999 WL 819640, at \*2 (E.D. Cal. Feb. 9, 1999) (citing *EPA v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 477 (9th Cir. 1988)).

<sup>17</sup> Pet., at 16-18 (citing 16 C.F.R. §§ 2.4, 2.7).

<sup>18</sup> 16 C.F.R. § 2.4.

<sup>19</sup> The narrowly tailored resolution that Petitioners desire is known as a "special resolution," and is one of three possible types suggested for FTC staff in the Commission's Operating Manual. See FTC Operating Manual, Chapter 3.3.6.7.4.1 to 3.3.6.7.4.4. The Commission has repeatedly rejected the proposition that such specificity is required in every investigation. See, e.g., *D. R. Horton, Inc.*, Nos. 102-3050, 102-3051, at 4 (July 12, 2010) ("The Commission is not required to identify to Petitioners the specific acts or practices under investigation"), available at <http://www.ftc.gov/os/quash/100712hortonresponse.pdf>; *Dr. William V. Judy*, No. X000069, at 4-5 (Oct. 11, 2002) (sustaining validity of CIDs issued pursuant to an omnibus resolution), available at <http://www.ftc.gov/os/quash/021011confirmanthonyltr.pdf>; *In re Assocs. First Capital Corp.*, 127 F.T.C. at 914 ("[R]ecitation of statutory authorities provides adequate notice to Petitioner as to [the] purposes of the investigation."). To the extent that courts have considered the issue, they also have rejected the proposition that the Commission is so constrained. *FTC v. National Claims Serv., Inc.*, No. S 98-283 FCD DAD, 1999 WL 819640, at \*2; *O'Connell*, 828 F. Supp. at 170-71.

<sup>20</sup> 16 C.F.R. § 2.7(a).

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the authorizing resolution. Accordingly, the resolution in this case satisfies the Commission's Rules.<sup>21</sup>

Petitioners also challenge the resolution as insufficiently specific in light of the legislative history of the Federal Trade Commission Improvements Act of 1980, which added a new Section 20 of the FTC Act.<sup>22</sup> Petitioners allege that this legislative history shows that Congress intended the FTC to provide more than “a vague description of the general subject matter of the inquiry . . .[.]”<sup>23</sup> and that the resolution here does not meet Congress's expectations.

We reject this argument for the same reason we rejected Petitioners' other arguments: the Commission's resolution satisfies the requirements of the statute.<sup>24</sup> It informs Petitioners of the nature of the conduct constituting the alleged violation—unfair or deceptive acts or practices involving consumer privacy and/or data security—and it identifies the applicable provision of law—Section 5 of the FTC Act. Moreover, even as Congress expressed its desire for specific notice, it nonetheless cautioned against reading too much into Section 20: “[T]his requirement is

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<sup>21</sup> Petitioners also contend that the resolution fails to conform to the FTC's Operating Manual. Pet., at 17-18. However, the sufficiency of staff's compliance with the Operating Manual is of no concern to Petitioners because the Operating Manual confers no rights on them. See FTC Operating Manual, Chapter 1.1.1 (“Failure by the staff or the Commission to adhere to procedures outlined by this Operating Manual does not constitute a violation of the Rules of Practice nor does it serve as a basis for nullifying any action of the Commission or the staff.”) See also *FTC v. Nat'l Bus. Consultants, Inc.*, 1990 U.S. Dist. LEXIS 3105, 1990-1 Trade Cas. (CCH) & 68,984, at \*29 (E.D. La. 1990) (reading Chapter 1.1.1 to find that the Operating Manual was “not binding”).

<sup>22</sup> Pet., at 18, 20-21, 24.

<sup>23</sup> S. Rep. No. 96-500, at 23 (1979).

<sup>24</sup> See 15 U.S.C. 57b-1(c)(2) (“Each civil investigative demand shall state the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation.”); see also *O'Connell*, 828 F. Supp. at 170-71; *Dr. William V. Judy*, No. X000069, at 4-5 (rejecting a challenge to a resolution based on the legislative history of Section 20), available at <http://www.ftc.gov/os/quash/021011confirmanthonyltr.pdf>.

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not intended to be overly strict so as to defeat the purpose of the act or to breed litigation and encourage the parties investigated to challenge the sufficiency of the notice.”<sup>25</sup> We find that the resolution meets all legal requirements.<sup>26</sup>

Finally, Petitioners claim that the CID exceeded the FTC’s jurisdiction by requesting information about employees, a group it contends is distinct from “consumers” for purposes of Section 5. Pet., at 28-32. We need not entertain this claim because challenges to the FTC’s jurisdiction or regulatory coverage are not properly raised through challenges to investigatory process. See, e.g., *FTC v. Ken Roberts Co.*, 276 F.3d 583, 586 (D.C. Cir. 2001) (citing *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5 (1st Cir. 1996)). However, we choose to adopt this modification because staff already offered to modify the CID definitions to exclude employee information. Pet., Exh. 11, at 3.

**B. The CID is not overbroad, unduly burdensome, or indefinite.**

Petitioners also advance a series of arguments about the CID specifications, claiming that the CID is overbroad and asks for information not reasonably related to the investigation, in particular, information related to WHR’s corporate parent WWC and its affiliates.<sup>27</sup>

An administrative subpoena is valid if the requested information is “reasonably relevant” to the purposes of the investigation.<sup>28</sup> Reasonable relevance is defined broadly in agency law enforcement investigations. As the D.C. Circuit has stated, “The standard for judging relevancy in an investigatory

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<sup>25</sup> S. Rep. No. 96-500, at 23 (1979).

<sup>26</sup> *Ken Roberts Co.*, 276 F.3d.

<sup>27</sup> Pet., at 33-36.

<sup>28</sup> *Linde Thomson Langworthy Kohn & Van Dyke, P.C. v. RTC*, 5 F.3d 1508, 1516 (D.C. Cir. 1993) (citing *Invention Submission Corp.*, 965 F.2d at 1089; *FTC v. Anderson*, 631 F.2d 741, 745 (D.C. Cir. 1979); *FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977)).

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proceeding is more relaxed than in an adjudicatory one . . . . The requested material, therefore, need only be relevant to the *investigation*—the boundary of which may be defined quite generally, as it was in the Commission’s resolution here.”<sup>29</sup> Courts thus place the burden on Petitioners to show that the Commission’s determination is “obviously wrong” and that the information is irrelevant.<sup>30</sup>

Here, as Petitioners admit, Commission staff provided an explanation of the relevance of these requests.<sup>31</sup> More generally, staff’s investigation focuses on a series of breaches of WHR’s data security processes that are managed by other Wyndham entities.<sup>32</sup> In light of this, CID specifications that probe the details of the information security systems developed by Petitioners and their affiliates are relevant to this investigation. Petitioners have not met their burden of showing that this information is irrelevant, or that the Commission’s request for it is “obviously wrong.”

Petitioners further claim the CID is unduly burdensome, for the following reasons: (1) they have already spent over \$5 million in responding, including producing over one million pages, and staff should now have enough information; (2) responding to the interrogatories will require six months and significant additional costs; (3) responding to the document requests that ask for “all documents” relating to a given subject will require about 10 weeks and \$1 million to produce documents from an additional three custodians; and (4) responding to the document requests that ask for “documents sufficient to identify” a given subject are “hugely burdensome” and will require 6 months and \$2.75 million to produce documents from the same three custodians. In sum,

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<sup>29</sup> *Invention Submission Corp.*, 965 F.2d at 1090 (emphasis in original; internal citations omitted) (citing *Carter*, 636 F.2d at 787-88, and *Texaco*, 555 F.2d at 874 & n. 26).

<sup>30</sup> *Invention Submission Corp.*, 965 F.2d at 1090 (citing *Texaco*, 555 F.2d at 882) (“The burden of showing that the request is unreasonable is on the subpoenaed party.”); *Texaco*, 555 F.2d at 877 n.32. *Accord FTC v. Church & Dwight Co., Inc.*, 756 F. Supp. 2d 81, 85 (D.D.C. 2010).

<sup>31</sup> Pet., at 33 (citing Pet., Ex. 11, at 2).

<sup>32</sup> Pet., Exh. 11, at 2.

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Petitioners claim that responding to the CID will require an additional \$3.75 million, on top of what they have spent to date, and 1 to 2 years' additional time.<sup>33</sup>

Of course, the recipient of a CID must expect to incur some burden in responding to a CID.<sup>34</sup> The responsibility of establishing undue burden rests on Petitioners,<sup>35</sup> who must show that compliance threatens to seriously impair or unduly disrupt the normal operations of their business.<sup>36</sup> Likewise, a CID is not unreasonably broad where the breadth of the inquiry is in large part attributable to the magnitude or complexity of the subject's business operations.<sup>37</sup> Petitioners' estimate is not insubstantial, but we find that they have not sustained their burden.

First, Petitioners' estimate is neither specific nor detailed and does not account for factors that may reduce the cost and time of production. For one, Petitioners have not sufficiently addressed the availability of e-discovery technology, such as advanced analytical tools and predictive coding, to enable fast and efficient search, retrieval, and production of electronically stored information (ESI).<sup>38</sup> While Petitioners do tally the potential costs

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<sup>33</sup> Pet., at 36-39; *see also* Pet., Exh. 4, at 2-4.

<sup>34</sup> *See FTC v. Shaffner*, 626 F.2d 32, 38 (7th Cir. 1980); *Texaco*, 555 F.2d at 882.

<sup>35</sup> *See Texaco*, 555 F.2d at 882; *In re Nat'l Claims Serv., Inc.*, 125 F.T.C. 1325, 1328-29 (1998). *See also EEOC v. Maryland Cup Corp.*, 785 F.2d 471, 476 (4th Cir. 1986); *FTC v. Standard American, Inc.*, 306 F.2d 231, 235 (3d Cir. 1962) (appellants have the burden to show unreasonableness of the Commission's demand and make a record to show the "measure of their grievance rather than [asking the court] to assume it") (citing *Oklahoma Press Publ'g Co. v. Walling*, 327 U.S. 186, 217-18 (1946); *United States v. Morton Salt Co.*, 338 U.S. 632, 654 (1950)).

<sup>36</sup> *See Shaffner*, 626 F.2d at 38; *Texaco*, 555 F.2d at 882.

<sup>37</sup> *See Texaco*, 555 F.2d at 882.

<sup>38</sup> *See, e.g., Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309, 318 (S.D.N.Y. 2003) (Sheindlin, J.) ("Electronic evidence is frequently cheaper and easier to produce than paper evidence because it can be searched automatically, key words can be run for privilege checks, and the production can be made in electronic form obviating the need for mass photocopying."); John Markoff, *Armies of Expensive Lawyers, Replaced by Cheaper Software*, NEW YORK

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of an ESI production and refer to a vendor, these costs are unsupported by any detailed breakdown or itemization.<sup>39</sup>

Petitioners' estimate also does not account for the effect of Instruction K, which permits Petitioners to identify, without having to reproduce, documents that were previously provided to the Commission.<sup>40</sup> To the extent that Petitioners' cost estimate includes production of duplicate materials, Instruction K permits Petitioners to avoid this expense and reduces the potential burden. Though Petitioners respond that staff, and not they, should bear the burden of avoiding duplicative document requests,<sup>41</sup> Petitioners are the ones with the most information about their document collections and productions to date. In fact, Petitioners have already identified the areas of overlap between the Access Letter and the CID.<sup>42</sup> The Access Letter instructed Petitioners to identify which of the documents produced answered the

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TIMES, Mar. 5, 2011, at A1, *available at*, <http://www.nytimes.com/2011/03/05/science/05legal.html>).

<sup>39</sup> Pet., Exh. 4, at 2-4. The lack of factual support for the claim of undue burden is underscored by the fact that the estimated costs appear out of proportion to the number of custodians involved. According to the declaration from Korin Neff, WHR spent approximately \$2.5 million *per custodian* for its first production, and now estimates that it will spend approximately another \$3.75 million for three custodians, or \$1.25 million *per custodian*, in response to the CID. *Id.* One explanation for the cost of the production to date may be the fact that WHR produced a large number of irrelevant and nonresponsive materials, including, among others, multiple copies of third party software licenses, in various languages; numerous magazines and newsletters not specific to WHR; and, human resources materials. This may explain why WHR could generate more than one million pages from only two individuals.

<sup>40</sup> Pet., Exh. 1, at 7 (“K. Documents that may be responsive to more than one specification of this CID need not be submitted more than once; however, your response should indicate, for each document submitted, each specification to which the document is responsive. If any documents responsive to this CID have been previously supplied to the Commission, you may comply with this CID by identifying the document(s) previously provided and the date of submission.”).

<sup>41</sup> Pet., at 39.

<sup>42</sup> See Pet., Exh. 2, at Exhs. C, D. As Petitioners point out, WHR has already responded to 42 out of the 89 interrogatories and subparts in the CID, and 25 of the 38 document requests and subparts. Pet., Exh. 2, at 2.

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specifications in the Access Letter.<sup>43</sup> It is not unduly burdensome for Petitioners to compare their Access Letter response with the CID to identify duplicates.

Second, Petitioners have not established that this will seriously disrupt their operations. As expressed in *Texaco* and other key cases, some cost to recipients of process is expected, and the burden posed by this cost is evaluated in relation to the size and complexity of a recipient's business operations. In *Texaco*, for instance, the court affirmed enforcement of a subpoena that the company claimed would require 62 work-years and \$4 million for compliance.<sup>44</sup> As in that case, it appears that the burden here may be a consequence of size—in 2010, Wyndham had an annual revenue of more than \$3.8 billion—as well as the complexity of the corporate structure Wyndham has adopted.<sup>45</sup> Thus, full compliance with the CID, even if it were to reach the estimates included in the petition, is unlikely to “pose a threat to the normal operation of” Wyndham “considering [its] size.”<sup>46</sup>

Third, Petitioners have claimed that the requests that ask for documents “sufficient to describe” the subject of the request present a “huge cost” and “extreme burden,” particularly because the companies do not keep records in the manner called for.<sup>47</sup> It is unclear why a request that calls for documents “sufficient to describe” should be more burdensome than a request that calls for “all documents”; by definition, documents “sufficient to describe” should involve fewer than “all documents.” The fact that Petitioners do not keep records in the manner that matches the request is not unusual and by itself does not present a basis for quashing these requests. Because staff often does not know how a

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<sup>43</sup> See Pet., Exh. 3, at 2 (“Please Bates stamp your response and itemize it according to the numbered paragraphs in this letter.”).

<sup>44</sup> *Texaco*, 555 F.2d at 922 (Wilkey, J., dissenting).

<sup>45</sup> Wyndham Worldwide Corp., Annual Report (Form 10-K), at 34 (Feb. 22, 2011).

<sup>46</sup> *FTC v. Rockefeller*, 591 F.2d 182, 190 (2d Cir. 1970).

<sup>47</sup> Pet., at 38-39. See also Pet., Exh. 10, at 6.

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CID recipient keeps its records, staff crafts its requests broadly, but provides a recipient flexibility in responding by allowing the recipient to produce those documents “sufficient to describe.”

Fourth, the fact that Petitioners have already produced information to staff does not establish either that staff has sufficient information, or that further requests are unduly burdensome. The obligation is on Petitioners to show that the CID is unduly burdensome, not on staff to show that the CID is necessary.<sup>48</sup>

Fifth, we find that Petitioners have not sufficiently availed themselves of the meet-and-confer process required by the FTC’s Rules of Practice and the CID itself.<sup>49</sup> As we have previously said, this meet-and-confer requirement “provides a mechanism for discussing adjustment and scheduling issues and resolving disputes in an efficient manner.”<sup>50</sup> Thus, the meet-and-confer requirements offer a critical opportunity for the recipient of a CID to engage with staff in a meaningful discussion aimed at reducing the burden of compliance. Here, Petitioners did not engage in a good faith exchange with staff intended to identify and discuss issues of burden.<sup>51</sup> Instead, Petitioners raised many of the same arguments found in this petition, often verbatim, and did not respond to legitimate requests from staff for specific proposals for narrowing or limiting the CID’s scope. While staff was apparently willing to compromise on several issues, Petitioners demanded blanket and arbitrary caps on the number of document requests, interrogatories, and custodians. Petitioners cannot claim undue burden when they themselves undertook an inadequate meet-and-confer with staff.

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<sup>48</sup> Cf. *United States v. AT&T, Inc.*, No. 1:11-cv-01560, 2011 WL 5347178, at \*6 (D.D.C. Nov. 6, 2011) (“There is no requirement that AT&T demonstrate to Sprint’s satisfaction that the legal theories AT&T wishes to consider require documents beyond those [Sprint previously] supplied to DOJ . . .”).

<sup>49</sup> 16 C.F.R. § 2.7(d)(2); Pet. Exh. 1, at 5.

<sup>50</sup> *Firefighters Charitable Found., Inc.*, FTC File No. 102-3023, at 3 (Sept. 23, 2010).

<sup>51</sup> See Pet. Exhs. 9-15.

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Despite Petitioners' failure to carry their burden, we conclude that some modifications to the CID instructions may lessen Petitioners' costs of compliance. Accordingly, we amend the instructions to permit Petitioners to submit documents in lieu of interrogatories. This modification will allow Petitioners to avoid the time and expense of preparing interrogatory responses. In addition, to the extent that a document may be responsive to multiple interrogatories or document requests, Petitioners need not produce multiple copies but, pursuant to Instruction K, discussed above, may produce one copy of a relevant document, and then indicate each specification or interrogatory to which the document is responsive. This should mitigate the costs of compliance.

Finally, Petitioners argue that the CID is indefinite. This claim appears to restate several of Petitioners' other objections, including their claim of a lack of notice of the purpose and scope of the investigation, overbreadth, and burden.<sup>52</sup> For the reasons discussed above, this claim of indefiniteness is without basis.

**C. The CID was not issued for an improper purpose.**

Petitioners claim that the size and timing of the CID shows that its true purposes were either to coerce settlement, or to obtain discovery outside of the rules of civil procedure. The facts of the investigation refute this conclusion. Mid-investigation, Petitioners expressed an interest in exploring settlement talks as a means of resolving the matter short of a full-blown investigation and consequent possible law enforcement action. At Petitioners' request, staff voluntarily allowed them to suspend their production, in order to reduce the burden on Petitioners. But staff also advised Petitioners that they would resume their investigation should settlement talks fail. And, as Petitioners admit, when the CID was issued, it was no surprise.<sup>53</sup> In light of these circumstances, there is no evidence of improper purpose, either to coerce settlement or to obtain information outside of the information necessary to complete the investigation.

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<sup>52</sup> Pet., at 39-40.

<sup>53</sup> *Id.*, at 10.

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**III. CONCLUSION AND ORDER**

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** the Petition of Wyndham Hotels & Resorts and Wyndham Worldwide Corporation to Quash, or Alternatively, Limit Civil Investigative Demand be, and it hereby is, **DENIED IN PART AND GRANTED IN PART.**

**IT IS FURTHER ORDERED THAT** the Definition T, “Personal information,” be amended to exclude employee information as follows:

“**Personal information**” shall mean individually identifiable from or about an individual consumer, including, but not limited to: (1) first and last name; (2) home or other physical address, including street name and name of city or town; (3) e-mail address or other online contact information, such as instant messenger user identifier or a screen name; (4) telephone number; (5) date of birth; (6) government-issued identification number, such as a driver’s license, military identification, passport, or Social Security number, or other personal identification number; (7) financial information, including but not limited to: investment account information; income tax information; insurance policy information; checking account information; and **payment card** or check-cashing card information, including card number, expiration date, security number (such as card verification value), information stored on the magnetic stripe of the card, and personal identification number; (8) a persistent identifier, such as a customer number held in a “cookie” or processor serial number, that is combined with other available data that identifies an individual consumer; or (9) any information from or about an individual consumer that is combined with any of (1) through (8) above.

**IT IS FURTHER ORDERED THAT** the CID Instructions be modified to include the following instruction:

“**Q. Submission of Documents in lieu of Interrogatory Answers:** Previously existing documents

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that contain the information requested in any written Interrogatory may be submitted as an answer to the Interrogatory. In lieu of identifying documents as requested in any Interrogatory, you may, at your option, submit true copies of the documents responsive to the Interrogatory, provided that you clearly indicate the specific Interrogatory to which such documents are responsive.”

**IT IS FURTHER ORDERED THAT** all other responses to the specifications in the Civil Investigative Demand to Wyndham Hotels & Resorts and Wyndham Worldwide Corporation must now be produced on or before April 23, 2012.

By direction of the Commission.

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**LABMD, INC.***FTC File No. 102 3099 – Decision, April 20, 2012*RESPONSE TO LABMD, INC.'S AND ITS PRESIDENT, MICHAEL J.  
DAUGHERTY'S PETITIONS TO LIMIT OR QUASH THE CIVIL  
INVESTIGATIVE DEMANDS DATED DECEMBER 21, 2011

Dear Ms. Callaway, Ms. Grigorian, and Mr. Dayal:

On January 10, 2012, the Federal Trade Commission (“FTC” or “Commission”) received the above Petitions filed by LabMD, Inc. (“LabMD”) and its President, Michael J. Daugherty (collectively, “Petitioners”). This letter advises you of the Commission’s disposition of the Petitions, effected through this ruling by Commissioner Julie Brill, acting as the Commission’s delegate.<sup>1</sup>

For the reasons explained below, the Petitions are denied. You may request review of this ruling by the full Commission.<sup>2</sup> Any such request must be filed with the Secretary of the Commission within three days after service of this letter ruling.<sup>3</sup> The timely filing of a request for review by the full Commission shall not stay the return dates established by this ruling.<sup>4</sup>

**I. INTRODUCTION**

The FTC commenced its investigation into the adequacy of LabMD’s information security practices in January 2010, after a LabMD file had been discovered on a peer-to-peer (“P2P”) file

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<sup>1</sup> See 16 C.F.R. § 2.7(d)(4).

<sup>2</sup> 16 C.F.R. § 2.7(f).

<sup>3</sup> *Id.* This ruling is being delivered by e-mail and courier delivery. The e-mail copy is provided as a courtesy, and the deadline by which an appeal to the full Commission would have to be filed should be calculated from the date on which you receive the original letter by courier delivery.

<sup>4</sup> *Id.*

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sharing network.<sup>5</sup> The file, which Petitioners call the “1,718 File” because it is 1,718 pages long, is a spreadsheet of health insurance billing information for uropathology and microbiology medical tests of around 9,000 patients. It contains highly sensitive information about these consumers, including:

- Name;
- Social Security Number;
- Date of birth;
- Health insurance provider and policy number; and
- Standardized medical treatment codes.<sup>6</sup>

Such information can be misused to harm consumers.

The purpose of the investigation is to determine whether Petitioners violated the FTC Act by engaging in deceptive or unfair acts or practices relating to privacy or information security. The inquiry is authorized by Resolution File No. P954807, which provides for the use of compulsory process in investigations of potential Section 5 violations involving “consumer privacy and/or data security.”

The investigation began with voluntary information requests for documents and information about LabMD’s information security policies, procedures, practices, and training generally, as well as information about security incidents, including, but not limited to, the discovery of the 1,718 File on P2P networks. In response, LabMD produced hundreds of pages of documents, including supplements and responses to follow-up questions. To complete the investigation, staff requested issuance of CIDs to LabMD and Michael J. Daugherty, LabMD’s President.

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<sup>5</sup> P2P programs allow users to form networks with others using the same or a compatible P2P program. Such programs allow users to locate and retrieve files of interest to them that are stored on computers of other users on the networks.

<sup>6</sup> LabMD Pet., Ex. C, at Fig. 4. Because the LabMD and Daugherty Petitions make the same arguments (the Petitions differ only in details about the submitter), we generally cite only to LabMD’s Petition.

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The Commission issued the CIDs on December 21, 2011. Both require testimony relating to information security policies, practices, training, and procedures. They also include a limited number of interrogatories that require Petitioners to identify documents used by the witnesses to prepare for their testimony.<sup>7</sup> The LabMD CID also includes a single document request asking for only those documents that were both identified in response to the CID's interrogatories and had not been previously produced to staff.<sup>8</sup>

Petitioners seek to quash or limit the CIDs because, they claim, the CIDs “appear to be premised on” the download of the 1,718 File (hereinafter, the “File disclosure”).<sup>9</sup> Their principal objection relates to the merits of the investigation. In particular, they contend (without citing any authority) that the Commission must have a “justifiable” belief that a law violation has occurred before it can issue CIDs, and that the File disclosure cannot support such a belief. They claim that the File disclosure occurred not because LabMD failed to implement reasonable and appropriate security measures, but because the company was the victim of an illegal intrusion conducted by Tiversa (a P2P information technology and investigation services company) and Dartmouth College faculty using Tiversa's powerful P2P searching technology.<sup>10</sup> Further, Petitioners argue that no actual harm to consumers resulted from the File disclosure.<sup>11</sup> Accordingly, they contend that investigating either the File disclosure or the adequacy of LabMD's security practices is

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<sup>7</sup> LabMD Pet., Ex. A.

<sup>8</sup> LabMD Pet., Ex. A.

<sup>9</sup> LabMD Pet., at 1.

<sup>10</sup> Petitioners claim that in the course of a Department of Homeland Security-funded research project, Professor M. Eric Johnson of Dartmouth College's Tuck School of Business and Tiversa used Tiversa's P2P searching technology to search for and then download the file. LabMD Pet., at 3-4, 7, & Ex. F, at 10-12.

<sup>11</sup> The Petitions claim that there is no allegation of actual consumer injury from the File disclosure. LabMD Pet., at 7.

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improper because no law violation can have occurred, and that the CIDs therefore should be quashed.<sup>12</sup>

As discussed below, these arguments are undermined by: (1) the obvious point that an investigation necessarily must precede assessment of whether there is reason to believe a law violation may have occurred (in any matter); (2) the scope of the authorizing resolution; and (3) the language of the FTC Act. The resolution authorizes use of compulsory process in an investigation to determine whether Petitioners engaged in deceptive or unfair practices related to privacy or security. Petitioners' focus on the File disclosure is misplaced – it may bear on the adequacy of LabMD's security practices under the FTC Act but does not establish the investigation's scope under the resolution.<sup>13</sup> Further, in such an investigation Section 5 directs the Commission to consider whether security practices are unfair because they create a sufficient risk of harm, even if no harm has been reported.

Petitioners make two additional arguments in support of their Petitions. First, they argue that the resolution authorizing the CIDs did not provide them with sufficient notice of the purpose and scope of the investigation. Second, they argue that the FTC is without jurisdiction to pursue this investigation. Both of these additional arguments are equally without merit.

## II. ANALYSIS

### A. The applicable legal standards.

Compulsory process such as a CID is proper if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant to the

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<sup>12</sup> LabMD Pet., at 7-8.

<sup>13</sup> See, e.g., *CVS Caremark Corp.*, No. 072-3119, at 4 (Dec. 3, 2008) (confirming that the scope of an investigation authorized by Resolution P954807 properly included all of CVS' "consumer privacy and data security practices" (including its computer security practices) and could not be limited (as the company argued) to just known incidents of unauthorized disposal of paper documents in dumpsters).

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inquiry, as that inquiry is defined by the investigatory resolution.<sup>14</sup> Agencies have wide latitude to determine what information is relevant to their law enforcement investigations and are not required to have “a justifiable belief that wrongdoing has actually occurred,” as Petitioners claim.<sup>15</sup> As the D.C. Circuit has stated, “The standard for judging relevancy in an investigatory proceeding is more relaxed than in an adjudicatory one . . . . The requested material, therefore, need only be relevant to the *investigation* – the boundary of which may be defined quite generally, as it was in the Commission’s resolution here.”<sup>16</sup> Agencies thus have “extreme breadth” in conducting their investigations,<sup>17</sup> and “in light of [this] broad deference . . . , it is essentially the respondent’s burden to show that the information is irrelevant.”<sup>18</sup>

**B. The CIDs satisfy the foregoing standards.**

Petitioners argue that the CIDs are improper for several reasons. In particular, they claim no law violation could have occurred, by arguing that: (1) not even “perfect” security measures (let alone the reasonable security measure standard the

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<sup>14</sup> *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950); *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1088 (D.C. Cir. 1992); *FTC v. Texaco, Inc.*, 555 F.2d 862, 874 (D.C. Cir. 1977).

<sup>15</sup> LabMD Pet., at 6. *See, e.g., Morton Salt*, 338 U.S. at 642-43 (“[Administrative agencies have] a power of inquisition, if one chooses to call it that, which is not derived from the judicial function. It is more analogous to the Grand Jury, which does not depend on a case or controversy for power to get evidence but can investigate merely on suspicion that the law is being violated, or even just because it wants an assurance that it is not.”).

<sup>16</sup> *Invention Submission*, 965 F.2d at 1090 (emphasis in original, internal citations omitted) (citing *FTC v. Carter*, 636 F.2d 781, 787-88 (D.C. Cir. 1980), and *Texaco*, 555 F.2d at 874 & n.26).

<sup>17</sup> *Linde Thomsen Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508, 1517 (D.C. Cir. 1993) (citing *Texaco*, 555 F.2d at 882).

<sup>18</sup> *Invention Submission*, 965 F.2d at 1090 (citing *Texaco*, 555 F.2d at 882) (“burden of showing that the request is unreasonable is on the subpoenaed party”). *Accord FTC v. Church & Dwight Co.*, 756 F. Supp. 2d 81, 85 (D.D.C. 2010).

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Commission uses to determine whether a law violation may have occurred) could have prevented the File disclosure because Tiversa's technology "can penetrate even the most robust network security,"<sup>19</sup> and (2) no actual injury resulted from the File disclosure.

The Commission is not required, as a precondition to conducting a law enforcement investigation, to make a showing that it is likely that a law violation has occurred. The D.C. Circuit confirmed this point in *FTC v. Texaco, Inc.*, when it stated, "[I]n the pre-complaint stage, an investigating agency is under no obligation to propound a narrowly focused theory of a possible future case . . . . The court must not lose sight of the fact that the agency is merely exercising its legitimate right to determine the facts, and that a complaint may not, and need not, ever issue."<sup>20</sup> Here, Petitioners seek to quash the CIDs by asserting that LabMD's practices must have been reasonable under the FTC Act because the 1,718 File was retrieved using Tiversa's powerful searching technology. Accepting this argument would prevent the Commission from exploring relevant issues bearing on reasonableness, such as, for example, whether the company's security practices could have prevented the 1,718 File from being retrieved using the common P2P programs that are used by millions of computer users each day or whether there were readily available security measures LabMD did not implement that would have prevented even Tiversa's technology from successfully retrieving the file. Although such evidence (if it exists at all) could undermine their reasonableness claim, Petitioners nonetheless argue that the Commission cannot use CIDs to investigate whether the evidence exists unless it already has reason to believe it does exist. For this reason, Petitioners' argument that the strength of Tiversa's P2P searching technology

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<sup>19</sup> LabMD Pet., at 7.

<sup>20</sup> 555 F.2d 862, 874 (D.C. Cir. 1977). This holding from *Texaco* has been repeatedly reaffirmed, most recently in *FTC v. Church & Dwight*, 747 F. Supp. 2d 3, 6, *aff'd*, 2011 U.S. App. LEXIS 24587 (D.C. Cir. Dec. 13, 2011).

<sup>21</sup> 15 U.S.C. § 45(n) (an unfair practice is one that "causes or *is likely to cause* substantial injury to consumers"); *see also* FTC Policy Statement on Unfairness, 104 F.T.C. 949, 1073 & n.15 (1984).

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precludes the possibility that a law violation occurred, regardless of the state of LabMD's security, must fail.

Similarly, Petitioners' assertion that no law violation can have occurred because no actual harm has been shown also fails because, under Section 5, a failure to implement reasonable security measures may be an unfair act or practice if the failure is *likely* to cause harm. No showing of actual harm is needed.<sup>21</sup>

Both arguments conflate the purpose of a CID with the purpose of a future potential complaint. A CID can only compel information necessary for an investigation, and the investigation may or may not result in allegations of a law violation.<sup>22</sup>

Additionally, Petitioners have claimed that the CIDs are burdensome, but they have not come forward with any support for these assertions. Instead, they make only bald statements that the CIDs are "highly burdensome," "unduly burdensome," "costly and burdensome," and "deeply burdensome."<sup>23</sup> Having offered no factual information about the alleged burdens of complying with

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<sup>22</sup> Petitioners also argue that the CIDs are improper for other reasons. They claim that because security issues posed by P2P programs were common (according to Tiversa), such issues could not constitute an unfair or deceptive practice in violation of the FTC Act. LabMD Pet., at 7-8 & n.34. This argument is unavailing. The fact that a particular practice may be pervasive or widespread has no bearing on whether the FTC may investigate it as also deceptive or unfair. Indeed, accepting Petitioners' argument would confine the FTC to investigating only those activities that were rare or uncommon, thus crippling the agency's law enforcement mission. Along the same lines, Petitioners contend that the risks of P2P technology, and the resulting potential liabilities to businesses, were not known in 2008, when the File disclosure occurred. In support of this claim, they assert that the FTC did not notify businesses or publish guidance about P2P until 2010. LabMD Pet., at 8. In fact, many, including the FTC, warned about the risks presented by P2P programs years before the File disclosure occurred. *See, e.g.*, FTC Staff Report, "Peer-to-Peer File Sharing Technology: Consumer Protection and Competition Issues" (June 2005), available at <http://www.ftc.gov/reports/p2p05/050623p2prpt.pdf>; Prepared Statement of the Federal Trade Commission Before The Committee on Oversight and Government Reform, United States House of Representatives (July 24, 2007) (discussing P2P programs and risks), available at <http://www.ftc.gov/os/testimony/P034517p2pshare.pdf>.

<sup>23</sup> LabMD Pet., at 7, 9, & 10.

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the CIDs, Petitioners have not sustained their burden to demonstrate that the CIDs are unduly burdensome.<sup>24</sup>

Such a showing would be difficult here in any event. Notwithstanding Petitioners' description, the CIDs call primarily for testimony, not documents. Thus, it seems unlikely that compliance would require large-scale or time-consuming document production. Furthermore, to the extent that the CIDs call for narrative responses, they merely require Petitioners to identify documents related to the requested testimony. In fact, there is only one specification that requires the production of documents, and even that specification is limited to documents identified in response to the interrogatories to the extent they were "not already been produced to the FTC."<sup>25</sup>

Finally, Petitioners, without explaining its relevance, contend that the timing of the CIDs is "troubling," coming after LabMD's conduct had been reviewed by two congressional committees, and after LabMD filed suit against Tiversa and others alleging conversion and trespass, among other violations, based on the File disclosure in 2008.<sup>26</sup> Though Petitioners seem to believe that there is some connection between their rejection of Tiversa's offer to provide LabMD with information security services, their subsequent lawsuit, and the FTC's investigation, the chronology of the investigation does not support such a conclusion. The FTC first contacted LabMD for information in January 2010, well

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<sup>24</sup> See, e.g., *Texaco*, 555 F.2d at 882 ("The burden of showing that the request is unreasonable is on the subpoenaed party.") (citing *United States v. Powell*, 379 U.S. 48, 58 (1964)); accord *EEOC v. Maryland Cup Corp.*, 785 F.2d 471, 476 (4th Cir. 1986) (subpoena is enforceable absent a showing by recipient that the requests are unduly burdensome); *FTC v. Standard American, Inc.*, 306 F.2d 231, 235 (3d Cir. 1962) (recipient has responsibility to show burden and must make "a record . . . of the measure of their grievance rather than ask [the court] to assume it"); *In re Nat'l Claims Serv., Inc.*, 125 F.T.C. 1325, 1328-29 (1998) (FTC ruling that petition to quash must substantiate burden with specific factual detail).

<sup>25</sup> LabMD Pet., Ex. A.

<sup>26</sup> LabMD Pet., at 9 & Ex. F.

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before LabMD filed its lawsuit against Tiversa in October 2011.<sup>27</sup> Moreover, the claim that LabMD's conduct was reviewed by congressional committees does not appear to be based on evidence presented in the Petitions. Although Petitioners have attached as exhibits three instances of congressional testimony by Tiversa, none identifies LabMD by name or discusses the specifics of the File disclosure.

**C. The resolution provides sufficient notice of the purpose and scope of the FTC's investigation.**

Under the FTC Act, a CID is proper when it "state[s] the nature of the conduct constituting the alleged violation which is under investigation and the provision of law applicable to such violation."<sup>28</sup> It is well-established that the resolution authorizing the process provides the requisite statement of the purpose and scope of the investigation,<sup>29</sup> and also that the resolution may define the investigation generally, need not state the purpose with specificity, and need not tie it to any particular theory of violation.<sup>30</sup>

Despite this, Petitioners object that Resolution File No. P954807 did not provide sufficient notice of the purpose and scope of the investigation, and they further claim that this resolution is inadequate under the standard developed by the D.C. Circuit in *FTC v. Carter*, 636 F.2d 781, 788 (D.C. Cir. 1980).<sup>31</sup>

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<sup>27</sup> We note further that this suit came more than three years after the solicitations Petitioners complain of in their Petitions. LabMD Pet., Ex. F, at 1, 17-23.

<sup>28</sup> 15 U.S.C. § 57b-1(c)(2).

<sup>29</sup> *Invention Submission*, 965 F.2d at 1088; *accord Texaco*, 555 F.2d at 874; *FTC v. Carter*, 636 F.2d 781, 789 (D.C. Cir. 1980); *FTC v. Anderson*, 631 F.2d 741, 746 (D.C. Cir. 1979).

<sup>30</sup> *Invention Submission*, 965 F.2d at 1090; *Texaco*, 555 F.2d at 874 & n.26; *FTC v. Nat'l Claims Serv., Inc.*, No. S 98-283 FCD DAD, 1999 WL 819640, at \*2 (E.D. Cal. Feb. 9, 1999) (citing *EPA v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 477 (9th Cir. 1988)).

<sup>31</sup> LabMD Pet., at 10-12.

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Petitioners' first argument reads the governing standard too narrowly. Resolution File No. P954807 authorizes the use of compulsory process:

to determine whether unnamed persons, partnerships, corporations, or others are engaged in, or may have engaged in, deceptive or unfair acts or practices related to consumer privacy and/or data security, in or affecting commerce, in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended.<sup>32</sup>

This general statement of the purpose and scope of the investigation is more than sufficient under the standard for such resolutions, and courts have enforced compulsory process issued under similarly broad resolutions.<sup>33</sup>

Petitioners' reliance on *Carter* is also misplaced. While *Carter* held that a bare reference to Section 5, without more, "would not serve very specific notice of purpose," the Court approved the resolution at issue in that case, noting that it also referred to specific statutory provisions of the Cigarette Labeling and Advertising Act, and further related it to the subject matter of the investigation.<sup>34</sup> With this additional information, the Court felt "comfortably apprised of the purposes of the investigation and the subpoenas issued in its pursuit . . . ."<sup>35</sup>

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<sup>32</sup> LabMD Pet., Ex. A.

<sup>33</sup> See *FTC v. Nat'l Claims Serv.*, 1999 WL 819640, at \*2 (finding omnibus resolution referring to FTC Act and Fair Credit Reporting Act sufficient); *FTC v. O'Connell Assoc., Inc.*, 828 F. Supp. 165, 171 (E.D.N.Y. 1993) (enforcing CIDs issued pursuant to omnibus resolution). The Commission has repeatedly rejected similar arguments about such omnibus resolutions. See, e.g., *Firefighters Charitable Found.*, No. 102-3023, at 4 (Sept. 23, 2010); *D. R. Horton, Inc.*, Nos. 102-3050, 102-3051, at 4 (July 12, 2010); *CVS Caremark Corp.*, No. 072-3119, at 4 (Dec. 3, 2008).

<sup>34</sup> *Carter*, 636 F.2d at 788.

<sup>35</sup> *Id.*

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The resolution here, like the one in *Carter*, does not cite solely to Section 5, but also recites the subject matter of the investigation: “deceptive or unfair acts or practices related to consumer privacy and/or data security.” Since the resolution here discloses the subject matter of the investigation in addition to invoking Section 5, the resolution provides notice sufficient under *Carter* of the purpose and scope of the investigation.

As a final note, the history of the investigation itself undermines Petitioners’ argument that the present CIDs do not sufficiently advise them of the nature and scope of the investigation. Petitioners have been under investigation since January 2010 and have engaged in repeated discussions with staff. At no point have Petitioners indicated they did not understand the purpose or scope; in fact, Petitioners have already produced hundreds of pages of documents in response to staff requests. Moreover, the Petitions under consideration here present highly detailed and factual arguments going to the very merits of the investigation. The Commission has previously found that such interactions may be considered along with the resolution in evaluating the notice provided to Petitioners.<sup>36</sup>

**D. Petitioners’ challenge to the FTC’s regulatory authority is premature and without basis.**

Petitioners’ final argument is that the FTC lacks jurisdiction to conduct the instant investigation.<sup>37</sup> Petitioners assert that LabMD is a health care company and that the information disclosed in the

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<sup>36</sup> *Assoc. First Capital Corp.*, 127 F.T.C. 910, 915 (1999) (“[T]he notice provided in the compulsory process resolutions, CIDs and other communications with Petitioner more than meets the Commission’s obligation of providing notice of the conduct and the potential statutory violations under investigation.”).

<sup>37</sup> Petitioners also claim that the resolution does not meet the requirements established by the FTC’s Operating Manual. LabMD Pet., at 10. As discussed above, by disclosing the statutory basis and subject matter of the investigation, the resolution does provide notice as required by the Operating Manual. That said, the Operating Manual, by its own terms, is advisory. It is not a “basis for nullifying any action of the Commission or the staff.” Operating Manual, § 1.1.1.1. See also *FTC v. Nat’l Bus. Consultants, Inc.* 1990 U.S. Dist. LEXIS 3105, 1990-1 Trade Cas. (CCH) ¶68,984, at \*29 (E.D. La. March 19, 1990).

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1,718 File is protected health information (“PHI”) under the Health Insurance Portability and Accountability Act (“HIPAA”). Accordingly, they contend, the adequacy of their security practices with respect to this information is subject to the exclusive jurisdiction of HHS.<sup>38</sup>

As an initial matter, it is well-established that challenges to the FTC’s jurisdiction are not properly raised through challenges to investigatory process. As the D.C. Circuit stated: “Following *Endicott [Johnson Corp. v. Perkins]*, 317 U.S. 501, 509 (1943), courts of appeals have consistently deferred to agency determinations of their own investigative authority, and have generally refused to entertain challenges to agency authority in proceedings to enforce compulsory process.”<sup>39</sup> The reasons for such a rule are obvious. If a party under investigation could raise substantive challenges in an enforcement proceeding, before the agency has obtained the information necessary for its case – essentially requiring the FTC to litigate an issue before it can learn about it – then the FTC’s investigations would be foreclosed or substantially delayed.<sup>40</sup> Thus, Petitioners’ basic challenge to the FTC’s jurisdiction is premature and will not support quashing the instant CIDs.

In any event, the claim that HHS has exclusive jurisdiction to investigate privacy and data security issues involving PHI is without basis. Petitioners essentially invoke the doctrine of implied repeal to assert that HIPAA and its Privacy and Security Rules displace FTC jurisdiction. But implied repeal is “strongly

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<sup>38</sup> LabMD Pet., at 12-13.

<sup>39</sup> *FTC v. Ken Roberts Co.*, 276 F.3d 583, 586 (D.C. Cir. 2001) (citing *United States v. Sturm, Ruger & Co.*, 84 F.3d 1, 5 (1st Cir. 1996)); *United States v. Construction Prods. Research, Inc.*, 73 F.3d 464, 468-73 (2d Cir. 1996); *EEOC v. Peat, Marwick, Mitchell & Co.*, 775 F.2d 928, 930 (8th Cir. 1985); *Donovan v. Shaw*, 668 F.2d 985, 989 (8th Cir. 1982); *FTC v. Ernstthal*, 607 F.2d 488, 490 (D.C. Cir. 1979); accord *Oklahoma Press Publ’g Co. v. Walling*, 327 U.S. 186, 213-14 (1946).

<sup>40</sup> *Texaco*, 555 F.2d at 879.

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disfavored,” for two reasons.<sup>41</sup> First, courts have recognized that agencies may have overlapping or concurrent jurisdiction, and thus that the same issues may be addressed and the same parties proceeded against simultaneously by more than one agency.<sup>42</sup> Second, courts rarely hold that one federal statute impliedly repeals another because “when two statutes are capable of co-existence, it is the duty of the courts . . . to regard each as effective.”<sup>43</sup> Thus, repeals by implication will only be found where the Congressional intent to effect such a repeal is “clear and manifest.”<sup>44</sup>

Petitioners can point to no such “clear or manifest” evidence that Congress intended HIPAA or its rules to displace the FTC Act. The authority Petitioners cite for the proposition that HHS has exclusive jurisdiction does not address such repeal.<sup>45</sup> To the contrary, there is ample evidence against such implied repeal. For one, the same authority cited by Petitioners – the preamble to the Privacy Rule – expressly provides that entities covered by that Rule are “also subject to other federal statutes and regulations.”<sup>46</sup>

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<sup>41</sup> *Galliano v. United States Postal Serv.*, 836 F.2d 1362, 1369 (D.C. Cir. 1988).

<sup>42</sup> *FTC v. Cement Inst.*, 333 U.S. 683, 694 (1948); *see also Texaco*, 555 F.2d at 881 (“[T]his is an era of overlapping agency jurisdiction under different statutory mandates.”); *Thompson Med. Co. v. FTC*, 791 F.2d 189, 192 (D.C. Cir. 1986). Because agencies have overlapping jurisdiction, they often work together. For instance, the FTC and HHS collaborated on the investigation of CVS Caremark Corporation. *See CVS Caremark Corp.*, No. 072-3119, at 7 (Aug. 6, 2008).

<sup>43</sup> *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 155 (1976) (quoting *Morton v. Mancari*, 417 U.S. 535, 551 (1974)).

<sup>44</sup> *Id.* at 154.

<sup>45</sup> LabMD Pet., at 12 (citing 65 Fed. Reg. 82,462, 82,472 (Dec. 28, 2000)). This Federal Register notice is the Notice of Public Rulemaking for the Privacy and Security Rules under HIPAA. The excerpt cited by Petitioners does not address the scope of HHS’ enforcement jurisdiction, but rather discusses the delegation of enforcement authority from the Secretary of HHS to HHS’ Office for Civil Rights. 65 Fed. Reg. 82,472 (Dec. 28, 2000).

<sup>46</sup> 65 Fed. Reg. 82,462, 82,481 (Dec. 28, 2000).

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Also, this preamble includes an “Implied Repeal Analysis,” which is silent as to any implied repeal of the FTC Act.<sup>47</sup> Recent legislation shows that, if anything, Congress intended the FTC and HHS to work collaboratively to address potential privacy and data security risks related to health information. The American Recovery and Reinvestment Act of 2009, for instance, required HHS and the FTC to develop harmonized rules for data breach notifications by HIPAA-covered and non-HIPAA-covered entities, respectively. *See* 74 Fed. Reg. 42,962, 42,962-63 (Aug. 25, 2009). Thus, HIPAA and its Rules do not serve to repeal FTC jurisdiction, which is overlapping and concurrent to HHS’.

This is particularly appropriate where, as here, the consumer information at issue included more than just health information. The consumer information exposed in the 1,718 File also included names, Social Security numbers, and dates of birth. While this information can be considered PHI under HIPAA when combined with health information, the information clearly exposes consumers to the risk of identity theft and is exactly the kind of sensitive personal information that the Commission is charged with protecting under Section 5 of the FTC Act and other statutes. Petitioners have provided no proper basis to challenge the investigation as an exercise of the Commission’s jurisdiction under these authorities.

### III. CONCLUSION AND ORDER

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** LabMD, Inc.’s Petition to Limit or Quash the Civil Investigative Demand be, and hereby is, **DENIED**; and

**IT IS FURTHER ORDERED THAT** Michael J. Daugherty’s Petition to Limit or Quash the Civil Investigative Demand be, and hereby is, **DENIED**; and

**IT IS FURTHER ORDERED THAT** Commission staff may reschedule the investigational hearings of LabMD and Michael J. Daugherty at such dates and times as they may direct in writing,

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<sup>47</sup> *Id.* at 82,481-487.

## Responses to Petitions to Quash

in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6); and

**IT IS FURTHER ORDERED THAT** all other responses to the specifications in the Civil Investigative Demands to LabMD, Inc. and Michael J. Daugherty must now be produced on or before May 11, 2012.

By direction of the Commission.

Responses to Petitions to Quash

**GOOGLE INC.**

*FTC File No. 111 0163 – Decision, June 18, 2012*

RESPONSE TO SAMSUNG TELECOMMUNICATIONS AMERICA, LLC'S  
PETITION TO LIMIT SUBPOENA *DUCES TECUM*  
DATED FEBRUARY 9, 2012

Dear Messrs. Huffman and Stoltz and Ms. Williams:

On April 23, 2012, the Federal Trade Commission (“FTC” or “Commission”) received the above Petition filed by Samsung Telecommunications America, LLC (“Samsung”). This letter advises you of the Commission’s disposition of the Petition, effected through this ruling by Commissioner Julie Brill, acting as the Commission’s delegate.<sup>1</sup>

For the reasons explained below, the Petition is denied. You may request review of this ruling by the full Commission.<sup>2</sup> Any such request must be filed with the Secretary of the Commission within three days after service of this letter ruling.<sup>3</sup> The timely filing of a request for review by the full Commission shall not stay the return dates established by this ruling.<sup>4</sup>

**I. INTRODUCTION**

In 2011, in connection with an investigation of Google, Inc., the FTC issued a resolution authorizing its staff to use compulsory process

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<sup>1</sup> See 16 C.F.R. § 2.7(d)(4).

<sup>2</sup> 16 C.F.R. § 2.7(f).

<sup>3</sup> *Id.* This ruling is being delivered by e-mail and courier delivery. The e-mail copy is provided as a courtesy, and the deadline by which an appeal to the full Commission would have to be filed should be calculated from the date on which you receive the original letter by courier delivery.

<sup>4</sup> *Id.*

## Responses to Petitions to Quash

[t]o determine whether Google Inc. may be engaging, or may have engaged, in any unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended, by monopolizing, attempting to monopolize, or restraining competition in online or mobile search, search advertising, or Internet-related goods or services.<sup>5</sup>

On February 9, 2012, in furtherance of the investigation, the Commission issued a third-party subpoena *duces tecum* (“subpoena”) to Samsung.<sup>6</sup> Samsung manufactures and sells mobile phones and devices, many of which are installed with Google’s Android operating system as well as other mobile applications and services developed by Google and Google’s competitors. The subpoena required Samsung to provide the requested documents no later than March 9, 2012.<sup>7</sup>

On or about March 1, 2012, Samsung asked, and received, an extension of the return date to April 9, 2012, conditioned on Samsung producing documents responsive to Specifications 1, 2, and 11, no later than Monday, March 9.<sup>8</sup> FTC staff also agreed to obviate the requirement that Samsung obtain and produce documents from its corporate parent in Korea.<sup>9</sup>

On April 5, 2012, Samsung requested a second extension of the return date.<sup>10</sup> In subsequent discussions regarding the need for

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<sup>5</sup> Petition of Samsung Telecomm. of America, LLC, to Limit Subpoena Duces Tecum, File No. 111-0163, Google, Inc., Att. 1, Exh. A (Apr. 21, 2012) [hereinafter Petition].

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

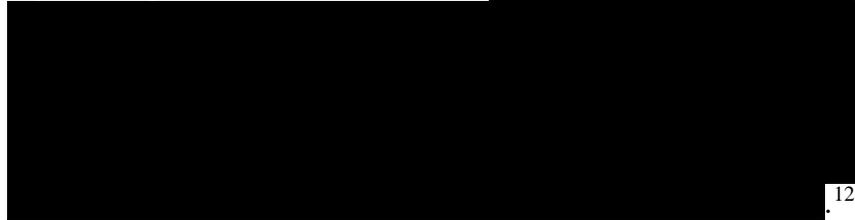
<sup>8</sup> *Id.* at Att. 4, Ex. B (E-mail from Gregory Huffman to Melissa Westman-Cherry (Mar. 2, 2012, 12:22 PM); *id.* at Att. 4, Ex. C (Letter from Melissa Westman-Cherry to Gregory Huffman (Mar. 2, 2012)).

<sup>9</sup> *Id.* at Att. 4, Ex. B (E-mail from Melissa Westman-Cherry to Gregory Huffman (Mar. 2, 2012, 10:27 AM); E-mail from Melissa Westman-Cherry to Gregory Huffman (Mar 2, 2012, 11:55 AM)).

<sup>10</sup> *Id.* at Att. 4, Ex. B (E-mail from Gregory Huffman to Melissa Westman-Cherry (Apr. 5, 2012, 6:15 PM)).

## Responses to Petitions to Quash

the extension, Samsung for the first time also asked staff to limit the required response in several respects.<sup>11</sup> Specifically, with regard to Specifications 5, 9, and 10, 



Samsung also asked staff to accept other limitations, including foregoing a search for informal agreements between Samsung and Google, and restated its request for an extension of the return date.

FTC staff accepted some of Samsung's proposals, modified the subpoena pursuant to 16 C.F.R. § 2.7(c), and extended the return date to April 23, 2012.<sup>13</sup> On April 11, 2012,

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On April 11,

Samsung claimed that their proposed search was going to be unduly burdensome.<sup>15</sup> On April 20, 2012, based on the results of the searches it had performed to date, Samsung requested a third extension of time. When staff declined a further extension, Samsung filed the instant petition.

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<sup>11</sup> *Id.* at Att. 4, Ex. C (Letter from Melissa Westman-Cherry to Gregory Huffman (Apr. 10, 2012)).

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> *Id.*, at Att. 4, Ex. B (Letter from Melissa Westman-Cherry to Gregory Huffman (Apr. 11, 2012)).

<sup>15</sup> *Id.*, at Att. 4, Ex. B. (E-mail from Melissa Westman-Cherry to Gregory Huffman (Apr. 11, 2012, 4:15 PM); E-mail from Richard Rosalez to Melissa Westman-Cherry and Gregory Huffman (Apr. 11, 2012, at 6:45 PM)).

## Responses to Petitions to Quash

**II. ANALYSIS**

Samsung's petition lodges objections to each of the specifications in the subpoena. Among these objections, Samsung claims the specifications: (1) are overly broad or unduly burdensome; (2) seek information not relevant to the investigation or not likely to lead to the discovery of relevant evidence; and (3) include vague terms or fail to seek documents with sufficient particularity.<sup>16</sup> For the following reasons, these objections fail.

**A. Samsung has not supported its claims of undue burden and overbreadth.**

We conclude that Samsung has failed to support its claims that the subpoena is overly broad and unduly burdensome. As the courts have clearly stated, “[a]ny subpoena places a burden on the person to whom it is directed. Time must be taken from normal activities and resources must be committed to gathering the information necessary to comply.”<sup>17</sup> Thus, the recipient of process bears the burden of demonstrating that this burden is undue.<sup>18</sup> Specifically, a recipient of FTC investigative process must show that compliance threatens to seriously impair or

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<sup>16</sup> Samsung objects generally that the subpoena calls for documents in the possession, custody, and control of its corporate parent in Korea, and goes on to assert that it cannot access these documents and therefore should not have to produce them. FTC staff has already agreed that Samsung need not obtain documents from its Korean parent. *Id.* at Att. 4, Ex. B (E-mail from Melissa Westman-Cherry to Gregory Huffman (Mar. 2, 2012, 10:27 AM); E-mail from Melissa Westman-Cherry to Gregory Huffman (Mar 2, 2012, 11:55 AM)). As this issue has been resolved, we need not address it here.

<sup>17</sup> *FTC v. Shaffner*, 626 F.2d 32, 38 (7th Cir. 1980); *accord FTC v. Texaco*, 555 F.2d 862, 882 (D.C. Cir. 1977).

<sup>18</sup> *Texaco*, 555 F.2d at 882; *In re Nat'l Claims Serv., Inc.*, 125 F.T.C. 1325, 1328-29 (1998). *See also EEOC v. Maryland Cup Corp.*, 785 F.2d 471, 476 (4th Cir. 1986); *FTC v. Standard American, Inc.*, 306 F.2d 231, 235 (3d Cir. 1962) (recipients of subpoena must show unreasonableness of the Commission's demand and make a record to show the “measure of their grievance rather than [asking the court] to assume it.”) (citing *United States v. Morton Salt Co.*, 338 U.S. 632, 654 (1950); *Okla. Press Publ'g Co. v. Walling*, 327 U.S. 186, 217-18 (1946)).

## Responses to Petitions to Quash

unduly disrupt the normal operations of its business.<sup>19</sup> Likewise, investigative process is not unreasonably broad where the breadth of the inquiry is commensurate with the magnitude or complexity of a recipient's business operations.<sup>20</sup>

Here, Samsung offers essentially three arguments to support its claim of burden.<sup>21</sup> First, noting that the subpoena calls for information about mobile phones, Samsung states that it manufactured over 300 different models of mobile phone during the period in question, each with a distinct configuration of software, and that collecting information related to each phone would be unduly burdensome.<sup>22</sup> Second,

may yield more than one million "hits" of possibly responsive documents that would have to be reviewed and produced.<sup>23</sup> Third, Samsung offers a declaration from a litigation support supervisor, who states that this review of the documents identified will require 2000 days of review time, assuming that a single reviewer reviews 500 documents per day (1 reviewer times

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<sup>19</sup> *Shaffner*, 626 F.2d at 38; *Texaco*, 555 F.2d at 882.

<sup>20</sup> *Texaco*, 555 F.2d at 882.

<sup>21</sup> The cases Samsung cites for the proposition that requests that ask for "all documents" are overly broad and unreasonable are inapposite. In *McKinley v. F.D.I.C.*, 807 F. Supp. 2d, 1 (D.D.C. 2011), the request at issue was directed to the FDIC under FOIA. The request did not ask for "all documents" but rather "any information available." *Id.* at 6-77. The court found that such requests for records that relate "in any way" did not enable FDIC staff to identify responsive records with reasonable effort. *Id.* In this case, however, FTC staff has not asked Samsung for documents that relate to subjects "in any way."

For the same reason, *Judicial Watch, Inc. v. Ex-Im Bank*, 108 F. Supp. 2d 19, 27-28 (D.D.C. 2000) is also inapposite. In *Judicial Watch*, the request at issue asked for contacts between two individuals and "companies, entities, and/or persons related or doing or conducting business *in any way* with the People's Republic of China." *Id.* at 26 (emphasis added). None of the requests in the FTC's subpoena to Samsung is similarly broad.

<sup>22</sup> Petition, *supra* note 5, at 3-4.

<sup>23</sup> *Id.*, at 5.

## Responses to Petitions to Quash

500 documents/per day times 2,000 days = 1 million documents).<sup>24</sup>

These arguments do not establish that the subpoena is overly broad or unduly burdensome. Samsung has not provided facts or details, such as reliable estimates of the costs of compliance, to support these claims. Instead, Samsung's objections to the specifications appear premised on the fact that they may result in many potentially responsive documents. But the volume of potentially responsive documents is not dispositive of the question whether a subpoena is unduly burdensome.<sup>25</sup> The searches may have resulted in many "hits," but ultimately it is Samsung's responsibility to show that the burden of compliance rises to the high threshold set by cases such as *Texaco* and Samsung has not offered solid evidence – or even alleged – that compliance here meets that standard.<sup>26</sup> Moreover, given the magnitude and complexity of the company's operations and the breadth of its product line, there is nothing unusual about the possibility that the subpoena potentially calls for many documents related to a large number of mobile devices.<sup>27</sup>

**B. Samsung has not shown that the information requested is irrelevant to this administrative investigation.**

Samsung has also objected to several specifications on the grounds they fail to seek information relevant to the subject matter of the investigation, or are not likely to lead to the discovery of relevant or admissible evidence.<sup>28</sup> As such,

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<sup>24</sup> *Id.*, Att. 5.

<sup>25</sup> *NLRB v. Carolina Food Processors, Inc.*, 81 F.3d 507, 513-14 (4th Cir. 1996) (“[A] subpoena is not unduly burdensome merely because it requires production of a large number of documents . . .”). *See also F.D.I.C. v. Garner*, 126 F.3d 1138, 1145-46 (9th Cir. 1997) (enforcing subpoena that called for over one million documents where recipients failed to demonstrate the requests were unduly burdensome).

<sup>26</sup> *See, e.g., Texaco*, 555 F.2d at 882.

<sup>27</sup> *Texaco*, 555 F.2d at 882.

<sup>28</sup> *See, e.g., Petition, supra* note 5, at 8-10.

## Responses to Petitions to Quash

Samsung seems to argue that the requirements of the subpoena do not comport with the requirements applicable to discovery requests propounded under the Federal Rules of Civil Procedure.<sup>29</sup>

However, the Federal Rules of Civil Procedure do not apply to agency investigations. “Unlike a discovery procedure, an administrative investigation is a proceeding distinct from any litigation that may flow from it.”<sup>30</sup> As the D.C. Circuit and other courts have recognized, “[t]he standard for judging relevancy in an investigatory proceeding is more relaxed than in an adjudicatory one . . . . The requested material, therefore, need only be relevant to the *investigation* – the boundary of which may be defined quite generally, as it was in the Commission’s resolution here.”<sup>31</sup> Agencies thus have “extreme breadth” in conducting their investigations,<sup>32</sup> and “in light of [this] broad deference . . . , it is essentially the respondent’s burden to show that the information is irrelevant.”<sup>33</sup>

Samsung’s conclusory assertions<sup>34</sup> do not satisfy this standard. As stated in the Commission’s investigatory resolution, the purpose of the investigation is to determine whether Google is

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<sup>29</sup> One such example is Samsung’s claim that the subpoena calls for irrelevant evidence, or evidence that is not reasonably likely to lead to the discovery of relevant or admissible evidence. These objections are premised on Fed. R. Civ. P. 26(b)(1), which addresses the scope of discovery in a civil action.

<sup>30</sup> *Linde Thomsen Langworthy Kohn & Van Dyke, P.C. v. Resolution Trust Corp.*, 5 F.3d 1508, 1513 (D.C. Cir. 1993) (citing *EEOC v. Deer Valley Unified Sch. Dist.*, 968 F. 2d 904, 906 (9th Cir. 1992); *EEOC v. Univ. of Notre Dame du Lac*, 551 F. Supp. 737, 742 (N.D. Ind. 1982), *rev’d on other grounds*, 715 F.2d 331 (7th Cir. 1983)).

<sup>31</sup> *FTC v. Invention Submission Corp.*, 965 F. 2d 1086, 1090 (D.C. Cir. 1992) (emphasis in original; internal citations omitted) (citing *FTC v. Carter*, 636 F.2d 781, 787-88 (D.C. Cir. 1980); *Texaco*, 555 F.2d at 874 & n.26)).

<sup>32</sup> *Linde Thomsen*, 5 F.3d at 1517 (citing *Texaco*, 555 F.2d at 882).

<sup>33</sup> *Invention Submission Corp.*, 965 F.2d at 1090 (citing *Texaco*, 555 F.2d at 882); accord *FTC v. Church & Dwight Co., Inc.*, 756 F. Supp. 2d 81, 85 (D.D.C. 2010).

<sup>34</sup> See, e.g., Petition, *supra* note 5, at 8-13.

## Responses to Petitions to Quash

engaged in “unfair methods of competition” by, *inter alia*, monopolizing, attempting to monopolize, or restraining competition in online or mobile search, search advertising, or Internet-related goods or services. Samsung is a manufacturer of mobile devices that are used by consumers for online or mobile search, for using Internet-related goods and services, and on which consumers receive search advertising. Thus, information about the relationship between Google and Samsung as it relates to those topics is plainly relevant to this investigation, and Samsung has offered nothing to challenge this conclusion.

**C. The subpoena specifications are not vague and identify the requested documents with sufficient particularity.**

Samsung also objects to Specifications 5 and 10 on the grounds that they include terms that Samsung finds vague, such as “business strategy,” “consideration, development and use,” or “competes with.” Samsung claims that it cannot identify which documents might be responsive to these requests.

Samsung has not shown that these terms have multiple meanings that make it difficult to determine which documents are responsive. Terms such as “business strategy,” or “consideration, development and use” are commonly employed by companies of Samsung’s size and complexity. In particular, we expect that Samsung, a global manufacturer of mobile devices, understands the term “competes with” in the context of mobile products and software. Furthermore, these terms appear in the subpoena in the context of specifications that contain additional guidance as to the limits and scope of the requests. For example, specification 5 includes examples of responsive documents, such as “strategic plans, business plans, marketing plans, advertising plans, pricing plans, technology plans, forecasts, strategies, and decisions; market studies; and presentations to management committees, executive committees, and boards of directors.”<sup>35</sup> Instead, it appears that Samsung objects to these terms because they call for many responsive documents, but, as discussed above, without more, this is not a proper basis for an objection.<sup>36</sup> For these

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<sup>35</sup> *Id.*, Att. 1, Ex. A, at 7.

<sup>36</sup> *Carolina Food Processors, Inc.*, 81 F.3d at 513-14.

## Responses to Petitions to Quash

reasons, Samsung's claim that the subpoena terms are vague or insufficiently particular fails.

**III. CONCLUSION AND ORDER**

For the foregoing reasons, **IT IS HEREBY ORDERED THAT** Samsung Telecommunications America LLC's Petition to Limit Subpoena Duces Tecum be, and it hereby is, **DENIED**; and

**IT IS FURTHER ORDERED THAT** all other responses to the specifications in the subpoena *duces tecum* must now be produced on or before July 2, 2012. Pursuant to Rule 2.7(c), 16 C.F.R. § 2.7(c), staff has the authority to determine the terms of satisfactory compliance, including allowing Petitioner to abide by previously-reached agreements to limit the production of documents and information responsive to the subpoena *duces tecum*.

By direction of the Commission.

Responses to Petitions to Quash

**LABMD, INC.***FTC File No. 102 3099 – Decision, June 21, 2012*RESPONSE BY THE FULL COMMISSION TO LABMD, INC.'S AND ITS  
PRESIDENT, MICHAEL J. DAUGHERTY'S PETITIONS TO LIMIT OR  
QUASH THE CIVIL INVESTIGATIVE DEMANDS  
DATED DECEMBER 21, 2011

Dear Mr. Fusco:

This letter advises you of the Commission's disposition of LabMD, Inc.'s and Michael J. Daugherty's request dated April 25, 2012, that the full Commission review the denial of their petition to limit or quash civil investigative demands.

The Commission issued the CIDs to LabMD and Mr. Daugherty on December 21, 2011. LabMD and Mr. Daugherty filed petitions to limit or quash the CIDs, which were received by the Commission on January 10, 2012. On April 20, 2012, Commissioner Brill directed the issuance of a letter denying both petitions and directing both petitioners to comply by May 11, 2012. That deadline was extended to June 8, 2012 due to emergency circumstances that you brought to the Commission's attention.<sup>1</sup>

The Commission affirms the ruling denying the petitions to limit or quash the civil investigative demands. The Commission has independently reviewed LabMD and Mr. Daugherty's petitions to limit or quash the CIDs, and their requests for full Commission review. The Commission has also reviewed the letter ruling issued by the Commission at the direction of Commissioner Brill, and hereby affirms that ruling, finding its conclusions to be valid and correct.

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<sup>1</sup> On April 30, 2012, you contacted the Commission's Office of the Secretary to request additional time to comply with the CID due to emergency circumstances. By letter dated May 7, 2012, the Commission modified the date to June 8, 2012.

## Responses to Petitions to Quash

Commissioner Rosch generally agrees with the Commission's decision to enforce the CIDs, but dissents from this ruling to the extent it permits staff to rely on a LabMD document found on a peer-to-peer file sharing network, out of concern about petitioners' allegations that a third party located this document through wrongdoing and for financially-motivated reasons. In this ruling, we make no findings of fact regarding that third party's conduct or the admissibility of this document, nor do we need to do so. In upholding the CIDs, the Commission allows staff to continue to use pertinent information—including information from or concerning any LabMD documents made available to users of peer-to-peer file-sharing networks and accessed by any third party—to conduct its data security investigation. Indeed, in our data security investigations, the Commission often uses information obtained by third parties concerning security vulnerabilities of entities that maintain substantial amounts of personal information. Although we understand petitioners have alleged that the third party in question has a financial incentive to use its patented monitoring tool to find information that has been improperly disclosed on peer-to-peer file sharing networks, that does not overcome the Commission's compelling public interest in seeking to protect consumers' sensitive health data by pursuing this investigation through all lawful means, including the use of this document.

The April 25, 2012 request for full Commission review also requested a hearing on the denial of the petitions. The FTC Rule governing petitions to quash or limit, 16 C.F.R. § 2.7, does not provide for such a hearing, however, and accordingly, this request will be denied.

For the forgoing reasons,

**IT IS ORDERED THAT** the April 20, 2012 letter ruling is **AFFIRMED**;

**IT IS FURTHER ORDERED THAT** LabMD's and Mr. Daugherty's request for a hearing is **DENIED**;

**IT IS FURTHER ORDERED THAT** Commission staff may reschedule the investigational hearings of LabMD and Michael J.

## Dissenting Statement

Daugherty at such dates and times as they may direct in writing, in accordance with the powers delegated to them by 16 C.F.R. § 2.9(b)(6)(2012); and

**IT IS FURTHER ORDERED THAT** all other responses to the specifications in the Civil Investigative Demands to LabMD, Inc. and Michael J. Daugherty must be produced on or before June 8, 2012.

By direction of the Commission, Commissioner Rosch dissenting, and Commissioner Ohlhausen not participating.

**Dissenting Statement of Commissioner J. Thomas Rosch**

I dissent from the Commission's vote affirming Commissioner Brill's letter decision, dated April 20, 2012, that denied the petitions of LabMD, Inc. and Michael J. Dougherty to limit or quash the civil investigative demands.

I generally agree with Commissioner Brill's decision to enforce the document requests and interrogatories, and to allow investigational hearings to proceed. As she has concluded, further discovery may establish that there is indeed reason to believe there is Section 5 liability regarding petitioners' security failings *independent* of the "1,718 File" (the 1,718 page spreadsheet containing sensitive personally identifiable information regarding approximately 9,000 patients) that was originally discovered through the efforts of Dartmouth Professor M. Eric Johnson and Tiversa, Inc. In my view, however, as a matter of prosecutorial discretion under the unique circumstances posed by this investigation, the CIDs should be limited. Accordingly, without reaching the merits of petitioners' legal claims, I do not agree that staff should further inquire - either by document request, interrogatory, or investigational hearing - about the 1,718 File.

## Dissenting Statement

Specifically, I am concerned that Tiversa is more than an ordinary witness, informant, or “whistle-blower.” It is a commercial entity that has a financial interest in intentionally exposing and capturing sensitive files on computer networks, and a business model of offering its services to help organizations protect against similar infiltrations. Indeed, in the instant matter, an argument has been raised that Tiversa used its robust, patented peer-to-peer monitoring technology to retrieve the 1,718 File, and then repeatedly solicited LabMD, offering investigative and remediation services regarding the breach, long before Commission staff contacted LabMD. In my view, while there appears to be nothing *per se* unlawful about this evidence, the Commission should avoid even the appearance of bias or impropriety by not relying on such evidence or information in this investigation.

# ADVISORY OPINION

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IN THE MATTER OF

## NATIONAL CONSUMER LAW CENTER

*FTC File No. P124802 - Opinion, May 3, 2012*

**Re: Whether the Holder Rule limits a consumer's right to an affirmative recovery to circumstances where the consumer can legally rescind the transaction or where the goods or services sold to the consumer are worthless.**

Dear Mr. Sheldon and Ms. Carter:

This letter is in response to the National Consumer Law Center's request for a Commission advisory opinion regarding the Federal Trade Commission's Trade Regulation Rule Concerning Preservation of Consumers' Claims and Defenses, 16 C.F.R. § 433, commonly known as the Holder Rule.<sup>1</sup> Specifically, you ask the Commission to affirm that the Holder Rule does not limit a consumer's right to an affirmative recovery to circumstances where the consumer can legally rescind the transaction or where the goods or services sold to the consumer are worthless. Your letter states that even though the plain language of the Rule is clear—which FTC staff confirmed in a 1999 opinion letter<sup>2</sup>—some courts continue to bar consumers from affirmative recoveries unless rescission is warranted.<sup>3</sup>

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<sup>1</sup> Your letter requesting an advisory opinion is co-signed by representatives from Public Citizen, U.S. PIRG, the Center for Responsible Lending, and the National Association of Consumer Advocates.

<sup>2</sup> See Attachment, FTC Staff Letter (Sept. 25, 1999).

<sup>3</sup> Your letter lists six cases that have been decided since the issuance of the 1999 FTC staff opinion letter that have held that a consumer may only obtain an affirmative recovery against a creditor under the Holder Rule when the seller's breach is so substantial that rescission and restitution are justified or where the goods or services sold to the consumer are worthless: *Rollins v. Drive-1 of Norfolk, Inc.*, No. 2:06cv375, 2007 WL 602089 (E.D. Va. Feb. 21, 2007); *Phillips v. Lithia Motors, Inc.*, No. 03-3109-HO, 2006 WL 1113608 (D.

## Advisory Opinion

The Holder Rule protects consumers who enter into credit contracts with a seller of goods or services by preserving their right to assert claims and defenses against any holder of the contract, even if the original seller subsequently assigns the contract to a third-party creditor. In particular, the Holder Rule requires sellers that arrange for or offer credit to finance consumers' purchases to include in their credit contracts the following Notice:

ANY HOLDER OF THIS CONSUMER CREDIT CONTRACT IS SUBJECT TO ALL CLAIMS AND DEFENSES WHICH THE DEBTOR COULD ASSERT AGAINST THE SELLER OF GOODS OR SERVICES OBTAINED [PURSUANT HERETO OR] WITH THE PROCEEDS HEREOF. RECOVERY HEREUNDER BY THE DEBTOR SHALL NOT EXCEED AMOUNTS PAID BY THE DEBTOR HEREUNDER.

16 C.F.R. § 433.2.

A creditor or assignee of the contract is thus subject to all claims or defenses that the consumer could assert against the seller. The Holder Rule does not create any new claims or defenses for the consumer; it simply protects the consumer's existing claims and defenses. The *only* limitation included in the Rule is that a consumer's recovery "shall not exceed amounts paid" by the consumer under the contract.

Thus, the plain language of the Rule permits a consumer to assert a seller's misconduct (1) to defend against a creditor's lawsuit for amounts owed under the contract and/or (2) to maintain a claim against the creditor for a refund of money the

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Or. Apr. 27, 2006); *Costa v. Mauro Chevrolet, Inc.*, 390 F. Supp. 2d 720 (N.D. Ill. 2005); *Comer v. Person Auto Sales, Inc.*, 368 F. Supp. 2d 478 (M.D.N.C. 2005); *Herrara v. North & Kimball Group, Inc.*, No. 01C7349, 2002 U.S. Dist. LEXIS 2640 (N.D. Ill. Feb. 15, 2002); *Bellik v. Bank of America*, 869 N.E.2d 1179 (Ill. App. Ct. 2007). You cite *Comer* as pointedly rejecting the FTC staff opinion letter. *Comer* notes that the staff letter is "not binding on the Commission." 368 F. Supp. 2d at 490.

## Advisory Opinion

consumer has already paid under the contract (*i.e.*, an affirmative recovery). Despite the Rule's plain language, however, some courts have imposed additional limitations on a consumer's right to affirmative recovery. Beginning with *Ford Motor Credit Co. v. Morgan*, 536 N.E.2d 587 (Mass. 1989),<sup>4</sup> these courts have allowed affirmative recovery only if the consumer is entitled to rescission or similar relief under state law.<sup>5</sup> Courts following the *Morgan* approach have not imposed any similar limitation on a consumer's right to raise the seller's misconduct as a defense in a lawsuit.

The Commission affirms that the Rule is unambiguous, and its plain language should be applied.<sup>6</sup> No additional limitations on a consumer's right to an affirmative recovery should be read into the Rule, especially since a consumer would not have notice of those limitations because they are not included in the credit contract. Had the Commission meant to limit recovery to claims subject to rescission or similar remedy, it would have said so in the text of the Rule and drafted the contractual provision

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<sup>4</sup> In *Morgan*, the court faced extensive consumer misconduct in connection with the financing of a car purchase. After experiencing problems with the car, the consumer concealed the automobile, removed the battery, removed or deflated the tires, and surrendered the automobile only after being found in contempt by the trial judge. He also delayed the sale of the automobile, during which time it was extensively vandalized, resulting in a total loss that was not recoverable due to the consumer's failure to obtain insurance. The creditor sued the consumer for the balance due under the contract, and the consumer filed a counterclaim based on the dealer's misrepresentations. Notably, in contravention of the one express limitation in the Holder Rule, the consumer sought recovery of an amount in excess of what the consumer had paid under the contract. The court ultimately held that the consumer was not entitled to any affirmative recovery, but he did not have to pay the remaining balance due. 536 N.E.2d at 588.

<sup>5</sup> See, *e.g.*, n.3, *supra*.

<sup>6</sup> See *Qwest Corp. v. Colorado Public Utilities Comm'n*, 656 F.3d 1093, 1099 (10th Cir. 2011) ("We begin with the plain language of the regulation. . . . If the regulation's language is clear, our analysis ends and we must apply its plain meaning.") (internal citations and quotations omitted); *Lozada v. Dale Baker Oldsmobile, Inc.*, 91 F. Supp. 2d 1087, 1095 (W.D. Mich. 2000) ("No basis exists for referring to the commentary to understand the meaning of language that is unambiguous on its face.").

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accordingly. It remains the Commission's intent that the plain language of the Rule be applied, which many courts have done.<sup>7</sup>

The purpose of the Holder Rule, as stated in the Rule's Statement of Basis and Purpose ("SBP"), supports this plain reading. The Commission adopted the Rule to provide recourse to consumers who otherwise would be legally obligated to make full payment to a creditor despite breach of warranty, misrepresentation, or even fraud on the part of the seller.<sup>8</sup> The Commission found that "the creditor is *always* in a better position than the buyer to return seller misconduct costs to sellers, the guilty party,"<sup>9</sup> and therefore concluded that "[s]ellers and creditors will be responsible for seller misconduct."<sup>10</sup> Moreover, the Commission considered, but firmly rejected, a suggestion by industry representatives that the Rule be amended so that a consumer "may assert his rights only as a matter of defense or setoff against a claim by the assignee or holder," finding instead that "[t]he practical and policy considerations which militate against such a limitation on affirmative actions by consumers are

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<sup>7</sup> See, e.g., *Lozada*, 91 F. Supp. 2d at 1094-95; *Simpson v. Anthony Auto Sales, Inc.*, 32 F. Supp. 2d 405, 409 n.10 (W.D. La. 1998); *Riggs v. Anthony Auto Sales*, 32 F. Supp. 2d 411, 416 n.13 (W.D. La. 1998); *Beemus v. Interstate Nat'l Dealer Servs., Inc.*, 823 A.2d 979, 984-85 (Pa. Super. Ct. 2003); *Jaramillo v. Gonzalez*, 50 P.3d 554, 561 (N.M. Ct. App. 2002); *Scott v. Mayflower Home Improvement Corp.*, 831 A.2d 564, 573-74 (N.J. Super. Ct. Law Div. 2001).

<sup>8</sup> See 40 Fed. Reg. 53506, 53507 (Nov. 18, 1975) ("The rule is directed at what the Commission believes to be an anomaly. . . . The creditor may assert his right to be paid by the consumer despite misrepresentation, breach of warranty or contract, or even fraud on the part of the seller, and despite the fact that the consumer's debt was generated by the sale.")

<sup>9</sup> *Id.* at 53523 (emphasis added); see also *id.* at 53509 ("Between an innocent consumer, whose dealings with an unreliable seller are, at most, episodic, and a finance institution qualifying as 'a holder in due course,' the financier is in a better position both to protect itself and to assume the risk of a seller's reliability."); *id.* at 53523 ("We believe that a rule which compels creditors to either absorb seller misconduct costs or return them to sellers, by denying sellers access to cut-off devices, will discourage many of the predatory practices and schemes. . . . The market will be policed in this fashion and all parties will benefit accordingly.")

<sup>10</sup> *Id.* at 53524.

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far more persuasive.”<sup>11</sup> For example, the Commission noted that some consumers may feel compelled to continue payments because of the threat of negative credit reporting and that “a stronger potential consumer remedy will encourage greater policing of merchants by finance institutions.”<sup>12</sup>

Thus, to give full effect to the Commission’s original intent to shift seller misconduct costs away from consumers, consumers must have the right to recover funds already paid under the contract if such recovery is necessary to fully compensate the consumer for the misconduct—even if rescission of the transaction is not warranted. Otherwise, whether a consumer is able to be fully compensated would depend on how much the consumer paid under the contract at the time of the dispute. For example, consider a consumer who finances the purchase of an automobile, later discovered to be defective, for \$10,000 and is entitled to compensation of \$3,000 based on the seller’s misrepresentations regarding the condition of the automobile. If the consumer has paid \$4,000 under the financing contract and still owes \$6,000, the consumer could withhold \$3,000 of the balance due and be fully compensated—a defensive posture sanctioned by *Morgan*. If, however, the consumer has paid \$8,000 and owes \$2,000, the *Morgan* approach would permit the consumer to withhold the remaining \$2,000 payment, but not affirmatively recover the additional \$1,000 that would be necessary to make the consumer whole.<sup>13</sup> There is no basis under the plain language and the intent of the Rule for such an anomalous result.

Courts that have followed the *Morgan* approach have misinterpreted two isolated comments in the SBP that accompanies the Rule. In part, the SBP states that affirmative recovery by the consumer “will only be available where a seller’s breach is so substantial that a court is persuaded that rescission

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<sup>11</sup> *Id.* at 53526.

<sup>12</sup> *Id.* at 53527.

<sup>13</sup> This example is drawn from Michael Greenfield & Nina Ross, *Limits on a Consumer’s Ability to Assert Claims and Defenses Under the FTC’s Holder in Due Course Rule*, 46 Bus. Law. 1135, 1140 (1991).

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and restitution are justified”<sup>14</sup> and that consumers “will not be in a position to obtain an affirmative recovery from a creditor, unless they have actually commenced payments and received little or nothing of value from the seller.”<sup>15</sup> However, when read in context of the entire SBP, including the SBP language highlighted above, the two SBP comments cited by *Morgan* and its progeny do not undermine the plain language of the Rule. As explained by one court that rejected the *Morgan* approach, “[w]here one or more parts of the [SBP] fully comport with the text of the rule while another, read in a particular way, is at odds with the plain language of the regulation, there exists no basis for giving controlling weight to an interpretation which narrows the language of the rule itself.”<sup>16</sup> These statements should be read as practical observations or predictions, instead of as contradicting the Rule. In most instances where there is significant consumer injury associated with seller misconduct but rescission is not warranted, the consumer is likely to find out about the injury shortly after the transaction is consummated, and thus is likely to stop payments before the claim amount is larger than the balance due. In other words, affirmative recoveries will be rare in cases where rescission is not justified because such recoveries occur only if the consumer’s claim is larger than what the consumer still owes on the loan.<sup>17</sup> When read in this context, the two SBP comments do not conflict with the rest of the SBP and the plain language of the Rule.

Thus, the Commission affirms the plain language of the Holder Rule and the intent of the Rule as discussed in the entire SBP. Specifically, the Rule places no limits on a consumer’s right to an affirmative recovery other than limiting recovery to a refund of monies paid under the contract. Further, the Rule does

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<sup>14</sup> 40 Fed. Reg. at 53524.

<sup>15</sup> *Id.* at 53527.

<sup>16</sup> *Lozada*, 91 F. Supp. 2d at 1096.

<sup>17</sup> *See id.* at 1095 (noting that the SBP “is susceptible of being understood as a statement of agency prediction that affirmative recoveries will occur only when courts are persuaded that the equities so require and when damages exceed the amount due on the account”); *accord Jaramillo*, 50 P.3d at 561.

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not limit affirmative recovery only to those circumstances where rescission is warranted or where the goods or services sold to the consumer are worthless.

By direction of the Commission.

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