

FEDERAL TRADE COMMISSION DECISIONS

**FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2007, TO DECEMBER 31, 2007**

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VOLUME 144



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DURING THE PERIOD
JULY 1, 2007, TO DECEMBER 31, 2007**

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FEDERAL TRADE COMMISSION DECISIONS

**FINDINGS, OPINIONS, AND ORDERS
JULY 1, 2007, TO DECEMBER 31, 2007**

IN THE MATTER OF

**EVANSTON NORTHWESTERN HEALTHCARE
CORPORATION**

AND

ENH MEDICAL GROUP, INC.

**OPINION OF THE COMMISSION AND ORDER IN REGARD TO
ALLEGED VIOLATIONS OF SEC. 7 OF THE CLAYTON ACT**

Docket 9315; File No. 011 0234

Opinion, August 2, 2007 – Order, August 2, 2007

Complaint, February 10, 2004 – Initial Decision, October 20, 2005

The complaint concerns the merger of Evanston Northwestern Healthcare Corporation (“ENH”) and Highland Park Hospital in January 2000. The merger also folded the Highland Park Independent Physician Association into ENH Medical Group. The complaint alleged that the merger violated Section 7 of the Clayton Act by significantly reducing competition in the market for general acute care inpatient hospital services sold to private payers in northeast Cook County and southeast Lake County, Illinois. The complaint also alleged that ENH Medical Group violated Section 5 of the FTC Act requiring private payers to accept increased prices for hospital and physician services or face termination of both. Following an administrative hearing, the Administrative Law Judge issued an Initial Decision, 144 F.T.C. 19, ruling that the effect of the acquisition of Highland Park by ENH substantially lessened competition in violation of Section 7 of the Clayton Act and ordered the divestiture of the Highland Park Hospital Assets. On appeal, the Commission upheld the Initial Decision, finding that the merger enabled ENH to exercise market power, and that that ENH used this market power to increase its average net prices for acute inpatient hospital services by a substantial amount, but rejected divestiture as a remedy. The Commission issued an Order to cease and desist. The Order also requires the Respondents to file with the Commission a detailed proposal for implementing the injunctive relief ordered.

Complaint

Participants

For the *Commission*: Thomas H. Brock, Jeff Dahnke, Philip M. Eisenstat, Jamel R. Franklin, Renee S. Henning, Albert Y. Kim, Jeanne H. Liu, John Martin, Christopher L. Marvine, Paul J. Nolan, Chul Pak, Nancy Park, Stephanie A. Parks, Anthony R. Saunders, Stephen W. Sockwell, Jr., Kristina E. Van Horn, Steve Vieux, Oscar Voss, and Goldie V. Walker.

For the *Respondents*: Tracy J. Allen, Keitha Clopper, David E. Dahlquist, Michael A. Del Negro, Christopher B. Essig, Duane M. Kelley, J. Ethan McComb, and Scott C. Walton, Winston & Strawn LLP, Chicago, Illinois; Charles B. Klein, Jay L. Levine, Rebecca C. Morrison, Adam S. Nadelhaft, Jennifer H. Scott, Michael L. Sibarium, and Patrick A. Tillou, Winston & Strawn LLP, Washington, D.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, having reason to believe that respondent Evanston Northwestern Healthcare Corporation (“ENH”) has violated and is violating Section 7 of the Clayton Act, and that respondent ENH Medical Group, Inc. (“ENH Medical Group”), has violated and is violating Section 5 of the Federal Trade Commission Act, 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 in that respect as follows:

NATURE OF THE CASE

1. This complaint concerns the merger of ENH and Highland Park Hospital (“Highland Park”) in January 2000. The merger combined ENH’s Evanston and Glenbrook hospitals located in Cook

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Cook County, Illinois with Highland Park Hospital, the nearest hospital to the north. Shortly after the merger, ENH negotiated uniform prices for the three hospitals as a single system and raised prices at all three locations, the largest of which was at ENH. The price increases that resulted from the merger are large and far beyond those achieved by comparable hospitals during this time period.

2. The merger also folded the Highland Park Independent Physician Association (“IPA”) into ENH Medical Group, creating a larger group that included both ENH salaried physicians as well as other independent physicians. Following the merger, ENH Medical Group engaged in price fixing of physician services by negotiating with third party payers for uniform prices for both the salaried physicians and non-salaried, independent physicians. This conduct deprived commercial payers, employers, and individuals the benefits of competition in physician services.

3. After merging the hospitals and the physician groups, ENH conducted negotiations with private payers by offering hospital services and physician services as a package. In many instances, ENH required private payers to accept its terms for both hospital and physician services or face termination of both hospital and physician contracts.

BACKGROUND ON THE ENH HOSPITALS AND MEDICAL GROUP

4. ENH is a non-profit corporation organized, existing, and doing business under, and by virtue of, the laws of Illinois, with its office and principal place of business located at 1301 Central Street, Evanston, Illinois 60201. For the fiscal year ending September 30, 2000, ENH had revenues of about \$735 million.

5. ENH owns and operates Evanston Hospital (“Evanston”), a 466-bed acute care hospital located in Evanston, Illinois, Glenbrook Hospital (“Glenbrook”), a 136-bed acute care hospital

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located near Evanston, and Highland Park, a 234-bed acute care hospital also located near Evanston.

6. Prior to the merger Highland Park was offering a broad range of medical and surgical services. In addition, Highland Park was pursuing the offering of open heart surgery through regulatory filings with the state of Illinois and through formation of a joint venture with Evanston.

7. ENH is the sole member or owner of ENH Faculty Practice Associates (“Faculty Practice Associates”), an Illinois non-profit corporation located at 1301 Central Street, Evanston, Illinois 60201. Faculty Practice Associates was organized in 1990 under its former name Evanston Medical Specialists Foundation. It currently employs about 500 physicians who primarily serve the patients of ENH.

8. ENH Medical Group is a for-profit corporation organized, existing, and doing business under, and by virtue of, the laws of Illinois, with its office and principal place of business located at 1301 Central Street, Evanston, Illinois 60201. Faculty Practice Associates, which ENH controls, is the sole shareholder of ENH Medical Group.

JURISDICTION

9. ENH is, and at all relevant times has been, engaged in commerce within the meaning of the Clayton Act. Before their merger with ENH, Highland Park, a non-profit Illinois corporation, and its parent Lakeland Health Services, Inc., a non-profit Illinois corporation, were engaged in commerce within the meaning of the Clayton Act. ENH’s merger with Highland Park constitutes an acquisition under the Clayton Act.

Complaint

10. ENH Medical Group is, and at all relevant times has been, engaged in commerce within the meaning of the Federal Trade Commission Act.

11. ENH Medical Group is a corporation within the meaning of Section 4 of the Federal Trade Commission Act.

THE MERGER

12. On or about January 1, 2000, ENH and Lakeland Health Services, Inc., completed a merger by which Lakeland Health Services, Inc., and its subsidiary, Highland Park, merged with and into ENH. There was no merger or acquisition price in connection with this transaction. In August 1999, ENH estimated the fair market value of Highland Park at \$233,528,000.

13. The merger placed Evanston, Glenbrook, and Highland Park under the control of ENH. The merger established one board of directors, one management staff, and one medical staff. Since the merger, ENH has collectively negotiated prices for all three hospitals.

14. Prior to the merger, ENH and Highland Park, along with several other hospitals, were members of a joint venture known as the Northwestern Healthcare Network. Under that joint venture, ENH and Highland Park and the other members maintained separate management and negotiated prices independently. At the time of the merger negotiations, members of the Northwestern Healthcare Network planned to exit from or dissolve the joint venture. They dissolved the joint venture on January 3, 2000, two days after ENH and Highland Park consummated the merger.

**COUNT I: MERGER OF HOSPITALS IN VIOLATION OF
CLAYTON ACT §7**

15. The allegations of paragraphs 1 through 14 are incorporated by reference as though fully set forth herein.

Complaint

PRODUCT MARKET

16. The relevant product market is general acute care inpatient hospital services sold to private payers, including commercial payers, managed care plans, and self-insurance plans (collectively, “private payers”). General acute care inpatient hospital services are a broad cluster of basic medical and surgical diagnostic and treatment services that include an overnight stay in the hospital by the patient. General acute care inpatient hospital services exclude (i) services at hospitals that serve solely military and veterans; (ii) services at outpatient facilities that provide same-day service only; (iii) sophisticated services known in the industry as “tertiary services” that include such services as open heart surgery and transplants; and (iv) psychiatric, substance abuse, and rehabilitation services.

GEOGRAPHIC MARKET

17. The relevant geographic market in which to analyze the merger is the geographic area directly proximate to the three ENH hospitals and contiguous geographic areas in northeast Cook County and southeast Lake County, Illinois. This geographic area, in which a significant number of individuals who seek hospital care at the three ENH hospitals reside, spans (and may be narrower than) the densely populated suburban corridor that runs for about 15 miles north-south along the shore of Lake Michigan, and extends roughly ten miles west of the Lake. The existence of this relevant geographic market is evidenced, among other things, by the ability of ENH, once it controlled Highland Park as well as the Evanston and Glenbrook hospitals, profitably to impose significant and non-transitory price increases upon private payers in their purchase of acute care hospital services at those hospitals.

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CONCENTRATION

18. As a result of the merger, ENH has been able to exercise market power in the relevant market. The merger of ENH and Highland Park created the largest hospital system in the relevant market. This market is highly concentrated and the combination significantly increased market concentration. The merger resulted in a post-merger HHI increase in excess of 500 points to a level exceeding 3000 points.

ENTRY CONDITIONS

19. It is unlikely that entry into the market would remedy, in a timely manner, the anticompetitive effects from the merger. Entry is difficult and likely to take more than two years because of the time required to plan for and to complete construction of an acute care hospital.

20. Government regulations also make entry difficult. The Illinois Health Facilities Planning Act, 20 Illinois Code § 3960, restricts entry in this market. The Act prevents firms from entering the market by building a hospital without first obtaining a permit from the Illinois Health Facilities Planning Board (“Planning Board”), which administers the Act. The Planning Board has issued detailed regulations, 77 Illinois Administrative Code § 1100, governing the administration of the Act.

21. For a prospective entrant, the prospects for receiving from the Planning Board a permit to build a new hospital are highly uncertain. The Illinois Health Facilities Planning Act, along with the regulations issued by the Planning Board, authorize the Planning Board to deny applications for permits based on various factors. These include, among others, the potential for duplication of health care services; the desire for orderly development of health care facilities; and the background, character, and financial fitness of the applicant.

Complaint

22. Obtaining a permit to build a new hospital may take several years. The Illinois Health Facilities Planning Act authorizes adversely affected companies to seek judicial review under Illinois Administrative Review Law of any final decision of the Planning Board. The regulations of the Planning Board define adversely affected persons to include the incumbent hospitals in the area. These hospitals have a right to intervene in the Planning Board proceedings and to seek judicial review. The time period from application at the Planning Board to completion of judicial review can take several years.

23. The Illinois Health Facilities Planning Act also restricts expansion by current market participants. It requires a permit to expand capacity by more than 10 beds or more than 10 percent of current capacity, whichever is less.

LACK OF MERGER EFFICIENCIES

24. The merger was not necessary to permit the parties to achieve overriding efficiencies to vindicate the merger. Should the matter of efficiencies be placed properly in issue, the evidence establishes that the merger has not led to lower costs at ENH that led to lower prices for consumers. Rather, the merger has led to large cost increases at ENH that coincided with large price increases for consumers. The ability of ENH and Glenbrook hospitals to increase these operating costs and their charges for general acute care inpatient hospital services, without a corresponding improvement in quality of care, further reflects the market power exercised by the hospitals after the merger.

25. Prior to the merger, ENH's Evanston and Glenbrook hospitals had operating costs comparable to area hospitals and other comparable hospitals. Following the merger, the operating costs at the Evanston and Glenbrook hospitals increased substantially, and much more than experienced by area hospitals and other comparable hospitals.

Complaint

26. Salaries account for the largest portion of operating costs. Following the merger, salary expenses at ENH's Evanston and Glenbrook hospitals increased substantially, and much more than experienced by area hospitals and other comparable hospitals.

VIOLATION

27. The merger of ENH and Highland Park has substantially lessened competition in the relevant market, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

**COUNT II: MERGER OF HOSPITALS IN VIOLATION OF
CLAYTON ACT §7**

28. The allegations of paragraphs 1 through 14 and 19 through 26 are incorporated by reference as though fully set forth herein.

COMPETITIVE EFFECTS OF MERGER

29. Following the merger, ENH established a strategy of negotiating with private payers on behalf of the three hospitals as a single system. In many instances, this policy, with the addition of Highland Park to ENH, effectively forced private payers to accept price increases that were significantly higher than the price increases of other comparable hospitals, or face the loss of all three hospitals from their networks. Such a loss would have a significant adverse impact on their ability to market their managed care products.

30. Following the merger, ENH raised prices more than the price increases implemented by other comparable hospitals. Private payers regarded the ENH price increases as unwarranted. ENH also required many private payers to agree to pay prices set at a discount off of ENH's list prices in lieu of predetermined per diem prices for each day of inpatient care, a feature of many of the hospitals' pre-merger contracts with their major payers. Any

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pricing system based on list prices makes hospital payments less predictable for private payers and facilitates the hospitals' ability to impose unilateral price increases (by raising list prices). ENH raised its list prices several times following the merger.

31. Following the merger, ENH proposed large price increases to its major private payers. All but one of these large customers accepted ENH's significant postmerger increases rather than try to sell a health plan without any of the three ENH hospitals. In each of the following cases in which it sought to raise prices, ENH also negotiated with the payer hospital and physician services as a package, requiring each payer to accept ENH's terms for the package or otherwise lose both contracts.

(a) United Healthcare of Illinois, Inc. ("United") is a commercial payer that conducts business in the state of Illinois. As a result of the merger, United faced significantly higher prices for inpatient care. In 2000, ENH raised United's (i) health maintenance organization ("HMO") rates by about 52% at the Evanston and Glenbrook hospitals and 38% at Highland Park and (ii) preferred-provider-organization ("PPO") rates by about 190% for the Evanston and Glenbrook hospitals and 20% for Highland Park as measured by United. As is typical for commercial payers, the vast majority of United's payments to ENH and other local hospitals are made at HMO or PPO rates. ENH also forced United to pay on the basis of discounts from list prices, which makes payments for hospital services less predictable and potentially even more costly.

(b) Private HealthCare Systems ("Private HealthCare") is a commercial payer that conducts business in the state of Illinois. As a result of the merger, Private HealthCare faced significantly higher prices for inpatient care. In 2000, ENH raised Private Healthcare's rates at the Evanston and Glenbrook Glenbrook hospitals by about 40% as measured by Private

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HealthCare. Evanston also forced Private HealthCare to pay for some services on the basis of discounts from list prices, which makes payments for hospital services less predictable and potentially even more costly.

(c) CIGNA Corporation (“CIGNA”) is a commercial payer that conducts business in the state of Illinois. As a result of the merger, CIGNA faced significantly higher prices for inpatient care. In 2000, ENH raised CIGNA’s (i) HMO rates by about 15-20% and (ii) PPO rates by about 30% as measured by CIGNA. Evanston also forced CIGNA to pay on the basis of discounts from list prices, which makes payments for hospital services less predictable and potentially even more costly.

(d) Aetna Inc. (“Aetna”) is a commercial payer that conducts business in the state of Illinois. As a result of the merger, Aetna faced significantly higher prices for inpatient care. In 2000, ENH raised Aetna’s rates by about 45-50% over three years or about 15% per year as measured by Aetna.

(e) Humana Inc. (“Humana”) is a commercial payer that conducts business in the state of Illinois. As a result of the merger, Humana faced significantly higher prices for inpatient care. In 2000, ENH raised Humana’s PPO rates by about 50-60% as measured by Humana.

(f) Preferred Plan, Inc. (“Preferred Plan”) is a commercial payer that conducts business in the state of Illinois. As a result of the merger, Preferred Plan faced significantly higher prices for inpatient care. In 2000, ENH raised Preferred Plan’s rates by about 24% as measured by Preferred Plan. ENH also forced Preferred Plan to pay on the basis of discounts from list prices, which makes payments for hospital services less predictable and potentially even more costly.

Complaint

(g) HFN, Inc. (“HFN”) is a commercial payer that conducts business in the state of Illinois. As a result of the merger, HFN faced significantly higher prices for inpatient care. In 2000, ENH raised HFN’s exclusive provider organization (“EPO”) rates by about 21% for Highland Park and 25% at Evanston and Glenbrook hospitals and raised HFN’s PPO rates by higher amounts as measured by HFN.

(h) Blue Cross is a commercial payer that conducts business in the state of Illinois, and the largest commercial payer in the Chicago area. Following the merger, ENH proposed a large price increase in both inpatient care and physician services to Blue Cross. Blue Cross challenged ENH’s physician pricing practices as illegal, after which ENH withdrew the proposed price increases to Blue Cross.

VIOLATION

32. The merger of ENH and Highland Park enabled ENH to raise its prices to private payers above the prices that the hospitals would have charged absent the merger. Consequently, the merger has substantially lessened competition in a line of commerce in a section of the country, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18.

**COUNT III: PRICE FIXING OF PHYSICIAN SERVICES IN
VIOLATION OF FTC ACT § 5**

33. The allegations of paragraphs 1 through 14, 26 and 31 are incorporated by reference as though fully set forth herein.

34. In many instances, ENH also followed a strategy of negotiating hospital services and physician services (through ENH Medical Group) as a package deal, requiring private payers to accept the terms offered for both hospital and physician services, or face termination of both.

Complaint

35. Faculty Practice Associates, which ENH controls, employs about 460 physicians. These salaried physicians have medical offices in several locations in Cook and Lake counties. For these salaried physicians, Faculty Practice Associates or ENH owns or rents office space for them, employs nurses and other staff that work at the offices, purchases computer technology and other office equipment, and purchases malpractice insurance. ENH Medical Group negotiates prices for the services performed by these salaried physicians. These salaried physicians provide services for a fee charged to commercial payers that ENH Medical Group collects.

36. ENH Medical Group also negotiates prices on behalf of about 450 non-salaried or independent physicians. ENH refers publicly to these physicians as affiliated physicians in contrast to the salaried physicians. These independent or affiliated physicians work at several dozen medical offices in Cook and Lake counties. The independent physicians rent their own office space, hire nurses and other staff, pay for their own computer technology and other office equipment, and purchase their malpractice insurance. The independent physicians provide services for a fee charged to commercial payers that they collect through their own office personnel or administrators.

37. Both the salaried physicians and independent physicians include specialists and primary care physicians that provide comparable services in the same geographic area. In the absence of the price fixing described herein, the salaried physicians and the independent physicians compete in the sale of physician services. This competition reduces the cost of physician services charged to commercial payers that offer health plans to employers and individuals. This competition also improves the quality of services.

38. The ENH Medical Group has negotiated and entered into commercial contracts that contain uniform price terms that cover the

Complaint

the services of both the salaried physicians and the independent physicians. Nearly all of the commercial contracts provide for reimbursement on the basis of fee-for-service, as opposed to capitation or other alternative reimbursement methods. For these commercial contracts, the salaried physicians and the independent physicians do not share expenses, revenues, or profits, or otherwise otherwise share any financial risk.

39. The salaried physicians and the independent physicians have not engaged in any meaningful efficiency-enhancing integration. They do not share information technology systems to enhance services. Nor do they comply or seek to comply with common performance standards or clinical protocols to enhance services.

40. About 300 of the 450 independent or affiliated physicians formerly contracted through the Highland Park IPA. Following the merger, the ENH Medical Group established prices for about 910 physicians – about 460 salaried physicians and 450 independent physicians, including about 300 formerly affiliated with the Highland Park IPA. Following the merger, the ENH Medical Group raised prices.

41. The prices charged for physician services are often set by reference to Medicare's Resource Based Relative Value System ("RBRVS"), a system used by the U.S. Centers for Medicare and Medicaid Services to determine the amount to pay for physician services to Medicare patients. The RBRVS approach provides a method to determine fees for specific services. Commercial payers often contract with individual physicians or physician groups at a price level specified as some percentage of the RBRVS fee for a particular year, such as 110% of RBRVS.

42. An alternative reimbursement method is for physicians to charge on the basis of capitation. Under capitation, the physician or

Complaint

or physician group charges a set per-member-per-month fee rather than separate fees for specific services.

43. In 2000, ENH Medical Group negotiated price increases for the salaried physicians and independent physicians. In some instances, ENH Medical Group converted capitated contracts to fee-for-service contracts with higher effective rates. In other instances, ENH Medical Group raised the amount of the fee-for-service reimbursement. The price increases negotiated and implemented in 2000 after the merger include the following:

(a) ENH Medical Group negotiated an increase in the price for Private HealthCare's PPO from 125% of Medicare RBRVS to 140%.

(b) ENH Medical Group negotiated an increase in the price for United's PPO from 125% of Medicare RBRVS to 140%, and for United's HMO from a capitated rate that was comparable to 110% of Medicare RBRVS to 125%.

(c) ENH Medical Group negotiated an increase in the price for Aetna's PPO from 110% of Medicare RBRVS to 140%.

(d) ENH Medical Group negotiated an increase in the price of CIGNA's PPO from 135% of Medicare RBRVS to 150%, and for CIGNA's HMO from 115% of Medicare RBRVS to 135%.

(e) ENH Medical Group negotiated an increase in the price for One Health's HMO from 125% of Medicare RBRVS to 140%, and for One Health's PPO from 130% of Medicare RBRVS to 152.5%.

44. By establishing these and other price increases on behalf of the salaried physicians and the independent physicians, ENH Medical Group engaged in illegal price fixing in restraint of trade.

Complaint

This conduct deprived commercial payers, employers, and individuals of the benefits of competition among physicians.

Complaint

VIOLATION

45. The contracting for physician services engaged in by ENH Medical Group on behalf of its independent physicians constitutes unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

NOTICE

Notice is hereby given to the respondents that the tenth day of May, 2004, at 10:00 a.m., or such later date as determined by an Administrative Law Judge of the Federal Trade Commission, is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Avenue, NW, Room 532, 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 and Clayton Acts 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 twentieth (20th) 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 the complaint, the answer shall consist of a statement that you admit 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

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basis on which the Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer, you you may, however, reserve the right to submit proposed findings and and conclusions under § 3.46 of the Commission's Rules of Practice Practice for Adjudicative Proceedings and the right to appeal the initial decision to the Commission under § 3.52 of said Rules.

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 shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the complaint and to enter an initial decision containing such findings, appropriate conclusions, and order.

The Administrative Law Judge will schedule an initial prehearing scheduling conference to be held not later than 14 days after the last answer is filed by any party named as a 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, NW, Room 532, Washington, D.C. 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 5 days of receiving a Respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in in any adjudicative proceedings in this matter that the merger of ENH and Highland Park, or any joint venture that combines them, challenged in this proceeding violates Section 7 of the Clayton Act, Act, as amended, the Commission may order such relief against

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respondents as is supported by the record and is necessary and appropriate, including, but not limited to:

1. Divestiture of Highland Park, and associated assets, in a manner that restores the hospital as a viable, independent competitor in the relevant market, with the ability to offer such services as Highland Park was offering and planning to offer prior to its acquisition by ENH.
2. A ban, for a period of time, on any transaction between ENH and the restored Highland Park that combines their hospitals or other health facilities in the relevant section of the country, except as may be approved by the Commission.
3. A requirement that, for a period of time, ENH provide prior notice to the Commission of acquisitions, mergers, consolidations, or any other combinations of its hospital or other health facilities in the relevant markets with other hospitals or health facilities 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 anti-competitive effects of the transaction or to restore Highland Park as a viable, independent competitor in the relevant market.

Should the Commission conclude from the record developed in any adjudicative proceedings in this matter that ENH Medical Group is in violation of Section 5 of the Federal Trade Commission Act, as alleged in the complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including, but not limited to, an order that ENH Medical Group shall:

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1. Cease and desist from fixing, raising, stabilizing, establishing, maintaining, adjusting, or tampering with any fee or aspect of the fee charged for any physician's service, where the physician is not employed by ENH Faculty Practice Associates, and such conduct is not ancillary to an integrated joint venture.
2. File periodic compliance reports with the Commission.
3. Take other appropriate measures of steps to correct or remedy, or prevent the recurrence of, the anti-competitive practices engaged in by ENH Medical Group.

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 tenth day of February, 2004.

By the Commission, Commissioner Harbour dissenting.

INITIAL DECISION

By Stephen J. McGuire, Chief Administrative Law Judge

I. INTRODUCTION**A. Overview and Summary of Decision**

In January 2000, Evanston Hospital ("Evanston") and Glenbrook Glenbrook Hospital ("Glenbrook") merged with Highland Park Hospital ("Highland Park") to form the Evanston Northwestern

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Healthcare Corporation (“ENH” or “Respondent”). Over four years later, on February 10, 2004, Complaint Counsel for the Federal Trade Commission (“FTC”) filed a Complaint challenging the merger under Section 7 of the Clayton Act, 15 U.S.C. § 18, asserting that the merger has substantially lessened competition.

This case presents a rare opportunity to examine “the actual effect of concentration on price in the hospital industry.” See *United States v. Rockford Memorial Corp.*, 898 F.2d 1278, 1280 (7th Cir. 1990). Since the enactment of the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. § 18a), most enforcement actions are initiated prior to the proposed merger. In those cases, courts must rely on predictions based on market concentration data. In this consummated merger case, however, there is significant post-acquisition evidence to evaluate in assessing whether the probable effect of the merger will be to “substantially lessen competition.”

This opinion follows the traditional Clayton 7 approach in assessing whether there is a reasonable probability that the merger is likely to result in anticompetitive effects in a relevant market. First, the relevant product market and geographic market are determined. Then, the Court analyzes whether anticompetitive effects are probable, using both market concentration statistics and post-acquisition evidence. Finally, Respondent’s procompetitive justifications and affirmative defense are assessed.

The relevant product market in this case is found to be general acute care inpatient services sold to managed care organizations, including primary, secondary, and tertiary inpatient services. The relevant geographic market is found to be the area encompassing the following seven hospitals: Evanston, Glenbrook, Highland Park, Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. See Attachment 1 (DX 8173, map). The post-merger market concentration level, as measured by the Herfindahl-Hirschman Index (“HHI”), is found to be 2739, with an

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an increase of 384. This corresponds to a “highly concentrated” market and the presumption that the merger is likely to “create or enhance market power.” Horizontal *Merger Guidelines*, § 1.51 (1992, as amended 1997), reprinted in 4 Trade Reg. Rep. (CCH) P 13,104.

Contemporaneous and post-acquisition evidence establishes that ENH exercised its enhanced post-merger market power to obtain price increases significantly above its premerger prices and substantially larger than price increases obtained by other comparison hospitals. As a result of the elimination of Highland Park as a competitor, Respondent was able to convert existing price methodologies to managed care organizations to much more favorable post-merger terms than either Evanston or Highland Park could have achieved alone. The evidence further shows that Respondent, in 2002 and 2003, continued to unilaterally raise rates in its chargemaster, which significantly increased the prices paid by managed care organizations for ENH services. The empirical evidence presented by Complaint Counsel’s expert ruled out explanations for the price increases other than market power.

Complaint Counsel’s expert compared price increases implemented by ENH post-merger to price increases implemented by other hospitals in her control groups and found that, across all managed care plans, ENH’s price increases exceeded the control groups by 11 to 18%, i.e., if other hospitals raised their prices by 10%, ENH raised its prices by 21 to 28%. Even under Respondent’s expert’s calculations, ENH’s post-merger price increases were 9 to 10% higher than price increases by hospitals in his control groups. This evidence confirms the predictive assessments made by the structural market analysis of market concentration.

The evidence presented by Respondent fails to rebut the government’s *prima facie* case. Upon review, the Court has

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determined that Respondent's learning about demand theory is flawed, is inconsistent with Respondent's contemporaneous actions, actions, and is based upon unreliable empirical analysis. In addition, addition, Respondent's few merger specific improvements to Highland Park do not constitute a sufficiently procompetitive justification to outweigh the competitive harm resulting from the merger. Thus, neither of Respondent's main defenses, the learning about demand theory, nor the quality of care improvements improvements argument, justify the substantial post-merger price increases to managed care organizations and, ultimately, consumers. Respondent's other defenses -- its nonprofit status, ease of entry, and that Highland Park was a failing firm -- and Respondent's affirmative defense -- that Evanston and Highland Park were already a single entity at the time of the merger -- are similarly unpersuasive. The only viable explanation for Respondent's anticompetitive prices is that the merger, through elimination of a competitor, enhanced ENH's market power.

Complaint Counsel proved that the challenged merger has substantially lessened competition in the product market of general acute inpatient services and in the geographic market of the seven hospitals described above. Therefore, Complaint Counsel has established a violation of Section 7 of the Clayton Act under Count I of the Complaint. Count II of the Complaint, an alternate pleading, is not dispositive and therefore dismissed as moot.

The appropriate remedy for the violation is full divestiture of Highland Park from ENH, which, with ancillary relief, is specified more fully in the attached Order. This is the most effective remedy to restore competition to that which would have existed without the merger and which is necessary and in the public interest to eliminate the ill effects of the acquisition offensive to the statute.

B. Summary of Complaint and Answer

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The Complaint in this case charges three counts. Count I alleges that the merger of ENH and Highland Park has substantially lessened competition in the alleged relevant product and geographic market, in violation of Section 7 of the Clayton Act. Complaint PP 16-17, 27. Count II also charges that the merger of ENH and Highland Park has substantially lessened competition, in violation of Section 7 of the Clayton Act, but does not allege a relevant product or geographic market. See Complaint PP 28-32 (the paragraphs alleging the relevant product and geographic markets in Count I, paragraphs 16-18, are not incorporated by reference into Count II). Complaint Counsel argues that Counts I and II are alternative approaches to establishing a violation of Section 7 of the Clayton Act. CCB at 51; Closing argument, Tr. 6546-47.

Count III of the Complaint, which includes all claims against ENH Medical Group, Inc., was resolved by a consent agreement with the Commission. The consent agreement was approved and ordered by the Commission on May 17, 2005.

Respondent filed an Answer to the Complaint on March 17, 2004; a First Amended Answer on July 12, 2004; and a Second Amended Answer on January 11, 2005 (“Answer”). In its Second Amended Answer, Respondent denied the material allegations of Counts I and II of the Complaint and asserted the following defenses: the Complaint fails to state a claim upon which relief can be granted; prior to the merger, Evanston and Highland Park were not separate persons as required for the application of Section 7 of the Clayton Act; the Complaint and the relief sought are not in the public interest; the merger yielded significant procompetitive efficiencies that outweigh any alleged anticompetitive effects; and the merger facilitated significant improvements in the quality of patient care throughout the ENH system that outweigh any alleged anticompetitive effects. Answer, p. 1-15, 20-21.

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C. Procedural Background

The final prehearing conference was held on February 8, 2005. Trial commenced on February 10, 2005 and continued for eight weeks. Over 1600 exhibits were admitted and forty-two witnesses testified in person. On May 20, 2005, the parties filed post hearing briefs, proposed findings of fact, and conclusions of law. On June 24, 2005, the parties filed responses in reply to the briefs and proposed findings of fact. Closing arguments were heard on July 7, 2005. The hearing record was closed pursuant to Commission Rule 3.44(c) by Order dated July 18, 2005.

By Orders dated February 9, 2005, April 6, 2005, June 8, 2005, August 8, 2005, and October 7, 2005, the Rule 3.51(a) deadline for filing the Initial Decision within one year of the Complaint was extended to December 12, 2005. This Initial Decision is filed within ninety days of the close of the record, pursuant to Commission Rule 3.51(a).

D. Evidence

This Initial Decision is based on the exhibits properly admitted admitted in evidence, the transcript of trial testimony, and the briefs, briefs, proposed findings of fact and conclusions of law, and replies replies thereto submitted by the parties. Citations to specific numbered findings of fact in this Initial Decision are designated by by "F."¹

¹ References to the record are abbreviated as follows:

- CX – Complaint Counsel Exhibit
- RX – Respondent's Exhibit
- JX – Joint Exhibit
- Tr. – Transcript of Testimony before the Administrative Law Judge
- Dep. – Transcript of Deposition
- CCFF – Complaint Counsel's Proposed Findings of Fact
- CCRFF – Complaint Counsel's Response to Respondents' Proposed Findings of Fact
- CCB – Complaint Counsel's Post Hearing Brief

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Under the Commission’s Rules of Practice, a party or a non-party may file a motion seeking *in camera* treatment for material, or portions thereof, offered into evidence. 16 C.F.R. § 3.45(b). The Administrative Law Judge may order that such material be placed *in camera* only after finding that its public disclosure will likely result in a clearly defined, serious injury to the entity requesting *in camera* treatment. 16 C.F.R. § 3.45(b). Pursuant to Commission Rule 3.45(b), several orders were issued granting *in camera* treatment to material that met the Commission’s strict standard. In addition, when the parties sought to elicit testimony at trial that revealed information that had been granted *in camera* treatment, the hearing went into an *in camera* session.

In instances where a document or trial testimony had been given *in camera* treatment, but the portion of the material cited to in this Initial Decision does not 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”). *in camera* material that is used in this Initial Decision is indicated in bold font and braces (“{ }”) in the *in camera* version; it is redacted from the public version of the Initial Decision, in accordance with 16 C.F.R. § 3.45(f).

This Initial Decision is based on a consideration of the whole record relevant to the issues and addresses the material issues of fact and law. All findings of fact in this Initial Decision are

CCRB – Complaint Counsel’s Post Hearing Reply Brief
RFF – Respondent’s Proposed Findings of Fact
RRFF – Respondent’s Response to Complaint Counsel’s Proposed Findings of Fact
RB – Respondent’s Post Hearing Brief
RRB – Respondent’s Post Hearing Reply Brief

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supported by reliable, probative, and substantial evidence, as required by 16 C.F.R. § 3.51(c)(1) and *In re Chicago Bridge & Iron Iron Co.*, 2005 WL 120878, Dkt. No. 9300, at 2 n.4 (Op. of FTC Comm’n January 6, 2005) (also available at <http://www.ftc.gov/os/adjpro/d9300/index.htm>). 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.*, 102 F.T.C. 1362, 1670 (1983). Further, administrative 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). Proposed findings of fact 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.

II. FINDINGS OF FACT

A. The Merger

1. The Merging Parties

a. Evanston Northwestern Healthcare

1. Evanston Northwestern Healthcare (“ENH”) is a nonprofit corporation with its office and principal place of business located at 1301 Central Street, Evanston, Illinois 60201. Complaint P 4; Answer P 4.

2. Prior to merging with Lakeland Health Services in 2000, Evanston was comprised of Evanston Hospital, Glenbrook Hospital, ENH Medical Group, ENH Research Institute, and ENH Homecare Services. CX 84 at 6.

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3. Evanston Hospital has been affiliated with the Northwestern Feinberg School of Medicine (“Northwestern Medical School”) since at least 1930. Neaman, Tr. 1282. Evanston strengthened its academic relationship with Northwestern Medical School between 1992 and 1996. RX 584 at ENH JH 2951-52; RX 132 at ENH JH 275-77.

4. Mark Neaman, who joined Evanston in 1973, has served as its Chief Executive Officer (“CEO”) since 1992. Neaman, Tr. 1278. Jeffrey Hillebrand, who joined Evanston on a full time basis in 1979, has served as its Chief Operating Officer (“COO”) since 1998. Hillebrand, Tr. 1826-27, 2009.

(1) Evanston Hospital

5. Evanston Hospital has more than 400 beds and is located in Evanston, Illinois. Neaman, Tr. 1291.

6. Evanston had .34 residents per bed in 1999. RX 1912 at 60.

7. Evanston offered obstetrical services, pediatric services, a skilled nursing facility, psychiatric care, neurosurgery, radiation therapy, cardiology services, orthopedics, trauma centers, and the Kellogg Cancer Care Center. CX 84 at 8, 15; CX 681 at 2; Newton, Tr. 299; Spaeth, Tr. 2083-84; Neaman, Tr. 1292.

8. Evanston provides a wide array of inpatient and outpatient services, from basic hospital services (such as obstetrics) to more intensive services (such as cardio-angiogenesis). Rosengart, Tr. 4496; Neaman, Tr. 1291.

(2) Glenbrook Hospital

9. Glenbrook Hospital “Glenbrook”), located in Glenview, Illinois, is a community hospital that was developed, built, and

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opened by Evanston in 1977. CX 84 at 7; Neaman, Tr. 1286, 1292; 1292; Hillebrand, Tr. 1827.

10. Glenbrook is located 12.6 miles and 26 minutes west of Evanston. RX 1912 at 20-21, *in camera*.

11. Glenbrook has approximately 125 to 150 beds. Neaman, Tr. 1292; CX 681 at 1-2.

12. Glenbrook provides inpatient and outpatient services, but it does not provide obstetrics services. Neaman, Tr. 1292.

13. Glenbrook has a Kellogg Cancer Care Center, center of excellence in orthopedics, and does a significant amount of work in neurology, particularly movement disorders. Neaman, Tr. 1292; CX 681 at 2.

(3) ENH Research Institute

14. The ENH Research Institute, founded in 1996, performs translational clinical research, meaning research that is taken to the bedside. Neaman, Tr. 1289-90. The ENH Research Institute's translational research is directly related to ENH's nucleus of clinical activities, such as oncology, cardiology, imaging, and patient outcomes. Hillebrand, Tr. 2007.

15. The ENH Research Institute receives funding from the federal government, including the National Institutes for Health ("NIH"), the National Cancer Institute, and the Department of Defense. Hillebrand, Tr. 2007-08; Neaman, Tr. 1290.

16. In 2004, NIH restructured its clinical research initiatives, including the creation of the Patient Reported Outcome Measurement Information System ("PROMIS"), which is a top NIH priority for measuring the quality of healthcare. Hillebrand, Tr. 2008. In 2004, and as part of the PROMIS initiative, the ENH

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Research Institute was named the National Coordinating Center for for NIH's patient outcome studies. Hillebrand, Tr. 2009.

17. ENH has over \$100 million in NIH grants. Neaman, Tr. 1290. In terms of NIH funding, ENH ranks twelfth nationally and first in Illinois. Neaman, Tr. 1290.

b. Lakeland Health Services, Inc.

18. Lakeland Health Services, Inc. ("Lakeland Health"), the parent company of Highland Park Hospital ("Highland Park") prior to the merger, was a nonprofit Illinois corporation with its principal place of business located at 718 Glenview Avenue, Highland Park, Illinois 60035. CX 541 at 1; Newton, Tr. 472; RX 563 at ENH TH 1572.

19. Before merging with Evanston, Lakeland Health Services was comprised of Highland Park Hospital, Highland Park Hospital Foundation, and the for profit Lakeland Health Ventures, Inc. CX 84 at 11. Lakeland Health Services was incorporated in 1982 as a holding company. CX 84 at 12; RX 563 at ENH TH 1572; RX 218 at ENHL TH 229-30.

(1) Highland Park Hospital

20. Highland Park Hospital ("Highland Park") is located at 718 Glenview Avenue, Highland Park, Illinois 60035, and first opened in 1918. CX 1874 at 1; CX 84 at 12; RX 123.

21. Highland Park is located 13.7 miles and 27 minutes north of Evanston, along Lake Michigan. RX 1912 at 20-21, *in camera*; Belsky, Tr. 4889.

22. Highland Park has approximately 150 to 200 beds. Neaman, Tr. 1292; CX 84 at 11, 16, In 1999, Highland Park had no residents. RX 1912 at 60.

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23. Highland Park had a medical staff of 562 physicians in 1999. CX 84 at 1, 12.

24. Prior to the merger, Highland Park offered obstetrical services, including: a level II perinatal center; pediatric services; diagnostic services; a skilled nursing facility; a fertility center; psychiatric care; neurosurgery; radiation therapy; cardiology services, including an adult cardiac catheterization lab; an oncology program; and a level II trauma center. CX 84 at 13, 15; CX 699 at 24; Newton, Tr. 299; Spaeth, Tr. 2083-88.

25. Ronald Spaeth was Highland Park's president and CEO from 1983 up until the merger. Spaeth, Tr. 2235.

(2) Highland Park Hospital Foundation

26. The Highland Park Hospital Foundation was Highland Park's fund-raising arm before the merger. Styer, Tr. 4954. The Highland Park Foundation was tasked with soliciting funds to support Highland Park from individuals and corporations in the general Highland Park community. Styer, Tr. 4954-55, 5001. The Highland Park Foundation was dissolved immediately before, and in anticipation of, the merger. Styer, Tr. 4953.

(3) Other Ventures

27. Lakeland Health Ventures, Inc. were for-profit entities owned by Lakeland Health Services. These entities included: Lakeland Primary Care Associates, physician practice management services, real estate ventures, and joint ventures, including a fitness center and a mail order pharmacy. CX 681 at 3; RX 563 at ENH TH 1572.

28. Highland Park also owned 50% of Highland Park Healthcare, Healthcare, Inc., a physician-hospital organization "PHO"). RX 563 563 at ENH TH 1572. The remaining 50% was owned by the

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Highland Park Independent Physicians Association. Chan, Tr. 789, 789, *in camera*.

2. Premerger Background**a. NH North**

29. As early as 1994, Neaman and Spaeth, the CEOs of Evanston and Highland Park, respectively, shared the view that hospitals should “stand united” in order to get “better pricing” and “leverage.” CX 1802 at 2-3.

30. Evanston, Highland Park, and Northwest Community Hospital discussed a collaboration as far back as 1996. CX 6305 at 7 (Stearns, Dep.); Neaman, Tr. 1017-18. The entity that would have been created as the result of the proposed merger of Highland Park, Evanston, and Northwest Community Would have been called NH North. Neaman, Tr. 1017-18.

31. One principle of NH North was to be “an entity that differentiates its product, its brand and is indispensable to the marketplace.” CX 395 at 2. The idea behind this branding strategy was to use name-brand to differentiate NH North in such a way that it would be very distinctive and very desirable in the minds of customers. Neaman, Tr. 1363-64.

32. An August 1996 planning document for NH North prepared prepared by Evanston’s CEO, Neaman and Evanston’s COO, Hillebrand explained that for NH North to achieve “market influence” and “indispensability,” it had to achieve “differentiation” “differentiation” and “cost leadership.” CX 394 at 13; Neaman, Tr. 1018-19; Hillebrand, Tr. 1790-91. According to the planning document, “differentiation” was to be achieved through “superior outcomes,” “brand equity,” and “best physicians.” CX 394 at 13; Hillebrand, Tr. 2020-21. “Cost leadership” was to be achieved through reducing “cost per unit of care,” “develop[ing] pathways,”

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pathways,” and “hospital & physicians common incentives.” CX 394 at 13; Hillebrand, Tr. 2020-21.

33. Bain & Company (“Bain”), a consulting firm to Evanston, was involved in strategizing for NH North. Neaman, Tr. 1024. Bain listed two “key tactics” that should be used by NH North to “gain incremental market share.” RX 477 at ENH JH 349. The two “key tactics” were: (1) “improved/coordinated physician recruitment and development”; and (2) “developing and leveraging brand name.” RX 477 at ENH JH 349.

34. The three-way discussions between Highland Park, Evanston, and Northwest Community with regard to the creation of NH North broke down in 1997 as the result of differences over the proposed merged entity’s organization (such as the composition of the board), personality conflicts, and a lack of interest on the part of Northwest Community. CX 6305 at 7-9 (Stearns, Dep.); Neaman, Tr. 1035; Hillebrand, Tr. 1791-92.

b. Northwestern Healthcare Network

35. The Northwestern Healthcare Network (“Network”) was a system of Chicago area hospitals formed pursuant to an affiliation agreement dated October 23, 1989. CX 6306 at 2 (Mecklenburg, Dep.); RX 22 at NHN 322.

36. The earliest formal discussions concerning the formation of the Network were among a group of hospitals already related to one another through a common affiliation with Northwestern University Medical School. These hospitals included Evanston, the Rehabilitation Institute of Chicago, and Children’s Memorial Medical Center (“Children’s Memorial”). CX 6306 at 2 (Mecklenburg, Dep.).

37. The founding members of the Network were Evanston, Lakeland Health (Highland Park’s parent), Northwestern Memorial,

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Memorial, and Children's Memorial. Neaman, Tr. 963; CX 1780 at 1.

38. Pursuant to the affiliation agreement, the Network became the "sole member" of the member hospitals, in accordance with the Illinois General Not For Profit Corporation Act of 1986, as amended. RX 22 at NHN 339, 372.

39. Under the Network, the member hospitals continued to operate as independent entities, operating for their own self-interest. Newton, Tr. 307, 311.

(1) Purposes of the Network

40. The Network hospitals came together to respond to anticipated marketplace behavior in terms of managed care contracting and in terms of exclusive contracting with certain managed care organizations. RX 70 at NHN 873; CX 6306 at 4 (Mecklenburg, Dep.).

41. In particular, the Network was formed, in part, with an eye toward handling the anticipated trend towards capitated contracts, pursuant to which a managed care organization paid a group of providers a fixed amount of dollars per member per month, thus placing all financial risk on that group of providers. Neaman, Tr. 1360.

42. The Network negotiated contracts for the provision of hospital services by its member hospitals with the International Brotherhood of Teamsters, Health Network, Great West, and MultiPlan. CX 6307 at 18 (Schelling, Dep.). The Network negotiated a capitated home health, services agreement with Humana and entered into an agreement with North American Medical Management. CX 6307 at 5-6 (Schelling, Dep.).

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43. While capitated contracts did come to Chicago in the mid-1990's, they never became the major factor many had predicted. Neaman, Tr. 1360-61. Thus, one of the driving forces behind the formation of the Network did not materialize in the Chicago area marketplace. RX 584 at ENH JH 2951.

44. Evanston participated in the Network based on its belief that the then-existing Rush, Humana (at that time, Humana owned several hospitals in the Chicago area, including the former Michael Reese Hospital), and Evangelical (a precursor to the Advocate system) systems of ownership of several hospitals in the Chicago area would be the operating model for the future. RX 357 at ENH JH 10385.

45. Highland Park participated in the Network to enhance its quality of care and its perception in the marketplace. Spaeth, Tr. 2194.

(2) Structure of the Network

46. The Network Affiliation Agreement among the four hospital members created a council of governors, consisting of seven representatives named by each of the member hospitals. RX 22 at NHN 340; CX 1780 at 12. The Network Affiliation Agreement gave the council of governors control over the Network, including, inter alia, the authority to appoint and to remove members of the board of directors of the Network. CX 1780 at 14.

47. In addition, the Network had its own executive and its own board of directors. CX 1780 at 12; CX 6306 at 5-6 (Mecklenburg, Dep.); Newton, Tr. 457.

(a) Separate Administrations

48. Under the Network Affiliation Agreement, the governing boards of each hospital retained "local autonomy and control," of their own hospitals. CX 1777 at 50, 52, 68.

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49. Each hospital member developed its own budget and operated independently. CX 6307 at 12-13 (Schelling, Dep.). Under the Network Affiliation Agreement, the Network hospitals were autonomous in their financial operations. CX 1777 at 50; CX 6307 at 12-13 (Schelling, Dep.).

50. Under the Network Affiliation Agreement, each institution continued to select, appoint, and employ its own chief executive officer (“CEO”). The duties, functions, and obligations continued to be determined by each institution. CX 1780 at 25.

51. Hospital members did not share day-to-day operational functions. Newton, Tr. 312.

52. The Network could not exercise its discretion to terminate the employment of the administrators of the individual member hospitals, except for limited, specifically defined reasons. CX 1831 at 13.

53. Under the Network Affiliation Agreement, a member of the Network could petition to withdraw from the Network if the Network attempted to implement network-wide managed care agreements that substantially favored one member hospital to the detriment of the withdrawing hospital. CX 1831 at 9-11.

54. Under the Network Affiliation Agreement, a member of the Network could petition to withdraw from the Network if the Network failed to exercise reasonable efforts to support the academic affiliation of that hospital. CX 1831 at 10.

(b) Separate Staffs

55. Each hospital in the Network maintained its own medical staff. Hillebrand, Tr. 1786; Newton, Tr. 312.

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56. Each hospital in the Network was responsible for the quality of care at its hospital. Newton, Tr. 312.

57. Under the Network Affiliation Agreement, each member of the Network retained the exclusive authority over granting medical staff privileges at its hospital. CX 1777 at 72.

58. Under the Network Affiliation Agreement, a member of the Network could petition to withdraw from the Network if the Network attempted to require members of that hospital's medical staff to become members or employees of a network-wide organization. CX 1831 at 10.

59. Under the Network Affiliation Agreement, the medical staff of each hospital remained autonomous. CX 1777 at 49-50, 52.

(c) Separate Services and Operations

60. Under the Network Affiliation Agreement, each institution retained autonomy and control over the local-based decisions related to the delivery of health care services. CX 1777 at 52.

61. Each member hospital of the Network developed its own hospital program expansion plans. CX 6307 at 12-13 (Schelling, Dep.).

62. Under the Network Affiliation Agreement, a member of the Network could petition to withdraw from the Network if the Network attempted to implement program expansions or consolidations that substantially favored one member hospital to the detriment of the withdrawing hospital. CX 1831 at 9-10.

63. Each hospital member of the Network maintained its own self-funded health insurance programs for its employees. CX 6307 at 22 (Schelling, Dep.).

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64. Each hospital member of the Network maintained its own structure and staff for managed care contracting. Newton, Tr. 312.

65. Each hospital member of the Network retained the authority to enter into a contract or to refuse to enter into a contract with each individual managed care organization. The Network did not have the authority to enter into a contract binding on the individual member hospitals. CX 6307 at 18, 20-21 (Schelling, Dep.).

66. The hospitals that were members of the Network continued to compete with each other, unilaterally negotiating contracts with managed care companies, “‘slicing’ each other up in the market,” and “undercutting each other.” CX 1768 at 3.

(d) Financial Independence

67. Under the Network Affiliation Agreement, the network hospitals were autonomous in their financial operations. CX 1777 at 50; *see* CX 6307 at 12-13 (Schelling, Dep.).

68. Members of the Network only shared the cost of running the Network. There was no combined profit and loss or profit-sharing. Members’ balance sheets were separate. Newton, Tr. 311; Neaman, Tr. 973.

69. Member hospitals were not responsible for any debts incurred by other members of the Network. CX 6304 at 4 (Livingston, Dep.) (Evanston); CX 6306 at 5 (Mecklenburg, Dep.) (Northwestern Memorial Healthcare).

70. The Network Affiliation Agreement restricted the authority of the Network to transfer assets of any individual member hospital. CX 1777 at 62.

71. Under the Network Affiliation Agreement, a member of the the Network could petition to withdraw from the Network if the

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Network attempted to impose certain obligations to transfer assets to to another member of the Network. CX 1831 at 9.

(3) Dissolution of the Network

72. By 1998, the Network had evolved into a “trade association.” Neaman, Tr. 1008. As a trade association, the Network consisted of a general grouping of hospitals designed to support the general well-being of the association. Neaman, Tr. 1008-09.

73. The Network had limited success negotiating contracts with managed care organizations, in part, because it could not bring together the members for contract negotiations. Neaman, Tr. 965-66. Some members were not convinced the Network could get better terms from managed care organizations and, instead, negotiated independently. Neaman, Tr. 966.

74. The cost of running the Network outweighed the value received from the Network, and some questioned whether the Network could generate sufficient value. CX 6306 at 12 (Mecklenburg, Dep.).

75. All members of the Network, including Evanston and Lakeland Health, authorized the dissolution of the network on October 26, 1999. CX 1833 at 2; Neaman, Tr. 1017; CX 872 at 7; RX 592A at ENH RS 880.

76. The member hospitals voted to dissolve the Network rather than submit themselves to the “full control” of the Network. CX 2231 at 4; CX 872 at 7; CX 1833 at 2; Neaman, Tr. 1016-17; RX 592A at ENH RS 880; CX 6306 at 2 (Mecklenburg, Dep.); CX 6305 at 6-7 (Stearns Dep.).

77. The articles of dissolution were adopted by the Network on on December 22, 1999. CX 1833 at 2. The dissolution agreement went into effect on January 2, 2000. Neaman, Tr. 1016; CX 5 at 4.

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The articles of dissolution were filed on January 3, 2000. CX 1833 at 1-2.

3. Merger Agreement

78. The merger discussions that resulted in the merger between Evanston and Highland Park started in late 1998 or early 1999. CX 1 at 2; CX 2 at 7; CX 1879.

79. Neaman, Evanston's CEO, led the merger discussions from Evanston's side, while Spaeth, Highland Park's CEO, led Highland Park's efforts. Neaman, Tr. 1320; Spaeth, Tr. 2283. Neaman had overall responsibility for the merger and the subsequent merger integration. Neaman, Tr. 955.

80. In April 1999, Evanston and Highland Park signed an agreement to develop a cardiac surgery program at Highland Park. Rosengart, Tr. 4527-30; CX 2094 at 1, 6. In November 1999, the state approved a certificate of need ("CON") for an open heart surgery program at Evanston and Highland Park. Newton, Tr. 423.

81. The merging parties, including Evanston Northwestern Healthcare, Lakeland Health, and Highland Park, signed a letter of intent to merge effective July 1, 1999. Neaman, Tr. 1328; RX 567 at ENH MN 1365, 1390.

82. Simultaneous with the execution of the letter of intent, Evanston and Highland Park sent a press release to area employers, elected officials, managed care companies, and the press describing the merger. RX 563 at ENH TH 1568-76; Hillebrand, Tr. 1857-58; RX 564.

83. On October 29, 1999, the parties entered into an Agreement and Plan of Merger. RX 651. The effective date of the merger was January 1, 2000. RX 651 at ENH MN 1517.

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84. In the merger agreement, the parties agreed that Lakeland Health and Highland Park would be merged into Evanston Northwestern Healthcare and that Lakeland Health and Highland Park would no longer exist as separate corporations. CX 501 at 17.

85. The merger was consummated on January 1, 2000. CX 501 at 17.

86. ENH subsequently shut down most of the premerger joint ventures operated by Lakeland Health Ventures. Newton, Tr. 449.

4. Post-Merger ENH

a. ENH Hospitals

87. Since the merger, the nonprofit ENH healthcare delivery system consists of, among other things, the three hospitals (Evanston, Highland Park, and Glenbrook), a physician multispecialty faculty group practice, a research enterprise, and a charitable foundation. Neaman, Tr. 1281-83.

88. All three ENH hospitals operate as though they are a single hospital entity. Hillebrand, Tr. 1839-42. ENH has one Medicare identification number for all three hospitals. Hillebrand, Tr. 1840-41.

89. ENH consolidated all corporate activities at the Evanston campus and eliminated all corporate functions at Highland Park -- including human resources, purchasing, payor contracting, the business office, and information systems. Hillebrand, Tr. 1839-40; Neaman, Tr. 1345-46.

90. ENH instituted one billing system and one business office. Hillebrand, Tr. 1839-40. For example, ENH implemented a coordinated registration, scheduling, and charging system throughout its three hospitals. Hillebrand, Tr. 1840.

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91. After the merger, Highland Park physicians became part of the medical staff of Evanston and Glenbrook. If a physician had clinical privileges with ENH after the merger, the clinical privileges were good at any of the three hospital sites. RX 518 at ENH GW 2082; Hillebrand, Tr. 1840-41.

92. There are no other hospitals located between Highland Park, Glenbrook, and Evanston. Ballengee, Tr. 167-68; *see* Attachment 1 (DX 8173 (map)).

93. The three ENH hospitals form a triangle along Chicago's north shore. Newton, Tr. 351-52; *see* Attachment 1 (DX 8173 (map)).

94. The driving time from Evanston to Highland Park, or vice versa, is 27 minutes, and the distance is approximately 14 miles. RX 1912 at 20-21, *in camera*; Spaeth, Tr. 2157.

b. Healthcare Foundation of Highland Park

95. As a result of the merger, Evanston and Highland Park also created the Healthcare Foundation of Highland Park on January 1, 2000. Styer, Tr. 4951, 4971; Belsky, Tr. 4894; Spaeth, Tr. 2281. Evanston and the Highland Park Foundation signed the agreement creating the Healthcare Foundation of Highland Park in December 1999. RX 2037; Styer, Tr. 4977-78.

96. The establishment of a separate, post-merger foundation to serve Highland Park was designed to compensate the Highland Park community for the loss of control when Highland Park merged with Evanston. Kaufman, Tr. 5855-56.

97. The Foundation Agreement establishing the Healthcare Foundation of Highland Park describes the Foundation's mission to to support Highland Park and healthcare in the general Highland

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Park community. RX 2037 at HFHP 1356; Styer, Tr. 4951, 4979; Neaman, Tr. 1373.

98. Spaeth (President and CEO of Highland Park before the merger) has been the president of the ENH Foundation since February 2005. Spaeth, Tr. 2236; Neaman, Tr. 1326.

99. As the head of the ENH Foundation, Spaeth is responsible for growing “friends and funds” from ENH’s communities and to ensure that ENH has the support from these communities for the various healthcare programs that ENH provides. Spaeth, Tr. 2237; Neaman, Tr. 1327.

c. ENH Faculty Practice Associates

100. ENH Faculty Practice Associates is comprised of about 500 employed primary and specialty care physicians. Neaman, Tr. 1287-88.

101. The ENH Faculty Practice Associates does not include the approximately 1200 non-employed, private practice physicians who have admitting privileges at the three ENH hospitals. Neaman, Tr. 1282.

B. The Health Care Industry**1. Managed Care**

102. The competitive dynamics of healthcare markets are distinguishable from other markets in the United States economy. Haas-Wilson, Tr. 2453. This is in part because hospital services are differentiated products. Haas-Wilson, Tr. 2492; Baker, Tr. 4763; Noether, Tr. 5901.

103. “In the context of a differentiated product, it’s difficult to draw a bright line that hospitals inside the bright line are all competitors to each other, and then as soon as you cross that line, there’s no competitive pressure that’s exerted.” Noether, Tr. 5931.

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104. In addition, in the healthcare market, direct price competition for patients is often attenuated: patients generally pay only a portion of their bill and thus do not react to the entire amount of any change in price made by a hospital. Haas-Wilson, Tr. 2464.

105. There are four different institutional relationships relevant to understanding the competitive dynamics of hospital services. These institutional relationships are between: (1) hospitals and managed care organizations; (2) managed care organizations and employers; (3) employers and employees; and (4) patients and hospitals. Haas-Wilson, Tr. 2456, 2460-64 (discussing DX 7026).

a. Hospital – Managed Care Organization

106. The first institutional relationship related to competition for hospital services is the institutional relationship between hospitals and managed care organizations. This relationship is referred to as first stage competition in the economics literature. Haas-Wilson, Tr. 2456.

107. The first institutional relationship between hospitals and managed care organizations is particularly important because it is through this relationship that hospital prices are determined. Haas-Wilson, Tr. 2456. Hospitals sell their services to managed care organizations, and the managed care organizations are the consumer in this first stage competition. Haas-Wilson, Tr. 2456-57; Noether, Tr. 5906.

108. The managed care organization puts together its network of health care providers by choosing which hospitals will be included in its different plans' networks, as well as which physician organizations and which other ancillary healthcare

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providers will be included in the hospital networks that are offered offered as part of the health plan. Haas-Wilson, Tr. 2456-57.

109. Hospitals compete to be on the hospital network of the health plans offered by managed care organizations. Haas-Wilson, Tr. 2456-57. Managed care organizations build hospital networks to compete effectively with other managed care organizations for employer health plan contracts. Haas-Wilson, Tr. 2456-57.

110. The “customer” in the sale of inpatient hospital services is the managed care organization (as opposed to the individual patient). Noether, Tr. 5924-25; Haas-Wilson, Tr. 2456-57.

b. Managed Care Organization – Employer

111. The second institutional relationship related to competition for hospital services is the institutional relationship between the managed care organizations and employers. Health plans sell their products, such as HMO and PPO products, to prospective buyers or employers. Haas-Wilson, Tr. 2460-61.

112. In the employment-based healthcare insurance system in the United States, the employer selects which products of managed care organizations to offer as a fringe benefit to employees. Haas-Wilson, Tr. 2460-61.

113. Employers want to limit the amount of money that they spend on employee health benefits, and, as a result, price competition among managed care organizations is important. Haas-Wilson, Tr. 2461. Therefore, managed care organizations are interested in obtaining the lowest rates possible from the providers that they include in their networks, and this fosters price competition among hospitals and with other providers. Haas-Wilson, Tr. 2457-58.

114. Viewed from the standpoint of this second institutional relationship, managed care organizations compete with each other to

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to offer hospital networks that are both more attractive to employees and that have a low “premium” or price. Haas-Wilson, Tr. 2461. To be attractive to employers, managed care organizations must provide adequate networks that span the range of of basic and specialty services that employers demand, have good quality reputations, and are geographically convenient to employees and their families. Noether, Tr. 5936-37, 5944-45.

115. Consumers prefer a broad choice of hospitals in a hospital network. Haas-Wilson, Tr. 2461.

116. All health plan products have financial incentives to use providers who participate in the plan, although they vary in how “harsh” those incentives are. Haas-Wilson, Tr. 2461-62.

117. Managed care organizations compete on many factors, but the two most important factors are the attractiveness of the network and the price. Haas-Wilson, Tr. 2461.

118. Managed care organizations “are in the business of competing in part based on the provider networks that they put together.” Noether, Tr. 5936. The “managed care organization, to be able to compete, has to have a network that is attractive to enrollees who are the ultimate patients.” Noether, Tr. 5948.

c. Employer – Employee

119. The third institutional relationship related to competition for hospital services is the institutional relationship between employers and their employees. Employers who choose to offer health insurance to their employees are offering this health insurance coverage as a form of compensation to their employees. Nevertheless, the employee still bears costs of the health insurance because economic theory shows that the cost of that insurance is “shifted back” to the employee in the form of lower wages. Haas-Wilson, Tr. 2463.

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120. Managed care organizations construct hospital networks to create plans that are attractive to employers. Elzinga, Tr. 2407. The employers, in turn, are driven to provide a plan that is attractive to their employees, because employees may consider health care benefits in deciding where to accept employment. Elzinga, Tr. 2407. Therefore, managed care organizations must take patient preferences into consideration in constructing their hospital networks. Elzinga, Tr. 2407-08; Haas-Wilson, Tr. 2803, *in camera*; F. 252-55.

121. From the managed care organization's perspective, the criteria for placing and retaining a hospital in a network include price, reputation, services offered, and location. Mendonsa, Tr. 485 (discussing importance of location); Neary, Tr. 587 (discussing importance of competitive prices); Holt-Darcy, Tr. 1421 (discussing importance of licensing and accreditation); Dorsey, Tr. 1451 (discussing importance of offering appropriate level of care and services).

d. Patient – Hospital

122. The fourth institutional relationship related to competition for hospital services is the institutional relationship between patients and hospitals. When an employee or family member covered under an employer-based health insurance plan needs hospitalization, that patient will, together with his or her physician, select the hospital from which to obtain care. Frequently, the employee, because of the financial incentive offered by the health plan, will choose a hospital in the network. Haas-Wilson, Tr. 2463-64 (discussing DX 7026).

123. Hospitals compete, although not on price, to attract patients patients who are covered by the managed care organizations with which the hospital has contracts. Haas-Wilson, Tr. 2464. This competition for patients after the hospital has entered into contracts

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contracts with managed care organizations is called “second stage competition.” Haas-Wilson, Tr. 2465.

124. To attract patients, hospitals compete, in part, on the quality of care delivered. Noether, Tr. 6011 (“Patients are made better off when quality is improved, and they certainly use quality to the extent that they can evaluate it as one of the dimensions by which they choose hospitals.”).

125. The four institutional relationships related to competition for hospital services have changed over time as a result of the increasing prevalence of managed care. Prior to managed care, most people were covered by “indemnity-based” insurance. Under indemnity-based insurance, discussed more below, these four different institutional relationships would not have existed as is the case today under managed care competition. Haas-Wilson, Tr. 2463-65.

2. Government Insured and Uninsured

126. In the United States, the majority of people with private health insurance have their health insurance purchased through their employer. However, not everyone is covered by employer-based healthcare insurance. As discussed below, some people have government insurance, while other people are uninsured. Haas-Wilson, Tr. 2454.

a. Government Insured

127. Close to half of ENH’s hospital services are paid by the federal government. Neaman, Tr. 1312. The rates and schedules at which hospitals are reimbursed by the government for providing goods and services to individuals covered by Medicare and Medicaid are publicly available and non-negotiable. Neaman, Tr. 1312, 1317-18; Hillebrand, Tr. 1721.

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128. The prices in public health insurance programs are not determined by competitive market forces or negotiation, but rather are set unilaterally by the government. Haas-Wilson, Tr. 2455; Neaman, Tr. 1317-18.

129. The Medicare program “is a federal health insurance program that provides health insurance for the elderly and those individuals suffering from ... kidney failure and needing renal dialysis.” Haas-Wilson, Tr. 2454.

130. The Medicaid program is “a joint federal/state program” under which “individuals of low income receive health insurance coverage.” Haas-Wilson, Tr. 2454.

131. The federal insurance programs pay a case rate on the basis of the Diagnosis Related Group (“DRG”), which is a “grouping of inpatients into hundreds of separate categories based on their diagnoses and the procedures they undergo while hospitalized.” JX 8 at 5.

132. The DRG reimbursement is “a method of payment in which the reimbursement for inpatient hospital services is set based on the DRG into which a patient is classified. As a general rule, the amount of payment will not vary if the hospital renders significantly greater or less services in treating the patient than is the estimated average, or if the hospital incurs costs that are greater or less than the typical cost incurred by hospitals.” JX 8 at 5.

133. According to a 1999 document, 45% of Highland Park’s revenue came from managed care, 41% from Medicare, 2% from Medicaid, and 12% from other sources. CX 84 at 13. “[E]ssentially, the major payor mix was commercial and Medicare.” Newton, Tr. 301.

134. According to a 1999 document, 51% of Evanston’s revenue came from managed care, 34% from Medicare, 3% from Medicaid, and 12% from other sources. CX 84 at 8.

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135. At the start of trial in February 2005, nearly 50% of ENH's revenue came from government sources such as Medicare and Medicaid. Neaman, Tr. 1312.

b. Uninsured

136. People who do not have health insurance, either through the public sector or commercial plans, are referred to as "uninsured." Haas-Wilson, Tr. 2454.

137. After Medicare, Medicaid, and the top health plans, there remains for ENH approximately ten percent of gross revenues that fall into a separate category. Neaman, Tr. 1312. Most of this ten percent increment is charity care, although there are a small number of self pay patients in that mix as well. Neaman, Tr. 1312; Newton, Tr. 301.

138. Self pay patients are charged for services based on the hospital's chargemaster, which are essentially list prices. Porn, Tr. 5685; *see* F. 174-75.

3. Types Of Managed Care Plans

139. The purpose of a network is to provide employers and their employees with access to the facilities they want and a discount for using those hospitals. Mendonsa, Tr. 485.

140. Managed care plans generally fall within the broad HMO, POS, and PPO categories. "Nevertheless, the different types of managed care plans are difficult to distinguish because, over time, the managed care organizations have modified each type of plan to incorporate different elements of the other plans that consumers demand." JX 8 at 7.

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a. HMO

141. A Health Maintenance Organization (“HMO”) product provides prepaid health insurance coverage to members through a network of physicians, hospitals, and other health care providers that contract with the HMO to furnish such services. RX 1743 at 6. Under an HMO, the insurance company takes the risk. Neary, Tr. 585.

142. Traditionally, an HMO requires that a member’s primary physician approve access to hospitals, specialty physicians, and other health care providers. As a result, the HMO product is the most restricted form of managed care. RX 1743 at 6. The primary physician is called a gatekeeper, who manages the relationship with the patient and will refer the patient to a selected panel of specialists. Hillebrand, Tr. 1834. Pediatricians, family-medicine physicians, internists, and occasionally obstetricians act as gatekeepers. Hillebrand, Tr. 1834.

143. In an HMO network, there are significant economic incentives for the patient to only go to in-network providers. Hillebrand, Tr. 1759-60. HMO networks work on a fixed reimbursement methodology, and only provide benefits to patients if they go to in-network hospitals. Hillebrand, Tr. 1759-60. HMO members receive no benefits for out-of-network usage. Mendonsa, Tr. 477.

144. The “gatekeeper” HMO model has not sold well in Chicago. Hillebrand, Tr. 1834; Mendonsa, Tr. 479; Holt-Darcy, Tr. 1544, *in camera*. Consumers have rejected closed-panel HMOs and increasingly have demanded “choice.” RX 987 at FTC-LFH 229; Hillebrand, Tr. 1834; Mendonsa, Tr. 479. At most, Chicago had 25% HMO penetration, as compared to 50 to 60% in Los Angeles, New York, and the District of Columbia. Mendonsa, Tr. 479.

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145. In recent years, consumers have demanded broad hospital networks with few restrictions from their managed care plans. Hillebrand, Tr. 1761-62; RX 1189 at ENHL JL 14126; RX 1346 at BCBSI-ENH 5539. More tightly controlled, traditional HMOs have given way largely to more loosely structured Preferred Provider Organizations (“PPOs”) with large hospital networks and few financial incentives. RX 987 at FTC-LFH 229; Hillebrand, Tr. 1834.

146. At the same time, the distinctions between HMOs and PPOs have blurred. Noether, Tr. 5982. Many HMO plans offer substantial networks, and gatekeeper referrals are no longer always necessary. Noether, Tr. 5982; Hillebrand, Tr. 1834; Foucre, Tr. 881.

b. PPO

147. A PPO includes some elements of managed health care, but typically includes more cost-sharing with the member, through co-payments and annual deductibles. RX 1743 at 6. With a self-insured PPO product, the employer that contracts with the insurance company is responsible ultimately for the payment of expenses beyond the co-payment and deductible. Neary, Tr. 586.

148. PPOs provide members more freedom to choose a hospital or physician. RX 1743 at 6. In a PPO, the member is encouraged, through financial incentives, to use participating health care providers that have contracted with the PPO to provide services at more favorable rates. RX 1743 at 6. If a member chooses not to use a participating health care provider, the member maybe required to pay a greater portion of the provider’s fees. RX 1743 at 6.

149. A PPO plan offers employers the ability to have different co-payments, deductibles, and other means to make employees

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partially accountable and responsible for paying for their own care. Hillebrand, Tr. 1833-34.

c. POS

150. A point of service (“POS”) product tends to have a different configuration and generally involves a network smaller than a PPO network. Ballengee, Tr. 142. POS plans are traditionally between HMOs and PPOs in terms of flexibility and price. Ballengee, Tr. 142-43; Mendonsa, Tr. 479.

151. “A point of service product is one where the in-network benefit or the higher benefit is accessed if [a patient] utilize[s] a primary care physician as opposed to just in and out of network, but there is an out-of-network benefit in that product.” Mendonsa, Tr. 479.

152. With POS products, like with PPO products, the companies “that contracted with the insurance company are responsible ultimately for the payment of [healthcare services].” Neary, Tr. 586.

d. Indemnity Insurance

153. In the 1980's, the predominant form of managed care insurance in Chicago was indemnity insurance. Hillebrand, Tr. 1831-32. Managed care plans grew in importance, crowding out traditional indemnity insurance. Managed care became “the predominant form of commercial health insurance.” Hillebrand, Tr. 1832.

154. Indemnity insurance was insurance “where benefits were given to subscribers. Prices weren’t negotiated with the insurer.” Instead, the insurance company would pay the benefit on behalf of the patient. Hillebrand, Tr. 1832.

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155. Under indemnity insurance, the individual covered by insurance could select any hospital, and the insurance company would reimburse the individual for the cost of care according to the plan benefits. Under indemnity insurance, the customer of the hospital would be the individual patient, in contrast to under managed care, where the managed care organization acts as the consumer in first-stage competition. Haas-Wilson, Tr. 2465-67.

156. Under indemnity insurance, hospitals did not have to compete to be part of a network, so there was not the same kind of competition as there is under managed care. Because there was no competition for a place in the provider network under indemnity insurance, hospitals were not competing on price to obtain contracts with managed care organizations. Haas-Wilson, Tr. 2466.

e. Self Insurance

157. Administrative services only, or ASO, is the name given when the managed care insurer provides the administrative services, like claims processing, network development, and upkeep, for an employer who chooses to self insure. The employer bears the insurance risk and hires the insurance company to do just the administrative work, such as the bill-paying and the claims processing. Haas-Wilson, Tr. 2571, *in camera*.

4. Managed Care Contracting**a. Selective Contracting**

158. Managed care organizations typically do not contract with with all the hospitals in a given geographic area. Instead, they engage in selective contracting – the process by which managed care care organizations negotiate with hospitals. A managed care organization seeks to put together an attractive network for potential

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potential buyers, while at the same time keeping premiums (the prices at which it sells its products) low. Haas-Wilson, Tr. 2457.

159. Through the process of selective contracting, the managed care organization seeks to negotiate a lower price with the hospital while the hospital seeks to negotiate for a higher price. A bargain is struck between the two price objectives. Haas-Wilson, Tr. 2457-58.

160. The managed care organization will only include those hospitals in its hospital network with which there is this sort of bargain over price. Haas-Wilson, Tr. 2457-58.

161. The ability of the managed care organization to exclude a hospital from its network is a powerful tool that defines each side's bargaining position. Haas-Wilson, Tr. 2470; Noether, Tr. 6189.

162. "Selective contracting" has been one of the fundamental tools of managed care. Noether, Tr. 5980-81.

163. Different managed care plans include different numbers of hospitals depending on the extent to which selective contracting is used. Haas-Wilson, Tr. 2459-60. For example, in the Chicago area, the Great West Healthcare PPO includes 70 hospitals in its hospital network while the Blue Cross Blue Shield PPO includes 93. Haas-Wilson, Tr. 2459-60.

164. Private Healthcare Systems ("PHCS") contracts with 75 of around 80 to 85 general acute care hospitals in the Chicago area. Ballengee, Tr. 154. PHCS has excluded hospitals because their rates were too high relative to comparable hospitals, including the exclusion of the University of Chicago. Ballengee, Tr. 155-56, 189-90.

165. Aetna contracts with about 88 out of a total of 100 hospitals in the Chicago area. Mendonsa, Tr. 484. Aetna terminated

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terminated the Rush hospital system because Rush demanded higher prices than Aetna wanted to pay and because Aetna could maintain a viable network without the inclusion of Rush. Mendonsa, Tr. 568-69, *in camera*.

166. In general, PPO plans tend to include more hospitals than HMO plans, which tend to have more restrictive networks. Haas-Wilson, Tr. 2460.

167. Highland Park's CEO testified that he understood that every major insurer in the market had threatened to or actually had left hospitals out of their contracts. Spaeth, Tr. 2193.

b. Steering

168. Typically, managed care organizations are able to obtain discounts from providers' list prices if the managed care organizations can credibly promise to steer patient volume toward the providers. Dorsey, Tr. 1474-75. Such steerage can only occur if certain providers are "preferred" members of the plan's network. Hillebrand, Tr. 1760-61. Patients are given financial incentives, through lower out-of-pocket expenditures, to use the preferred providers. Hillebrand, Tr. 1759-60. Use of other providers is discouraged by forcing patients to pay larger amounts themselves. RX 1393 at ENHL BW 3691, *in camera*.

169. With the exception of capitation contracts, managed care organizations in Chicago have not successfully engaged in steering their enrollees from one hospital to another in exchange for better rates. Hillebrand, Tr. 1760-63.

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c. Reimbursement Methodologies

170. There are several price arrangements by which a managed care organization and a hospital can contract. The managed care organization can pay charges, per diem, per case, or discount off charges. *see, e.g., Holt-Darcy, Tr. 1521, in camera; Ballengee, Tr. 227, 229, in camera.*

171. Hospitals use a variety of contract reimbursement methodologies. Hillebrand, Tr. 1833. The different reimbursement methodologies described below can be used for different types of services in the same managed care organization contract. RX 387 at H 2637; RX 1503 at 3651, 3656-67, *in camera.*

172. These contracts are the result of individualized negotiations between the hospital system and managed care organizations. *see, e.g., Ballengee, Tr. 174-76; Mendonsa, Tr. 535-36, in camera; Dorsey, Tr. 1434-38; Foucre, Tr. 886-87; Holt-Darcy, Tr. 1503-04, in camera.*

(1) Discount Off Charges

173. A discount off charges rate is a negotiated discount from a hospital's list price or chargemaster. Chan, Tr. 667. A discount off charges contract is an arrangement by which managed care organizations pay a percentage discount off of the hospital's chargemaster list price for each component of a service rendered. Chan, Tr. 667; JX 8 at 5.

174. A charge description master, also known as a chargemaster, is a line-by-line listing of all of the clinical activities performed at a hospital. Neaman, Tr. 1349; Porn, Tr. 5638. The chargemaster contains all services provided at a hospital, including inpatient and outpatient services. Porn, Tr. 5646.

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175. A hospital's chargemaster reflects tens of thousands of predetermined itemized amounts (list prices) to be billed for each good or service the hospital provides. Each hospital maintains its own chargemaster. JX 8 at 4; Neaman, Tr. 1349; Hillebrand, Tr. 1710; Chan, Tr. 674; H. Jones, Tr. 4143.

176. ENH's chargemaster has 15,000-20,000 line items. Neaman, Tr. 1349; RX 641 at ENH KG 627.

177. Escalator clauses may protect a managed care organization from a hospital's chargemaster increases. Newton, Tr. 459. Such clauses are put into a discount off charges contract to protect the managed care organization in case charges go up. Mendonsa, Tr. 566-67, 558, *in camera*. For example, where a contract is for 50% of charges and the escalator clause is 5%, if the hospital were to raise its prices by 10%, then the discount would increase to 55% percent to offset the charge increase. Mendonsa, Tr. 567, *in camera*.

(2) Per Diem

178. Under the per diem reimbursement, the fixed rate per day is an all-inclusive amount for each day that the patient is in the hospital, regardless of the amount of services or the costs or charges for the services that actually must be rendered to that patient. JX 8 at 8-9.

179. A per diem is a predictable expense. Mendonsa, Tr. 524-25, *in camera*. A per diem means that managed care organizations pay a fixed amount to the hospital per day of inpatient stay regardless of what services are provided. Ballengee, Tr. 228, *in camera*. There can be different per diems for different categories of service, e.g., medical/surgical versus intensive care unit. Ballengee, Tr. 228, *in camera*.

(3) Case Rates

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180. A per case rate is an all-inclusive charge for an entire case (such as the delivery of a baby based on the length of stay). Ballengee, Tr. 229, *in camera*. Managed care organizations prefer case rates because, like per diem rates, they allow the managed care organizations to fix their costs and price their products accordingly for the coming year. Sirabian, Tr. 5740.

(4) Capitation

181. In capitated contracts, the parties typically negotiate a fixed amount that the provider receives for agreeing to care for each patient, regardless of how much care the patient seeks during the period in question. Mendonsa, Tr. 525, *in camera*; Holt-Darcy, Tr. 1537-38, *in camera*. Capitated contracts shift financial risk to providers, to align the incentives of those who provide care (the hospitals and physicians) with those who must pay for it. Mendonsa, Tr. 525, *in camera*; Holt-Darcy, Tr. 1537-39, *in camera*.

182. When health plans pay a fixed per diem or per case rate, it is not capitation. Hospital capitation has not been common in the Chicago market. Spaeth, Tr. 2129-30; Holt-Darcy, Tr. 1537-39, *in camera*; Mendonsa, Tr. 525, *in camera*.

5. Hospital Costs

183. Congress passed the Balanced Budget Act of 1997 (“Balanced Budget Act”) as part of a larger deficit reduction package. Pub. L. 105-33, 1997 H.R. 2015; Neaman, Tr. 1314; H. Jones, Tr. 4106. Overall, the Balanced Budget Act was intended to reduce the annual rate of Medicare spending growth. Neaman, Tr. 1314. The Balanced Budget Act did, in fact, reduce expenditures in a number of areas, including: general hospital payments, teaching, research, home care, and payments to physicians. Neaman, Tr. 1314-15.

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184. The reduction in general hospital payments placed significant strain on hospitals' abilities to cover many of their high fixed (or shared) costs. H. Jones, Tr. 4106, 4145-47; Noether, Tr. 5973. Additionally, these reductions limited hospitals' abilities to care for their uninsured patients. According to federal regulations, hospitals must provide emergency care to all who require it, regardless of their ability to pay. 42 U.S.C. 1395dd; 42 C.F.R. § 489.24.

185. Passage of the Balanced Budget Act coincided with a continuing decline in the growth of payments from managed care organizations. RX 1346 at BCBSI-ENH 5540. Traditionally, payments from private payors helped hospitals meet the costs of providing unprofitable services -- such as caring for the uninsured and training residents. RX 1393 at ENHL BW 3681, *in camera*. Meeting costs via cross-subsidization was practiced by some hospital administrators. Haas-Wilson, Tr. 2684-85.

186. Along with Medicare payment reductions and a declining ability to shift costs, hospitals have encountered other payment challenges since the Balanced Budget Act's passage: rising liability insurance costs' stock market declines; new expensive technological developments; and increased labor costs. RX 1393 at ENHL BW 3681, *in camera*; H. Jones, Tr. 4108.

187. Managed care organizations could absorb provider price increases without passing them on to consumers. For instance, Health Care Service Corporation, the parent of Blue Cross, posted net gains of over \$624 million in 2003, \$387 million in 2001 and \$173 million in 2000. RX 1587 at 7; RX 1198 at 6-7. Humana is one of the nation's largest publicly traded health benefits companies, based on 2003 revenues of \$12.2 billion. RX 1743 at 4, 4, 27. In 2003, PHCS reported that its net revenue climbed to \$153 million, an increase of 6% over 2002. RX 1615 at 3. Further, PHCS's earnings increased by "an astounding 50%" in 2003. RX 1615 at 3. Cigna posted net income of \$668 million in its 2003

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financial statements. RX 1742 at 54. As of February 2005, United Health Group was worth over \$30 billion. Foucre, Tr. 939; RX 1662 at 225, 227. First Health, which acquired CCN in August 2001, 2001, had net income of \$152,734,000 in 2003, up from \$132,938,000 in 2002, \$102,920,000 in 2001, and \$82,619,000 in 2000. RX 1661 at 50; RX 1469 at 104.

188. Managed care representatives testified that employees ultimately bear the cost of higher health care prices. When hospitals raise their rates to managed care organizations, those higher rates are passed on to the managed care organizations' employer groups and further to the employer groups' employees. Ballengee, Tr. 239, *in camera* (PHCS); Mendonsa, Tr. 483 (Aetna); Dorsey, Tr. 1450 (One Health).

189. A self-insured customer or large employer group, in the event of unforeseen increases in expenses, may pass on the costs to its employees. Mendonsa, Tr. 483-84; Ballengee, Tr. 239, *in camera*. Large employers can "raise the deductible, raise the co-payments and also charge more out of [the employee's] paycheck for the coverage." Mendonsa, Tr. 549, *in camera*.

190. "The big impact" of managed care organizations passing on large increases to their smaller business customers is "small insureds dropping coverage altogether and people not having insurance." Mendonsa, Tr. 483-84.

C. Relevant Market

1. Product Market

191. The relevant product market is the market for "general acute care inpatient services sold to managed care organizations." Haas-Wilson, Tr. 2451-52; *see* F. 192-211.

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192. Primary, secondary, and tertiary services are included in the relevant product market. Haas-Wilson, Tr. 2661; *see* F. 197-200.

193. ENH's economic expert, Dr. Monica G. Noether, Vice President, Charles River Associates, agrees that specialty hospitals that do not provide the full range of hospital services, that may be specialized either in a particular service or for a particular category of patients, are excluded from the relevant product market. Noether, Tr. 5924.

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a. Definitions

194. Acute care hospital services are “[s]ervices furnished to patients with acute needs for health care services, as distinguished from services furnished for chronic physical conditions through the provision of long-term inpatient care.” Noether, Tr. 5905; JX 8.

195. Inpatient hospital services are furnished to a patient who, to obtain the services, must stay overnight at the hospital. Ballengee, Tr. 144; Neary, Tr. 590; JX 8.

196. Outpatient hospital services are furnished to patients who do not require an overnight stay at the facility. CX 6321 at 82; Newton, Tr. 302; JX 8.

197. Primary services refers to the basic care that is typically provided by physicians or nurse practitioners who work with general and family medicine, internal medicine, pregnant women, and children. Noether, Tr. 6159. Primary services could include things such as basic hospital outpatient services and basic minor surgery. Neaman, Tr. 1293.

198. Secondary services refers to care given by a specialist or a facility upon referral by a primary care provider, and generally requires more skill, expertise, or equipment than primary care services. Noether, Tr. 6159.

199. Tertiary services refers to more complicated services than primary or secondary, but less complicated services than quaternary services. Haas-Wilson, Tr. 2491. Tertiary care generally means major surgical or medical procedures that are done within a hospital setting. Neaman, Tr. 1294.

200. Quaternary services refers to high-end services that are performed at some hospitals and not others. Neaman, Tr. 1294; Haas-Wilson, Tr. 2701, *in camera*. Quaternary services, which

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include solid organ transplants and treatment for severe burns, require very specific human capital, including trained nurses and doctors, and very specialized physical capital, including specialized specialized equipment. Haas-Wilson, Tr. 2701, *in camera*.

b. Services Provided by the Merging Parties

201. Before the merger, both Highland Park and Evanston had, among other things, operating rooms, pediatric services, obstetrical services, radiation therapy, cancer services, and psychiatric services. Spaeth, Tr. 2083-88.

202. Before the merger, both Highland Park and Evanston provided primary and secondary services. Holt-Darcy, Tr. 1507, *in camera*; Haas-Wilson, Tr. 2491, 2316. Evanston provided tertiary services before the merger, while Highland Park generally did not. Haas-Wilson, Tr. 2491.

203. None of the hospitals comprising ENH offer advanced, quaternary services, such as organ transplants and severe burn care. Haas-Wilson, Tr. 2665; Ballengee, Tr. 188-89.

c. Outpatient Services Not a Substitute for Inpatient Services

204. None of the outpatient centers in the Evanston area have 24-hour nursing or lodging of patients. Spaeth, Tr. 2076.

205. The physician determines whether a patient should be admitted to the hospital. Hillebrand, Tr. 1756; Spaeth, Tr. 2076; Newton, Tr. 302.

206. If a patient requires more than a day of medical or surgical services as an inpatient, managed care organizations cannot substitute outpatient services. Holt-Darcy, Tr. 1422-23; Newton, Tr. 302.

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207. Changes in inpatient pricing have no impact on patients switching from inpatient services to outpatient services. Neaman, Tr. 1210; Hillebrand, Tr. 1755-56.

208. When faced with a price increase for inpatient care from a hospital, managed care organizations could not add to the network outpatient only providers and exclude the higher priced hospitals. Haas-Wilson, Tr. 2663.

209. ENH set its inpatient rates independent of its outpatient rates and without concern that patients would switch to outpatient services. Neaman, Tr. 1210-11; Newton, Tr. 330-31.

210. When ENH developed its plan to negotiate higher prices, ENH management did not prepare or ask for any documents analyzing whether more patients would switch from inpatient to outpatient services as a result of changes in inpatient prices. Neaman, Tr. 1210-11; *see* Hillebrand, Tr. 1756.

211. ENH's expert agrees that inpatient and outpatient services are not functionally interchangeable. Noether, Tr. 6194.

2. Geographic Market

a. Elzinga-Hogarty Test and Patient Flow Data Are Not Relevant to the Geographic Market Analysis

212. The Elzinga-Hogarty test, which was developed for the beer and coal industries prior to the development of the *Merger Guidelines*, has been utilized in a number of hospital merger cases. Elzinga, Tr. 2374-76.

213. The Elzinga-Hogarty test is premised on the assumption that patient flow data affects market prices. Elzinga, Tr. 2356.

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214. Patient flow data is data regarding where patients go to obtain hospital services. Elzinga, Tr. 2356, 2375; Noether, Tr. 6203-04.

215. Under the Elzinga-Hogarty test, the geographic market is based on the area from which the hospital attracts its patients (its service area) and where patients within that service area go to receive healthcare. Elzinga, Tr. 2380-81.

216. Patient-flow data and the Elzinga-Hogarty test are inapplicable to geographic market definition for a differentiated product such as hospital services. Elzinga, Tr. 2384-85.

217. The first problem with use of patient flow data and the Elzinga-Hogarty test is the “payor problem,” which recognizes that in the hospital industry, managed care organizations pay for hospital services but patients are the ones who use the services. Elzinga, Tr. 2395.

218. Because patients do not set the price of hospital services, their willingness to travel tells us nothing about their sensitivity to price changes by the merging hospitals. Elzinga, Tr. 2395-97.

219. The second problem with patient flow analysis is that it incorrectly assumes that if some patients are willing to travel to distant hospitals, then others will travel as well in response to a change in hospital prices, thereby incorrectly suggesting a broader geographic market. Elzinga, Tr. 2385-90.

220. A “silent majority” of people will not travel in response to a change in hospital prices, and those people can be subject to an anticompetitive price increase. Elzinga, Tr. 2385-90.

221. Hospitals frequently consider patient flow data in evaluating competition and service areas. RX 518 at ENH GW

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2055-57, 2059; RX 2021 at ENH DL 3443, *in camera*; RX 135 at 4; 4; RX 1361 at 1; RX 1564, *in camera*.

222. However, basing geographic market definition on patient migration and patient flow data inherently will overstate the size of the geographic market for hospital services. Elzinga, Tr. 2393.

223. Patient flow data should not be used to determine the geographic market for hospital services, even apart from the Elzinga-Hogarty test, because the same payor and silent majority problems exist. Elzinga, Tr. 2417-18.

224. While Respondent's expert, Noether, did not use the Elzinga-Hogarty test for the purpose of defining the geographic markets, she did use patient flow analysis as one factor in defining the proposed geographic market. *see*, e.g., Noether, Tr. 5947-48.

225. Noether conceded that patient flow data is focused on which hospitals patients ultimately choose for care and that one would not want to rely on patient flow data by itself to determine the geographic market. Noether, Tr. 6203-04.

b. Market Participant Views**(1) Managed Care Organizations**

226. In the Chicago area, provider networks must include local hospitals. For example, PHCS's representative stated that people "do not like to drive by a local hospital and have to go to another hospital." Ballengee, Tr. 184.

227. Local hospitals in this particular geographic area are important to include in hospital networks because this was an area populated by "senior executives and decision-makers" who are "educated" and "outspoken" and it would be "real tough" for any managed care organization and employer "whose CEOs either use

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this place or that place to walk from [ENH] and 1700 of their doctors.” CX 4 at 2; Foucre, Tr. 901-02, 926; Spaeth, Tr. 2242; Newton, Tr. 360-61 (Within the triangle formed by the ENH hospitals live many executives who “make decisions about health benefits for their employers, employees,” and have “immense influence and power with the health plans.”).

228. This managed care testimony is consistent with economic literature findings that affluent consumers may be less willing to travel because they “impute a higher value to their time and consequently travel becomes more costly to them in the opportunity cost sense ... affluent people have to stay close to home ... so they can move on earning their – the high income that makes them affluent.” Elzinga, Tr. 2408.

229. Managed care representatives described Evanston and Highland Park as each other’s “main” competitors or “primary” alternative, thereby permitting managed care organizations to “trade off one for the other” or “work them against each other” in contract negotiations. Neary, Tr. 600-02; Ballengee, Tr. 166-70.

230. Aetna could constrain Evanston’s prices by utilizing Highland Park (and others) in its network as an alternative (and vice-versa). Mendonsa, Tr. 520, 530, *in camera*.

231. PHCS knew that if rate negotiations were not “going well” at Evanston or Highland Park, PHCS could turn to the other as the alternative and use this fact to work the negotiations favorably its way. Ballengee, Tr. 166-67.

232. One Health viewed Evanston and Highland Park as “main competitors” because their services were “comparable,” and the two hospitals drew patients from the same general population. Neary, Tr. 600-01.

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233. Managed care representatives testified that they needed ENH in their hospital networks. Ballengee, Tr. 179-80 (PHCS customers made it “very clear” that a network without ENH was not “marketable.”); Foucre, Tr. 901-02, 925-26, 931-34 (United concluded it “could not have a viable network that would support our sales and growth objectives” without ENH). For example, there was testimony that “people would choose either to go north to [Highland Park] or south to [Evanston]. They could go either way and receive the same services at the same level. So, it was pretty well assumed that we could have one or the other hospital in the network.” Ballengee, Tr. 166, 168 (migration tends to be north-south.).

234. The Unicare representative testified that she could have a viable network comprised of Highland Park, Advocate Lutheran General, Rush North Shore, and St. Francis or Evanston and Lake Forest. Holt-Darcy, Tr. 1518-20, *in camera*. Either of these alternative networks could “provide medical services adequately” and meet the “geographic access standards” of local Unicare customers. Holt-Darcy, Tr. 1519-20, *in camera*.

235. The Aetna representative testified that Evanston competed locally with Rush North Shore and St. Francis and that Highland Park competed locally primarily with Lake Forest. Mendonsa, Tr. 562, *in camera*.

236. The PHCS representative testified that premerger, Advocate Lutheran General, Rush North Shore, and St. Francis, were significant competitors to Evanston, and that Lake Forest was a significant competitor to Highland Park. Ballengee, Tr. 211-12.

237. The PHCS representative testified that for purposes of developing its network and deciding which hospitals to include in its network, she viewed the service and quality of Advocate Lutheran General, possibly Rush North Shore, and possibly

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Advocate Northside to be comparable to Evanston. Ballengee, Tr. 191-93.

238. When PHCS notified its customers about the merger, it identified “other contract providers within the same geographical area as that of Highland Park Hospital and Evanston,” including: Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, and Holy Family Medical Center. RX 712 at PHCS 891; Ballengee, Tr. 213-14.

239. The Great West representative testified that the main alternatives to ENH were: Advocate Lutheran General, St. Francis, Condell, and Northwestern Memorial. Neary, Tr. 630-31.

240. Great West provided its subscribers with a list of hospitals that were in its network that could be alternatives to ENH, including: Lake Forest, Advocate Lutheran General, St. Francis, and to the north, St. Therese and Victory Memorial (now the Vista hospitals). Dorsey, Tr. 1479-80.

241. The Unicare representative testified that ENH competes with Lake Forest, Rush North Shore, St. Francis, and Advocate Lutheran General to some degree. Holt-Darcy, Tr. 1596-98, *in camera*. According to the Unicare representative, Evanston also competes with the other tertiary hospitals in the Chicago area and may compete with Louis A. Weiss to some degree. Holt-Darcy, Tr. 1596-97, *in camera*. When asked whether Highland Park competes with Condell, Holt-Darcy replied “[l]ess so, because it is a little further west.” Holt-Darcy, Tr. 1596, *in camera*.

242. The United representative testified that Evanston competes with Advocate Lutheran General, Rush North Shore, and St. Francis and that Highland Park primarily competes with Lake Forest and Condell. Foucre, Tr. 941-44. The United representative also testified that Evanston competes with

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Northwestern Memorial in respect to certain services. Foucre, Tr.
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(2) ENH

243. Evanston and Highland Park viewed each other as competitors premerger. CX 1868 at 3; Neaman, Tr. 1046; Spaeth, Tr. 2088.

244. Highland Park, prior to the merger, considered its closest or primary competitor to be Lake Forest, although it also was “reasonably close” to Advocate Lutheran General, Rush North Shore, Evanston, and Condell. Spaeth, Tr. 2239-40; Chan, Tr. 730; CX 6305 at 5 (Stearns, Dep.); Krasner, Tr. 3700.

245. Spaeth, Highland Park’s President, indicated that he believed that managed care organizations could exclude Highland Park from a network and substitute Evanston, Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, and Condell. Spaeth, Tr. 2299.

246. Neaman, Evanston’s CEO, testified that Condell and Lake Forest were competitors of Evanston, but that Highland Park was not a substantial competitor of Evanston. Neaman, Tr. 1381-82.

247. ENH described its combined core service area as including: Evanston, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, downtown teaching hospitals, and “other” hospitals. CX 359 at 16.

248. According to ENH representatives, ENH’s major competitors for “more sophisticated” or “tertiary” services include: Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, Condell, Northwestern Memorial, Rush-Presbyterian-St. Luke’s, and University of Chicago, because all of these hospitals offer a comparable breadth and type of services. Hillebrand, Tr. 1748-51; Neaman, Tr. 1301.

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249. The merging parties recognized that hospital competition is local. “What Evanston does is provide total concentration” and that “[i]f one of your key objectives is to get geographic leverage on the employers in this area getting Northwestern [Memorial] doesn’t do much for you.” CX 4 at 9; Spaeth, Tr. 2213-14. *see* also CX 4 at 9 (board member noted that a merger with Northwestern Memorial would not provide “critical mass in the same area.”).

250. At an April 5, 1999, meeting of the medical staff executive committee at Highland Park, Neaman commented on the “geographic advantages” of a merger between Evanston and Highland Park. Spaeth, Tr. 2213-14; CX 2 at 7.

251. In a joint 1999 submission to an Illinois healthcare agency for approval to extend Evanston’s heart surgery program to Highland Park, the hospitals stated:

Last, a concept that is often misunderstood by persons not living in suburban communities is that many suburban residents rarely travel from their general area of residence for shopping, business and health care services. For this reason, many of the anxiety and convenience-related issues related to a resistance to travel for care, that are typically associated with smaller communities, also exist in the suburbs.

CX 413 at 83.

c. Other Factors Relevant to the Geographic Market Determination

252. Managed care organizations consider a variety of factors in building their hospital networks, including: patient preferences, geographic needs, marketing needs, credentialing, physician preferences, quality of services, breadth of services, ease of

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accessibility, and residence of the individuals who negotiate contracts with managed care plans. Elzinga, Tr. 2407; Haas-Wilson, Tr. 2803-05, *in camera*; Noether, Tr. 5937, 5949; Foucre, Tr. 885; Mendonsa, Tr. 485; Holt-Darcy, Tr. 1420-21; Ballengee, Tr. 151-53.

253. Employers are concerned about where their employees want to seek hospital care. Noether, Tr. 5936-37, 5948. Consequently, to the extent that patients value convenience, there is a derived demand by the managed care organizations for hospitals that are convenient to their enrollees. Noether, Tr. 5937; Elzinga, Tr. 2407.

254. The Unicare representative testified that a managed care organization wanted “to make sure that members have access to a hospital within 30 miles of where they live or work” in order “to meet the standards that the plans put together.” Holt-Darcy, Tr. 1420. Thus, the Unicare representative testified that “[y]ou look at geographic need, you look at marketing needs, you look at access” and that “[y]ou want to *see* what population you have or potentially have, what marketing thinks that they need in a particular service area.” Holt-Darcy, Tr. 1420.

255. Driving times may be a better measure of geographic proximity than driving distances because distances do not account for variations in road and/or traffic patterns that can affect patient preferences. Noether, Tr. 5933.

256. Noether computed the driving times from Evanston and Highland Park to other area hospitals. RX 1912 at 20-21, *in camera*. The actual driving time will vary for each patient, depending on where he or she lives or works. *see* Noether, Tr. 5929.

257. According to a Lake Forest customer survey report, dated November 8, 2001, consumers are willing to travel, on average, up

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up to 16 minutes for emergency care, 28 minutes to a primary care physician for routine care, 31 minutes for outpatient services, and 35 minutes to a hospital for an overnight stay. RX 1179 at LFH 845. 845.

258. The average driving distance from Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis to the closer of Evanston or Highland Park is 5.75 miles, while the average driving time is 12.75 minutes. *see* RX 1912 at 20, *in camera*.

259. The average driving distance from Condell and Resurrection to the closer of Evanston or Highland Park is 12.4 miles, while the average driving time is 24.5 minutes. *see* RX 1912 at 20, *in camera*.

260. By either mileage or minutes, the travel time from the closer of Highland Park or Evanston to the hospitals excluded from the geographic market is almost double the mileage or minutes from the closer of Highland Park or Evanston to the hospitals included in the geographic market. Compare F. 258 to F. 259.

261. Physician admitting practices are significant “because the physician is the one who is often the most responsible for choosing where a particular patient is going to be admitted to a hospital.” Noether, Tr. 5949.

d. Hospitals Included in the Geographic Market

262. The hospitals below, which are part of the geographic market, were all included in Respondent’s proposed geographic market. *see* Noether, Tr. 5928, 5960. In addition, Respondent’s proposed geographic market included two additional hospitals which are discussed *infra* in section II.C.2.e.

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(1) Evanston

263. *see* F. 5-8, 201-03.

(2) Glenbrook

264. *see* F. 9-13, 203.

(3) Highland Park

265. *see* F. 20-24, 201-03.

(4) Lake Forest

266. Lake Forest is 6.1 miles and 13 minutes (driving time) northwest of Highland Park. Neaman, Tr. 1304; Spaeth, Tr. 2239-40; Mendonsa, Tr. 555, *in camera*; RX 1310 at FTC-LFH 669; RX 1912 at 20-21, *in camera*.

267. Lake Forest is a 142 bed hospital with a very active obstetrics program, roughly the same size as Highland Park's obstetrics program. Hillebrand, Tr. 2005; RX 1912 at 60. Lake Forest Hospital does not provide any tertiary care. Neaman, Tr. 1304.

268. Lake Forest had no residents per bed in 1999. RX 1912 at 60.

269. There was a substantial overlap of admitting physicians who had privileges and admitted patients at both Highland Park and Lake Forest prior to the merger. Noether, Tr. 5950; RX 653 at ENH DL 4497. Once the merger was announced, a number of these physicians shifted their admissions to Lake Forest. Noether, Tr. 5950; RX 653 at ENH DL 4498.

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270. Lake Forest was identified in contemporaneous PHCS and Great West correspondence to patients as an alternative to ENH. RX 712 at PHCS 891; Ballengee, Tr. 213-14; Dorsey, Tr. 1478-80.

271. Managed care representatives testified that Lake Forest is a significant competitor to ENH. Ballengee, Tr. 212 (PHCS); Foucre, Tr. 944 (United); Holt-Darcy, Tr. 1596, *in camera* (Unicare); Mendonsa, Tr. 562, *in camera* (Aetna); Spaeth, Tr. 2239, 2299 (Highland Park).

(5) Advocate Lutheran General

272. Advocate Lutheran General is 10.2 miles or 21 minutes (driving time) west and slightly south of Evanston. Neaman, Tr. 1297; RX 1912 at 20-21, *in camera*; *see also* Mendonsa, Tr. 556, *in camera*.

273. Advocate Lutheran General is a 521 bed tertiary care hospital that is the largest hospital in the Advocate system, which itself consists of eight hospitals. Neaman, Tr. 1296-97; *see also* Ballengee, Tr. 225, *in camera*; RX 1503 at PHCS 3667, *in camera*; RX 1912 at 60; Mendonsa, Tr. 558, *in camera*. Through the end of 2000, Advocate Health Care was the overall market share leader in the Chicago metropolitan area and the largest hospital system in the Chicago area. RX 1053 at AHHC 363, *in camera*; Mendonsa, Tr. 558, *in camera*.

274. Advocate Lutheran General provides all basic services, cardiac surgery, and most everything in between. Neaman, Tr. 1297. Advocate Lutheran General also has a teaching relationship with the University of Illinois at Chicago Health Services Center. Neaman, Tr. 1297.

275. Advocate Lutheran General had .36 residents per bed in 1999. RX 1912 at 60.

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276. In terms of range of services, Advocate Lutheran General is the most similar to Evanston Hospital. Haas-Wilson, Tr. 2706, *in camera*. The United representative stated: “Lutheran General is the most comparable facility from type of services, quality of services, size of facility; however, it is the furthest away. It’s got a bit of geographic disadvantage, but it’s not terribly far away.” Foucre, Tr. 944.

277. Before the merger, patients who went to the emergency room at Highland Park or Lake Forest with a heart attack were referred to Advocate Lutheran General for more advanced care. Spaeth, Tr. 2241-42.

278. ENH, during contract negotiations with PHCS, considered giving a better rate to PHCS if PHCS excluded Advocate Lutheran General from its hospital network. Ballengee, Tr. 181-82.

279. Advocate Lutheran General was identified in contemporaneous PHCS and Great West correspondence to patients as an alternative to ENH. RX 712 at PHCS 891; Ballengee, Tr. 213-24; Dorsey, Tr. 1479-80.

280. Managed care representatives testified that Advocate Lutheran General is a significant competitor to ENH. Ballengee, Tr. 211 (PHCS); Foucre, Tr. 941-42 (United); Neary, Tr. 630-31 (Great West); Holt-Darcy, Tr. 1597, *in camera* (“to some degree”) (Unicare); Spaeth, Tr. 2239-40, 2299 (Highland Park).

(6) Rush North Shore

281. Rush North Shore is 3.7 miles or 9 minutes (driving time) southwest of Evanston Hospital. Spaeth, Tr. 2239-40; RX 1912 at 20-21, *in camera*.

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282. Rush North Shore has 150 to 200 beds and as of February 2005 it was affiliated with Rush-Presbyterian-St. Luke's, a major tertiary and academic hospital. The Rush-Presbyterian affiliation improved the breadth, quality, and the perception of services offered at Rush North Shore. Neaman, Tr. 1302.

283. Rush North Shore is geographically close to Evanston but does not have the same tertiary facilities as Advocate Lutheran General. Foucre, Tr. 945.

284. Rush North Shore had .12 residents per bed in 1999. RX 1912 at 60.

285. Rush North Shore was identified in contemporaneous PHCS correspondence to patients as an alternative to ENH. RX 712 at PHCS 891; Ballengee, Tr. 213-14.

286. Managed care representatives testified that Rush North Shore is a significant competitor to ENH. Ballengee, Tr. 211-12 (PHCS); Foucre, Tr. 941 (United); Spaeth, Tr. 2239-40, 2299 (Highland Park); Holt-Darcy, Tr. 1597, *in camera* (Unicare).

(7) St. Francis

287. St. Francis is located in Evanston and is 3 miles south of Evanston Hospital on the same street -- Ridge Avenue, only an 8 minute drive past Evanston. Neaman, Tr. 1303; Foucre, Tr. 941; RX 1912 at 20-21, *in camera*.

288. St. Francis has 300 to 400 beds. As of February 2005, St. Francis was part of the Resurrection System. Neaman, Tr. 1303. St. Francis's services range from cardiology and obstetrics to general surgery. RX 1854 at ENHE F16 426.

289. St. Francis is geographically close to Evanston but does not not have the same tertiary facilities that Advocate Lutheran General

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General has and has less of a perception as an equivalent facility. Foucre, Tr. 945.

290. St. Francis had .36 residents per bed in 1999. RX 1912 at 60.

291. St. Francis was identified in contemporaneous PHCS and Great West correspondence to patients as an alternative to ENH. RX 712 at PHCS 891; Ballengee, Tr. 213- 14.

292. Managed care representatives testified that St. Francis is a significant competitor to ENH. Ballengee, Tr. 212 (PHCS); Foucre, Tr. 942, 944-45 (United); Neary, Tr. 631 (Great West); Holt-Darcy, Tr. 1596, *in camera* (Unicare).

e. Hospitals Excluded from the Geographic Market

(1) Condell

293. Condell is 12.7 miles and 24 minutes (driving time) northwest of Highland Park. Neaman, Tr. 1304-05; Hillebrand, Tr. 2006; Spaeth, Tr. 2239-40; Mendonsa, Tr. 555, *in camera*; RX 1912 at 20-21, *in camera*.

294. Condell is a 163 bed hospital located in Libertyville, Lake County, which is one of the fastest growing areas in metropolitan Chicago. Neaman, Tr. 1326; Hillebrand, Tr. 2006; Mendonsa, Tr. 562, *in camera*; RX 1912 at 60.

295. As of February 2005, Condell provided a full array of services, including everything from general obstetrics to cardiac surgery. Neaman, Tr. 1305.

296. Condell had no residents per bed in 1999. RX 1912 at 60.

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297. Condell is not a significant competitor to ENH. Lake Forest, which is between Highland Park and Condell, is a more significant competitor to Highland Park. Holt-Darcy, Tr. 1596, *in camera* (Unicare) (Highland Park competes with Condell, “[l]ess so, because it is a little further west.”); Mendonsa, Tr. 562, *in camera* (Aetna) (Highland Park competes “[m]uch more with Lake Forest than Condell.”). But *see* Foucre, Tr. 944 (agreeing that Highland Park competes with Condell and Lake Forest) and Neary, Tr. 631 (Condell competes with ENH); Spaeth, Tr. 2239-40, 2299 (Highland Park).

(2) Resurrection

298. Resurrection Medical Center is 12.1 miles or 25 minutes (driving time) southwest of Evanston. Neaman, Tr. 1303-04; Ballengee, Tr. 263, *in camera*; RX 1912 at 20-21, *in camera*.

299. Resurrection has 350 staffed beds. RX 1912 at 60.

300. Resurrection had 0.17 residents per bed in 1999. RX 1912 at 60.

301. The Resurrection system is a large system, described by one managed care representative as a “system which we really need to keep.” Ballengee, Tr. 263, *in camera*. The Resurrection system includes St. Francis. Ballengee, Tr. 263, *in camera*.

302. There is conflicting testimony regarding whether the Resurrection system negotiated all of its hospitals as one contract or separately. Compare Ballengee, Tr. 263, *in camera*, with Foucre, Tr. 890-91.

303. Resurrection is not a significant competitor to ENH and was not identified by managed care organizations as an alternative to ENH. *see* F. 234-42.

(3) Other Hospitals

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304. Noether testified that “certainly from a geographic perspective, some of the other hospitals that are quite near the sort of minimum geographic area that I’ve described certainly probably place at least competitive pressure and maybe potentially could even be in the market” including: Holy Family, Swedish Covenant, and the Vista hospitals. Noether, Tr. 5930-31. Noether also testified that Northwestern Memorial places “substantial competitive constraint” on ENH and the other hospitals in the proposed geographic market even though it is located in downtown Chicago. Noether, Tr. 5931

305. Holy Family is 11.3 miles or 23 minutes (driving time) west of Evanston. RX 1912 at 20-21, *in camera*. Holy Family has 260 staffed beds and .02 residents per bed in 1999. RX 1912 at 60. PHCS was the only managed care organization which mentioned Holy Family. RX 712 at PHCS 891; Ballengee, Tr. 213-14.

306. Swedish Covenant is an urban hospital located 6.8 miles or 19 minutes (driving time) south of Evanston. Neaman, Tr. 1305; Newton, Tr. 296; RX 1912 at 20-21, *in camera*. As of February 2005, Swedish Covenant had 325 beds. Newton, Tr. 296. In 1999, Swedish Covenant had .13 residents per bed. RX 1912 at 60. Swedish Covenant operates an open heart surgery program with Evanston. Newton, Tr. 423-24; Hillebrand, Tr. 2045-46. The managed care representatives did not mention Swedish Covenant as a significant competitor to ENH.

307. The Vista hospitals include Vista Health St. Therese and Vista Health Victory Memorial and are located in Waukegan in northern Illinois and Victory Memorial is “almost up to Wisconsin.” Wisconsin.” Dorsey, Tr. 1480; Noether, Tr. 5956. The Vista hospitals are an average of 15.9 miles or 30 minutes (driving time) north of Highland Park. RX 1912 at 20-21, *in camera*; Ballengee, Tr. 163. Great West was the only managed care

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organization which mentioned the Vista hospitals as an alternative to to ENH. *see* Dorsey, Tr. 1479-80.

308. Northwestern Memorial is located in downtown Chicago, roughly 13 miles or 26 minutes (driving time) south of Evanston. Neaman, Tr. 1298; RX 1912 at 20-21, *in camera*. Northwestern Memorial is a tertiary hospital with more than 700 beds. Neaman, Tr. 1298. Northwestern Memorial is affiliated with the Northwestern Medical School and had .56 residents per bed in 1999. Neaman, Tr. 1299; RX 1912 at 60. Northwestern Memorial is the number one provider of obstetrical services in Illinois. Neaman, Tr. 1298. It has the premier obstetrics brand in Chicago because of its Prentice Women's Hospital and possesses the largest volume of delivering mothers in the Chicago area. Hillebrand, Tr. 2003-04. Great West was the only managed care organization which mentioned Northwestern Memorial as an alternative to ENH. *see* Dorsey, Tr. 1479-80.

D. Effects on Competition**1. Anticompetitive Effects****a. Market Concentration**

309. Given the available data, Respondent's expert, Noether, was not able to calculate exact market shares. Noether, Tr. 5961. Noether did, however, calculate proxy shares using the best available information, contained in the Medicare Cost Reports. Noether, Tr. 5961. The Medicare Cost Reports provide information on total net revenues, both inpatient and outpatient, across all managed care organizations. Noether, Tr. 5961. Noether calculated revenues of both inpatient and outpatient services and for inpatient services alone. Noether, Tr. 5961-62, 5964.

310. Noether also calculated Herfindahl-Hirschman Index ("HHI") statistics. Noether, Tr. 5962. HHI is a measure suggested by by the *Merger Guidelines* as a way of capturing market

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concentration to take into account all of the players in the market, and it takes the shares of each of those firms, squares them, and then then sums the squared shares. Thus, HHI is a statistic that can range range from zero, in the case of a infinite number of very small players, up to 10,000, which is 100 squared, if there were a single monopolist in the market. Noether, Tr. 5962-63.

311. Noether properly treated St. Francis and Resurrection Medical Center as separate hospitals, although the hospitals had merged in the late 1990's. Noether, Tr. 5963; Noether, 6248-49, *in camera*; RX 531 at 13916.

312. Noether prepared a chart of net inpatient revenue and market shares (annualized) from 1997 to 2002 including the hospitals in her proposed geographic market. The net inpatient revenue from each hospital for each year was added to establish the market total. Each hospital's revenue was divided by the market total to establish that hospital's market share. Noether, Tr. 5962; RX 1912 at 58, *in camera*.

313. Noether calculated the HHI using 1999 market shares. RX 1912 at 58, *in camera*; Noether, Tr. 5965.

314. Noether calculated the post-merger HHI by summing the squares of the market shares of the hospitals in her proposed geographic market as follows: { } = 1919. *see* Noether, Tr. 5962-65; RX 1912 at 58, *in camera*.

315. Noether calculated the change in HHI for her proposed market as 222. Noether, Tr. 5963; RX 1912 at 58, *in camera*.

316. Using the market shares from Noether's proposed geographic market, but recalculated to reflect the Court's defined geographic market allows a determination of the premerger HHI as follows: { } = 2355. *see* F. 323; RX 1912 at 58, *in camera*.

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317. Using the market shares from Noether's proposed geographic market, but recalculated to reflect the Court's defined geographic market allows a determination that the combined market shares of Evanston and Highland Park in 1999 was { } *see* F. 322; RX 1912 at 58, *in camera*.

318. Using the market shares from Noether's proposed geographic market, but recalculated to reflect the Court's defined geographic market allows a determination of the post merger HHI as follows: { } = 2739. *see* F. 322; RX 1912 at 58, *in camera*.

319. Using the concentration figures in F. 316 and F. 318, the increase in the HHI is 384 (2739 minus 2355).

320. The post-merger HHI of over 2700 in the Court's defined geographic market is well above the *Merger Guidelines*' threshold of 1800 indicating a concentrated market (Noether, Tr. 5963) and the increase of over 350 far exceeds the *Merger Guidelines*' threshold of 50 as signifying a significant increase in concentration.

321. To reflect the geographic market in this case, excluding Condell and Resurrection from Noether's chart of net inpatient revenue and market shares (annualized) from 1997 to 2002 yields the following net inpatient revenues:

NET INPATIENT REVENUE	1997	1998	1999	2000	2001	2002
Evanston Northwest Healthcare	{					
Highland Park Hospital						
Lake Forest Hospital						
Advocate						

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Lutheran General						
Rush North Shore Medical Center						
Saint Francis Hospital						
MARKET TOTAL						}

See RX 1912 at 58, in camera.

322. To reflect the geographic market in this case, excluding Condell and Resurrection from Noether's chart of net inpatient revenue and market shares (annualized) from 1997 to 2002, provides the following market shares:

MARKET SHARES	1997	1998	1999	2000	2001	2002
Evanston Northwest Healthcare	{					
Highland Park Hospital						
Lake Forest Hospital						
Advocate Lutheran General						
Rush North Shore Medical Center						
Saint Francis Hospital						}

See RX 1912 at 58, in camera.

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323. Even the HHI of 1919 calculated by Noether using Respondent's proposed geographic market exceeds the *Merger Guidelines*' threshold of 1800 indicating a concentrated market and the increase of 222 exceeds the *Merger Guidelines*' threshold of 50 as signifying a significant increase in concentration. *see* Noether, Tr. 5963; *Merger Guidelines* § 1.51.

324. Using the market shares from Noether's proposed geographic market, but recalculated to reflect the Court's defined geographic market, ENH increased its combined market share from approximately 35 to 40% from 1999 to 2002 while the market shares of the four competing hospitals in the geographic market fell from 1999 to 2002. F. 322.

325. In 1999, ENH identified the market share in its combined core service area as: Evanston, 44%; Highland Park, 11%; Lake Forest, 3%; Advocate Lutheran General, 7%; Rush North Shore, 14%; St. Francis, 7%; downtown teaching hospitals, 7%; and other, 7%. CX 84 at 21.

b. Contemporaneous and Post-Acquisition Evidence

326. The direct effects evidence of the ENH merger demonstrates that: (1) ENH achieved substantial price increases as a result of the merger; (2) empirical analysis establishes that ENH prices rose relative to other hospitals; and (3) alternative explanations of price increases are ruled out. F. 327-755.

**(1) ENH Achieved Substantial Price Increases
as a Result of the Merger**

327. The evidence demonstrates that: (a) Evanston and Highland Highland Park sought market power from the merger; (b) ENH sought to increase prices through contract negotiations and chargemaster increases; (c) managed care testimony confirms price

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price increases; and (d) ENH highlighted the managed care price increases as a merger accomplishment. F. 328-468.

**(a) Evanston and Highland Park Sought
Market Power from the Merger**

328. Present and former ENH executives testified that the contemporaneous assessment of the consequences of the merger found in ENH documents is an accurate reflection of contemporaneous discussions in the premerger and post-merger period. Neaman, Tr. 1192-95, 1196-97, 1200, 1203-05, 1207, 1209; Hillebrand, Tr. 1811-12; Spaeth, Tr. 2210-11; Newton, Tr. 369-70, 372-73.

329. ENH's board meeting minutes were reviewed by key personnel, including Neaman, Evanston's CEO, and accurately represented what occurred at the meetings. Attendees were free to speak candidly and honestly. Neaman, Tr. 1192-95.

(i) Evanston

330. Evanston's CEO, Neaman, acknowledged that one of Evanston's goals of the merger with Highland Park was to obtain better prices and better terms on contracts from managed care organizations for ENH. Neaman, Tr. 1036. In the late 1990's, health plans were decreasing rates for hospital services. Neaman, Tr. 1037-38. ENH and Highland Park hoped that the merged entity could strengthen the negotiating position of the hospitals with managed care organizations. Neaman, Tr. 1039; CX 19.

331. In 1998, Evanston's CEO and Highland Park's CEO wrote about the business environment confronting Evanston and Highland Park, stating that: "[p]ricing pressures will escalate on healthcare providers from both government and managed care." CX CX 19 at 1; Neaman, Tr. 1037-38. The recommendations included: included: "[s]trengthen negotiating positions with managed care

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through merged entities and one voice” and “[m]aintain and enhance enhance local community ties for long-term success -- make indispensable to marketplace.” CX 19 at 1; *see also* CX 442 at 4-5; 4-5; CX 2 at 7 “geographic advantages” of merger).

332. At a January 4, 1999 meeting between Evanston and Highland Park board members and medical staff leaders, Evanston representatives identified the opportunity to “strengthen negotiation capability with managed care companies through merged entities” as well as to bring advanced oncology and cardiac surgery to Highland Park. CX 1 at 3 (physician groups should “not compete with self”).

333. The minutes of an April 5, 1999 meeting record an Evanston representative as saying: “[g]rowth was seen as a real benefit to a possible merger. This would be an opportunity to join forces and grow together rather than compete with each other.” CX 2 at 7.

334. In a June 25, 1999 presentation about the proposed merger to Evanston’s board of directors, management reminded the board of the risk of “not undertaking [the] merger.” CX 84 at 58. Skokie Valley Community Hospital, located three miles to Evanston’s south, had been a “sleeping dog” competitor until it affiliated with the Rush system of hospitals, at which point Rush renamed it “Rush North Shore,” invested heavily in the hospital, and the former “sleeping dog” awoke to become a new, strong hospital. Hillebrand, Tr. 1794-97. The point of the story was clear: if Evanston did not act first, the same problem could occur to Evanston’s north, and another hospital system would come in to further strengthen Highland Park. Hillebrand, Tr. 1797.

335. In a September 29, 1999 meeting, Neaman reported to ENH department heads that the addition of Highland Park helps Evanston to “[i]ncrease our leverage, limited as it might be, with the managed care players and help our negotiating posture.” CX 1566 at 9; Neaman, Tr. 1138, *in camera*.

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336. Neaman's November 18, 1999 speech to the board of directors emphasized the same potential to increase leverage and enhance the negotiating posture with managed care players through the merged entity. RX 2015 at ENHL MO 3485.

(ii) Highland Park

337. As early as the fall of 1998, Highland Park leadership "had been approached and approached again by [Evanston]" to discuss the possibility of a relationship between the two institutions. CX 3 at 1.

338. Transcript remarks from a fall of 1998 meeting of Highland Park leadership state that: "[n]obody is able to apply or assemble enough power to deal with managed care areas. An affiliation [with Evanston] would enable [Highland Park] to exploit an area of the market in a meaningful way -- Evanston has a large effect." CX 3 at 1-2.

339. The three merging hospitals would form a triangle and "together would have a significant market penetration in these very affluent, attractive communities." Newton, Tr. 352.

340. Highland Park management foresaw that a merger with Evanston would build "negotiating strength with payers." CX 1869 at 7. Highland Park saw Evanston, Lake Forest, Northwest Community, and Condell as merger candidates, the attractiveness of each turning on "how concentrated could this market be for us." CX 1869 at 6; Newton, Tr. 353-54. Merging with Evanston would build the greatest pricing strength with managed care organizations. Newton, Tr. 349-50.

341. In November 1998, Highland Park responded to Evanston's Evanston's merger proposal. CX 1879 at 1-2. With respect to "competition and signals," Neele Steams, Highland Park's board chairman, recognized that a merger would allow the two health care

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care providers to “[s]top competing with each other.” CX 1879 at 3-3-4.

342. In 1999, Highland Park board members and doctors met to frankly discuss the merger. During this meeting, Spaeth, the president of Highland Park, stated:

[T]he reality in my view is that we are not looking at a rosie future economically on this site. Neither are they [Evanston]. We are not looking at the opportunity to control this market individually. The largest ... payors in this arena have consolidated and are big enough, strong enough, and probably bent on assuring that the physicians who practice here and at Evanston and the institutions don't make a hell of a lot of money. That is the reality and I am not even laying that on the insurers I am laying that on the employers. The same speech I have made over and over.

CX 4 at 1-2; Spaeth, Tr. 2210-11.

343. Spaeth continued by stating:

I think the ultimate benefit to these communities is pretty positive. There are cost economies, there are quality issues, there are ways to at least I think to push back on the managed care phenomenon and get the rates back where they ought to be if you are a big enough concerted enough entity which is important enough to the employers in this community. I think it would be real tough for any of the Fortune 40 companies in this area whose CEOs either use this place or that place to walk from Evanston, Highland Park, Glenbrook, and 1700 of their doctors.

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CX 4 at 2; Spaeth, Tr. 2210-11.

344. At that same meeting, another Highland Park representative expressed concerns regarding “the relative negotiating power of the payors,” which had become an “economic issue” for the hospital. CX 4 at 9; Spaeth, Tr. 2211-12.

345. At that same meeting, there was a comment on “the economic benefit of not being out there doing battle with one another in what will be a common battle ground if you want to call it that.” CX 4 at 1.

346. Another Board member stated: “I’ll tell you can put in the bank now Dr. and that is that the Fortune 40 are gonna win they have the economic power and as long as we maintain the divided front on the provider side you’re gonna get hammered its just economics always work.” CX 4 at 11.

**(b) ENH Sought to Increase Prices Through
Contract Negotiation and Chargemaster
Increases**

347. The record shows that ENH exercised its market power, attained through the merger, to raise prices. At least six mechanisms were employed to raise prices: (1) utilizing the higher Evanston or Highland Park rate until new contracts were negotiated; (2) moving managed care organizations to one contract for all three hospitals; (3) in renegotiating contracts, demanding the higher of Evanston or Highland Park rates plus a premium and discount off rates; (4) increasing discount off charges arrangements; (5) adopting the higher of the Evanston or Highland Park chargemaster prices; and (6) increasing ENH’s chargemaster prices four times in 2002 and 2003. F. 348-391; *see, e.g.*, CX 30 at 1, 3; CX 23 at 2; CX 26 at 1; CX 25 at 9; CX 31 at 1.

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(i) Higher of Evanston or Highland Park Rates Utilized Until New Contracts Negotiated

348. In a September 24, 1999 memorandum, Terry Chan, who was responsible for managed care contracting for Highland Park, compared Evanston and Highland Park inpatient rates, and stated that: “if the merged hospital and physician entities were successful in renegotiating hospital and physician contracts by January 1, 2000, with rates that are more favorable than the current Highland Park or ENH rates, (whichever is higher), there could be great potentials in improving payment rates for both hospitals and physicians.” CX 30 at 3.

349. In December 1999, ENH negotiators sent consent to assignment agreements to managed care organizations authorizing assignment of the higher of the Evanston or Highland Park rates. CX 5900 at 2-7; CX 5901 at 2; CX 5902 at 2, *in camera*.

350. In January 2000, while the status of many contracts was still in limbo, Chan instructed ENH’s billing department to “continue to use the current Highland Park Hospital rates” -- in the instances in which Highland Park had higher rates -- until all of the hospital contracts had been renegotiated. CX 5900 at 1; CX 1373 at 14, *in camera*.

351. Many managed care organizations that did not immediately consent to assign the higher of the two rates across all three hospitals later agreed during the negotiations with ENH. Ballengee, Tr. 174-75; Neary, Tr. 763-64, *in camera*; CX 5900 at 1.

352. “Conver[ting] all payer contracts to the most favorable rates” of the two hospitals was an “Opportunity Ite[m]” for the merged entity that Ernst & Young projected could provide anywhere from \$500,000 to \$1,000,000 in possible revenue enhancements. CX 2386 at 2.

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353. In fact, as of March 2000, converting the payor contracts to the more favorable rates had exceeded ENH's opportunity targets seven-fold. CX 2386 at 2. Ernst & Young's March 2000 update showed that ENH had enhanced its revenue by \$7 million dollars, a figure that was "ongoing." CX 2386 at 2; *see* CX 2234 at 2.

354. One month later, in May 2000, Ernst & Young reported that converting the payor contracts to the more favorable of the Highland Park or Evanston contract had increased ENH's revenue another \$3 million dollars, for a total of \$10 million in revenue enhancements that was "ongoing." CX 23 at 2.

**(ii) Managed Care Organizations Moved
to One Contract for All Three
Hospitals**

355. ENH began managed care contract renegotiations on behalf of both Evanston and Highland Park in the fall of 1999 and continued to the fall of 2000. Chan, Tr. 833-34, *in camera*; Hillebrand, Tr. 1868-69, 1707.

356. Evanston engaged Bain for consulting advice at the time of the merger. Neaman, Tr. 1159. The focus of Bain's 1999 merger consulting work for ENH was "growing net income by leveraging contracting and service line opportunities created by the Highland Park merger." CX 74 at 3. Bain assisted ENH in creating a "unified contracting strategy reflecting the combined entities" of Highland Park and Evanston. CX 66 at 2.

357. Bain representatives themselves helped negotiate certain ENH managed care contracts in the renegotiations relating to the Highland Park merger. Neaman, Tr. 1217-18. Bain issued its final report on the merger project on February 1, 2000. CX 67 at 1.

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358. During the winter of 1999, ENH senior management decided that the merged entity would put the three ENH facilities on the same contract and charge the same rate for all three facilities. Hillebrand, Tr. 1703-04; Newton, Tr. 363-65.

359. ENH demanded and received the same rate for all three facilities regardless of the level or complexity of services provided at each hospital. Foucre, Tr. 890; Ballengee, Tr. 176-77; Neary, Tr. 602; Neary, Tr. 756-60, *in camera*; Dorsey, Tr. 1447-50; CX 262 at 2, *in camera*.

360. Some managed care organizations opposed moving all three of the ENH facilities to the higher rates of the Evanston or the Highland Park contract because they did not value the three facilities equally. Neary, Tr. 603, 606; Holt-Darcy, Tr. 1560-61, *in camera*.

361. ENH presented an “all-or-nothing deal” to managed care organizations, regardless of complexity of services provided at each hospital. Holt-Darcy, Tr. 1528-29, *in camera*; Ballengee, Tr. 176-77; Neary, Tr. 602, Neary, Tr. 756, *in camera*; Dorsey, Tr. 1447-50; CX 262 at 2, *in camera*.

362. Under ENH’s billing system, managed care organizations “can’t distinguish between services at the three hospitals” to determine which services were rendered at a particular hospital in the system. Foucre, Tr. 890-92.

363. Evanston, Glenbrook, and Highland Park do not merit equal reimbursement rates. Dorsey, Tr. 1446-47.

364. ENH successfully moved all three ENH hospitals to the same contract and equalized the charges for all three sites post-merger. *see, e.g.,* { }.

365. ENH’s request to move all three hospitals in its system to one set of rates was unusual for a hospital system in the Chicago

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area. Foucre, Tr. 890-92; *see* Ballengee, Tr. 163-65; Dorsey, Tr. 1445-46; RX 1503 at PHCS 3648, *in camera*; Holt-Darcy, Tr. 1528, 1528, *in camera*.

366. Other hospital systems in the Chicago area differentiate rates based upon the level and complexity of service offerings of each hospital in the system. Foucre, Tr. 890-92; Ballengee, Tr. 163-65; Dorsey, Tr. 1446-47; RX 1503, *in camera*; *see* Holt-Darcy, Tr. 1528-30, *in camera*.

**(iii) Higher of Evanston or Highland Park
Rates Plus a Premium and Discount
Off Rates Demanded**

367. Recognizing ENH's "additional negotiating power and leverage with the payors"—one of the "benefits of the merger"—during the winter of 1999, ENH senior management decided that "the combined entity would use the better of the Highland Park or Evanston [contract rate] and then add a premium to that." Newton, Tr. 364-65; Hillebrand, Tr. 1705; Chan, Tr. 709-10.

368. Bain advised ENH to "sell" ENH's benefits to managed care by: emphasizing "the value ENH brings to a payor's network" such as brand, patient access, cost management, and quality, and to "[j]ustify premium pricing (i.e., above the competitive average)." CX 67 at 49.

369. The merged entity successfully negotiated prices above the premerger rates of either Evanston or Highland Park for numerous payors. Hillebrand, Tr. 1705.

370. Among ENH's "accomplishments" were the renegotiations renegotiations of the United, PHCS, Aetna, Blue Cross Blue Shield, Shield, and Cigna contracts, which collectively resulted in an annualized economic value of \$15 million for ENH (\$3 million per per managed care organization). CX 17 at 5-8. ENH realized an

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additional \$3 million annually from the renegotiation of the Humana Humana contract and from the renegotiation of other smaller PPO contracts combined (\$2 million for Humana and \$1 million for some some “smaller” PPO contracts combined). CX 17 at 5, 8.

371. Evanston “had never achieved” a price increase as high as \$18 million before the merger. Hillebrand, Tr. 1722.

372. Except for losing One Health for a short period of time, ENH lost no managed care organization customers over the course of the 2000 renegotiations. Hillebrand, Tr. 1707-08.

**(iv) Increased Discount Off Charges
Arrangements**

373. Post-merger, ENH succeeded with numerous managed care organizations in negotiating discount off charges arrangements, which were “more favorable” for ENH. CX 1373 at 14, *in camera*; RX 663 at ENHL TC 16939, *in camera*. Fixed rates tend to result in greater discounts – “up to 50%” – than discount off charges. Chan, Tr. 675.

374. As the Unicare representative explained, in discount off charges arrangements, the “hospital sets their own prices,” and managed care organizations “have no control over ... what the services are going to cost in any given admission or service.” Holt-Darcy, Tr. 1522-23, *in camera*.

375. Managed care organizations have no control over a hospital’s chargemaster increases. Neary, Tr. 609; Newton, Tr. 366; Holt-Darcy, Tr. 1522, *in camera*; Foucre, Tr. 898-900, 889; Mendonsa, Tr. 524-28, *in camera*. Under a discount off charges contract, the price that the managed care organization must pay to the hospital increases as the chargemaster list price increases, to the extent that the managed care organization does not negotiate a “ceiling,” such as a maximum or escalator clause. Porn, Tr. 5670.

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376. The merged entity was successful in moving a number of managed care organizations to discount off charges arrangements. Hillebrand, Tr. 1706, 1893; Hillebrand, Tr. 1947, *in camera*; { }

377. A discount off charges arrangement would be even more favorable to the merged entity if “Highland Park Hospital is adopting ENH’s charge master which is expected to generate higher gross charges than gross charges generated by Highland Park Hospital’s current charge master.” RX 663 at ENHL TC 16939, *in camera*.

**(v) Chargemaster Consolidation in 2000
to Higher of Evanston or Highland
Park Charge**

378. As part of the merger integration process, ENH consolidated the Highland Park and Evanston chargemasters in 2000. Hillebrand, Tr. 1710; Porn, Tr. 5643.

379. ENH created a combined chargemaster with the same rates for all three hospitals. Hillebrand, Tr. 1704; Porn, Tr. 5643.

380. In a “fairly simplistic analysis,” ENH examined the chargemasters at the two hospitals and adopted the higher of the Highland Park or Evanston chargemaster rates for each line item. Hillebrand, Tr. 1711, 1714-15; Noether, Tr. 6193; *see* CX 2240 at 11.

381. In January 2000, ENH’s transition team projected the overall increase in gross revenue from combining and increasing the charges at the three hospitals to be at least \$100,000,000. CX 2237 at 1; CX 42 at 2; CX 2462 at 1. Later ENH documents estimated the overall increase in gross revenues at \$100,000,000. CX 2238 at 1; CX 2239 at 1; CX 2384 at 2.

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382. For example, upon completion of merging the chargemaster items related to renal dialysis, that transition team's report reflected ENH's objective: "[h]ighest charge comparing those of EH and HPH utilized on new Charge Master." CX 2383 at 2. For renal dialysis alone, ENH's finance department estimated a \$1,324,497 "revenue enhancement" from selecting the higher of the Highland Park and Evanston rates. CX 2383 at 2.

383. As of September 30, 2000, only nine months after the merger, Neaman reported to ENH's board of directors that ENH's "Unified Pricing Structure" for the chargemaster had already resulted in \$5 million of annualized economic value. CX 2382 at 6.

**(vi) Four Chargemaster Price Increases
Instituted in 2002 and 2003**

384. ENH increased its chargemaster rates four times between 2002 and 2003. RX 1687 at ENHL BW 27653, *in camera*.

385. On April 15, 2002, ENH implemented increases to its chargemaster. These changes were projected to { } CX 45 at 8. This increase had a { } impact on ENH's fee schedule, depending on which estimate is used. CX 44 at 3; CX 45 at 8; RX 1687 at ENHL BW 27653, *in camera*.

386. After ENH raised its chargemaster prices in April 2002, Tom Hodges, ENH's executive vice-president for finance, wrote to ENH managers that "[f]or a number of reasons we want to be as quiet as possible and there are relatively few people who have seen the scope of the changes." CX 44 at 1.

387. According to Hillebrand, for chargemaster increases, "the only notification we make is to Blue Cross." Hillebrand added, "[w]e should not notify anyone beyond those where we have a contractual obligation to do so." CX 54 at 1.

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388. On October 1, 2002, ENH raised prices for its three hospitals by { } RX 1687 at ENHL BW 27653, *in camera*.

389. On June 1, 2003, ENH raised prices for its three hospitals by { } RX 1687 at ENHL BW 27653, *in camera*.

390. On October 1, 2003, ENH raised prices for its three hospitals by { } RX 1687 at ENHL BW 27653, *in camera*.

391. From 2002 to 2003, ENH's four chargemaster increases, taken together, represent a { } increase in the fee schedule. CX 44 at 3; CX 45 at 8; RX 1687 at ENHL BW 27653, *in camera*.

**(c) Managed Care Testimony Confirms
Price Increases**

392. Managed care representatives from United, PHCS, One Health (Great West), Aetna, and Unicare testified about their experiences negotiating contracts with the combined ENH entity. *see* F. 393-456.

(i) United

393. United, which was the second largest managed care organization in the Chicago area, had various contracts throughout the 1990's with both Evanston and Highland Park under the names of United affiliates including Share, Metlife, Metropolitan Life, Chicago HMO, Travelers, and MetraHealth. CX 5910 at 36-42; Hillebrand, Tr. 1868.

394. Before the merger in 2000, Highland Park and Evanston representatives formulated a strategy for the renegotiation of a contract with United. Hillebrand, Tr. 1873-74; Chan, Tr. 834, *in camera*.

395. Bain identified the United contract as a "1st Priority" contract with "upside revenue potential" for which the merged entity

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entity had “enough leverage to improve terms.” CX 75 at 9-10; CX CX 74 at 10. Bain advised ENH that United reimbursed Evanston 45 to 50% less than it paid Highland Park. Hillebrand, Tr. 1869; RX RX 684 at BAIN 44, *in camera*. Moreover, Bain informed Evanston Evanston that its outdated contract with United had cost the hospital hospital \$30 million over the preceding five years. Hillebrand, Tr. 1870; Neaman, Tr. 1340-41; RX 684 at BAIN 73, *in camera*; Haas-Haas-Wilson, Tr. 2851-52, *in camera*.

396. The negotiations resulted in { } Foucre, Tr. 890; CX 5174 at 11-12, *in camera*.

397. The United contract expired at the end of 2002. CX 5174 at 7. If neither party provided written notice of termination, then the contract renewed automatically for successive one-year terms. CX 5174 at 7. A separate provision of the contract allowed United to terminate the agreement at any time upon 90 days written notice if ENH’s standard charges increased by more than 6%. CX 5174 at 7.

398. In 2002, United stated that the merger had enabled ENH to “dominat[e] Chicago’s north shore, providing the only hospital locations ... ranging between Evanston and Highland Park, as well as a significant stretch of territory moving inland” and noting “the strategic importance of ENH’s geographic exclusivity.” CX 21 at 5.

399. In August 2002, United requested a renegotiation of United’s contract with ENH because, since the 2000 contract, ENH had been an “outlier” hospital with “much higher than the average reimbursement.” Foucre, Tr. 888.

400. United was concerned in part because the 2000 contract relied primarily on a discount off charges payment methodology, resulting in higher and higher reimbursements from United, which witnessed “alarmin[g] escalating costs in [ENH’s] billed charges” that were “outside of the norms for the market.” Foucre, Tr. 898, 889.

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401. In 2002, after exchanging proposals and counter-proposals a second time, United had made no progress towards achieving any of its business goals and considered terminating its existing contract with ENH. Foucre, Tr. 898-900.

402. United was also concerned that in 2002, “from quarter to quarter, the [chargemaster] increases were still occurring. It was not a one-time event.” Foucre, Tr. 1091, 1093, 1096, *in camera*; CX 2381 at 4, *in camera*; CX 6277 at 3, *in camera*.

403. { } Foucre, Tr. 1103-04, *in camera*.

404. Having had no success in lowering ENH’s prices, United pursued the more modest goal of asking ENH to stop increasing prices so much. Foucre, Tr. 906-09. { } CX 426 at 1, *in camera*.

405. The new contract between ENH and United was signed on April 14, 2004, with an effective date of June 1, 2004. Foucre, Tr. 887-88; CX 5176 at 1, 12.

406. { } Foucre, Tr. 1103, *in camera*.

407. { } Foucre, Tr. 1103-04, *in camera*.

408. Even today, with Lake Forest, Rush North Shore, St. Francis, and other neighboring hospitals in their network, United believes it cannot satisfy its customers without ENH. Foucre, Tr. 901-02, 925-26, 931-34.

(ii) PHCS

409. Prior to the merger, PHCS obtained competitive pricing from Evanston and Highland Park because PHCS “could choose

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between the two and work them against each other.” Ballengee, Tr. 167.

410. On December 1, 1999, ENH notified PHCS of the impending merger and sought to assign Highland Park’s rates. CX 171 at 1. In response to that letter, PHCS wanted to renegotiate the rates. CX 1539 at 2; CX 172 at 1.

411. Bain advised ENH that it had “significant leverage in negotiations with PHCS as they have strong North Shore presence and need us in their network.” CX 1998 at 44. Bain indicated that Highland Park’s premerger terms with PHCS were significantly more favorable than Evanston’s terms. Hillebrand, Tr. 1892-93; RX 684 at BAIN 43, *in camera*.

412. ENH justified the request for an increase by indicating that it was one system which controlled the marketplace. Ballengee, Tr. 176-77, 194.

413. The “best scenario” for PHCS customers, strictly looking at dollars, was to eliminate ENH and redirect enrollees to the surrounding hospitals, such as Lake Forest, Advocate Lutheran General, and St. Francis. Ballengee, Tr. 244-48, *in camera*; CX 46 at 1, *in camera*.

414. PHCS believed, however, that customers did not want to “buy the network if they did not have [ENH in] it.” Ballengee, Tr. 181, 183-84.

415. PHCS states in contemporaneous documents that ENH’s proposal had a rate structure similar to Highland Park’s premerger contract and that PHCS’s goal was contract terms between Evanston and Highland Park’s previous terms. CX 115 at 1.

416. PHCS had previously eliminated the University of Chicago from its network and relied instead on the other teaching hospitals. Ballengee, Tr. 155.

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417. As an inducement to ENH, PHCS offered to exclude from its network hospitals like St. Francis, Rush North Shore, and Condell in return for lower prices. Ballengee, Tr. 178-79, 181-82. ENH declined the offer, except to offer a nominal discount for the exclusion of Advocate Lutheran General. Ballengee, Tr. 182; Hillebrand, Tr. 1746-47.

418. PHCS agreed to the { } CX 117 at 1, *in camera*; CX 5072 at 23, *in camera*; Ballengee, Tr. 252, 255, *in camera*; Hillebrand, Tr. 1893; CX 116 at 2, *in camera*. { } Ballengee, Tr. 258-61, *in camera*; CX 5072 at 23, *in camera*; CX 117 at 1, *in camera*.

419. PHCS negotiated more favorable terms than it had with Highland Park before the merger, although the rates were significantly higher than its premerger contract with Evanston. Ballengee, Tr. 175-76.

(iii) One Health (Great West)

420. Great West Healthcare (“Great West”) was formerly known as One Health. Neary, Tr. 581.

421. In December 1999, ENH contacted One Health to request the renegotiation of its hospital contract. Neary, Tr. 595.

422. Bain noted the “substantial difference” between One Health’s Highland Park and Evanston rates. CX 75 at 9-10; Neary, Tr. 604. Bain advised ENH to “[a]chieve [Highland Park] terms or better” in its negotiations with One Health. CX 1998 at 43.

423. Having last renegotiated the Highland Park and Evanston contracts in 1996 and 1995, respectively, One Health “agreed that it had been several years since the contracts had been renegotiated and that it was appropriate to ... increase some of the rates.” Neary,

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Neary, Tr. 608. One Health-was willing to give a price increase { }
 } Neary, Tr. 762-63, *in camera*; CX 2085 at 1-6, *in camera*.

424. In the first half of 2000, ENH and One Health did not reach an agreement on the renegotiation of the PPO and HMO contracts. Neary, Tr. 598, 609-10; Dorsey, Tr. 1438. One Health accepted ENH's notice of termination. CX 266 at 1.

425. One Health's contract with ENH terminated on August 31, 2000. Neary, Tr. 610-11; Hillebrand, Tr. 1707-08, 1898; CX 5062 at 1.

426. One Health made provisions for women "who were in the third trimester of pregnancy" at the time of the contract termination. Neary, Tr. 619-20. While One Health was able to negotiate a continuation of benefits for those expecting mothers, ENH charged the health plan rates that were higher than contract rates that were in place under the 1996 premerger One Health contract. Neary, Tr. 620, 637; CX 5063 at 1.

427. One Health customers complained about not having access to ENH, although One Health pointed to Lake Forest, Northwest Community, Advocate Lutheran General, Rush North Shore, and St. Francis as substitutes. Dorsey, Tr. 1451-52, 1459; Neary, Tr. 611, 617.

428. In the months following the termination of the ENH contract, One Health's monthly membership reports began to reflect a "loss of membership within [the] network." Dorsey, Tr. 1452, 1488; Neary, Tr. 617.

429. Before discussions between ENH and One Health resumed resumed in early October 2000, Great West received a written notice notice of termination, effective December 31, 2000, from Lake Forest and its medical group. RX 949; RX 950. Since Lake Forest was the primary alternative to Highland Park, it would have been "very problematic" for Great West to have lost Lake Forest from the

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the network at the same time Great West had no contract with ENH. ENH. Dorsey, Tr. 1484.

430. One Health returned to ENH prepared to accede “essentially regardless of what the ultimate price was.” Neary, Tr. 618-19; Dorsey, Tr. 1439-42.

431. One Health accepted a new agreement with an effective date of January 1, 2001. Dorsey, Tr. 1439-42; CX 5067 at 4; CX 266 at 1.

432. { } Hillebrand, Tr. 1947, *in camera*; compare CX 5067 at 15, *in camera*, CX 5059 at 17, and CX 5065 at 17.

433. { } Neary, Tr. 765-66, *in camera*; Hillebrand, Tr. 1944, *in camera*; CX 5064 at 17, *in camera*.

(iv) Aetna

434. Aetna “would have walked away” from Evanston if faced with a significant price increase before the merger. Mendonsa, Tr. 530, *in camera*. “[T]here probably would have been a walk-away point with the two independently. But with the two together, that was a different conversation.” Mendonsa, Tr. 520, *in camera*.

435. With the merger of “three extremely important hospitals negotiating together in a very important geography,” Aetna was “extremely concerned.” Mendonsa, Tr. 530, *in camera*.

436. Bain identified Highland Park’s rates for Aetna’s PPO and POS products as higher than Evanston’s rates for those products. RX 762 at ENHL TC 9936, *in camera*. Evanston’s contract with Aetna was nearly four years old in November 1999, so Bain recommended renegotiation of the Aetna contract as a priority. CX 75 at 10; CX 5001 at 2.

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437. Aetna had not renegotiated its contract with Evanston since 1996 and expected ENH to make a proposal to renegotiate. Based on the 3% increase per year in Medical CPI between 1996 and 1999, Aetna calculated an appropriate increase compounded over three years to be { } Mendonsa, Tr. 533-34, *in camera*.

438. During the 2000 negotiations, ENH originally sought a discount off charges arrangement for PPO and POS plans. Hillebrand, Tr. 1896; RX 769 at ENH JL 2818-19, *in camera*. Aetna, however, did not agree to that payment methodology. Hillebrand, Tr. 1896.

439. ENH and Aetna ultimately agreed { } CX 5008 at 5-6, *in camera*; Hillebrand, Tr. 1896.

440. { } RX 855 at ENHL BW 11393, *in camera*; CX 5007 at 5. { } CX 5008 at 7, *in camera*.

441. Aetna agreed { } Mendonsa, Tr. 539, *in camera*; Hillebrand, Tr. 1948, *in camera*; CX 2447 at 1, *in camera*.

442. Aetna's increased rates under the post-merger contract with ENH became effective June 1, 2000. CX 5008 at 1.

443. { } Mendonsa, Tr. 561, 573, *in camera*.

444. { } Mendonsa, Tr. 544, 568-69, *in camera*.

445. { } Mendonsa, Tr. 517-18, 530, *in camera*.

446. Aetna believed it "couldn't walk away" from post-merger ENH because it would have "devastated us," "killed our marketing," and "shut down" Aetna's marketing to local employers. Mendonsa, Tr. 518, 520, 530, *in camera*.

(v) Unicare

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447. In 2000, Unicare acquired Rush Prudential, another managed care organization. Holt-Darcy, Tr. 1413. Prior to the merger, Rush Prudential had contracted with both Evanston and Highland Park, and Unicare had contracted with Evanston. Holt-Darcy, Tr. 1505-06, *in camera*.

448. { } Holt-Darcy, Tr. 1549-50, 1598, 1599-1601, *in camera*; CX 216 at 1; CX 5085 at 1; CX 5091 at 1.

449. With the merger, ENH proposed an unusual “all-or-nothing deal” in which there would be one rate for all three hospitals, regardless of the level of services at each facility – like the “Three Musketeers, all for one and one for all.” Holt-Darcy, Tr. 1529, *in camera*.

450. { } CX 215 at 1; CX 216 at 15, *in camera*; CX 5076 at 10; CX 5085 at 1; CX 5091 at 1. { } CX 124 at 2-3, *in camera*. { } Holt-Darcy, Tr. 1570-72, *in camera*.

451. Even if Unicare representatives had expected an increase in ENH contract rates after the merger – which they did not – the rates proposed by ENH in 2000 were above what Unicare considered to be a “reasonable” increase, { } Holt-Darcy, Tr. 1503-04, *in camera*. { } Holt-Darcy, Tr. 1504 *in camera*.

452. The result for Unicare { } Holt-Darcy, Tr. 1537, 1541, 1564, *in camera*.

453. { } Holt-Darcy, Tr. 1543, *in camera*. { } Holt-Darcy, Tr. 1542-43, *in camera*.

454. { } CX 5075 at 17-18, *in camera*; Holt-Darcy, Tr. 1582, *in camera*.

455. According to Unicare, ENH had indicated that it could obtain higher prices because it had “a lot more leverage now that

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they have three hospitals in their service area” and ENH had a “stronger presence” in the area, meaning ENH had “basically sewn up the North Shore geography.” Holt-Darcy, Tr. 1546, 1559-1559-60, *in camera*; CX 129 at 1, *in camera*.

456. Unicare would be in a bind without ENH, now a “key provider” in the North Shore. Holt-Darcy, Tr. 1552-53, *in camera*. ENH’s “contiguous service area” made it “hard, painful, for customers to *see* [ENH] leave the network.” Holt-Darcy, Tr. 1603, *in camera*.

**(d) ENH Highlighted the Managed Care
Price Increases as a Merger
Accomplishment**

457. In his January 6, 2000 update to the ENH executive committee, Hillebrand reported that “as a result of combining the medical staffs and Hospitals of the merger, [ENH] was able to re-negotiate a managed care contract that resulted in an additional \$3.5 million benefit” and that “other managed care contracts will be renegotiated over the next 100 days.” CX 5 at 5; Newton, Tr. 369-70.

458. The February 3, 2000 ENH board meeting minutes state: “Hillebrand commented on the recent re-renegotiation of managed care contracts and the ‘added value’ as a result of combining the medical staffs and hospitals. Other managed care contracts are in the process of being re-negotiated.” CX 6 at 7.

459. On March 14, 2000, Hillebrand drafted ENH’s 2001-2003 Strategic Plan. In the draft of the Strategic Plan, Hillebrand stated:

Through our growth initiatives, we will expand our presence in our marketplace in order to provide leverage to our market position as we negotiate relationships with the purchasers of care. Our goal

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will be to receive superior pricing for our services and to become indispensable to the purchaser of care care as they sell their product in our marketplace.

CX 2070 at 3.

460. The June 16, 2000 Highland Park health care services committee meeting minutes state:

Neaman reviewed the list of merger accomplishments. Important successes have been accomplished in managed care contracting. There has been a \$12 million improvement on the Hospital side and \$8 million to physicians' practices to date. The total improvements as a result of the merger are \$29.5 million, which greatly exceeds the Board approved \$19 million goal over three years.

CX 12 at 2.

461. On July 3, 2000, Neaman issued a memorandum with the subject "July 4, 2000 -- Interdependence Day" which summarized the first six months since the merger. In the memorandum, Neaman stated:

The major economic accomplishments in June were the successful re-negotiation of two of our HMO agreements..., that will collectively produce some \$6 million of additional revenues on an annualized basis. This brings the total managed care re-negotiation benefits to some \$16 million/year to the Institution. This figure does not include some \$10 million+ additional managed care monies going to our physicians.

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CX 13 at 1; CX 12 at 2; Neaman, Tr. 1200.

462. In the July 3, 2000 “Interdependence” memorandum, Neaman stated:

As we begin the July 4th holiday, it is safe to say that our success in the merger integration effort is not a product of our “independence,” but of our “interdependence.” Neither Evanston nor Highland Park alone could achieve these results. Our three Hospitals, together with our 1500 physicians as a “fighting unit,” appear to have helped provide at least a small advantage for an interim period.

CX 13 at 1.

463. At a September 27, 2000 meeting of the ENH board’s finance committee, Neaman emphasized the link between the merger and the managed care renegotiations. Neaman stated that “the larger market share created by adding Highland Park Hospital has translated to better managed care contracts.” CX 16 at 1.

464. Neaman’s October 2, 2000 “Final Report – Merger Integration Activities” memorandum to the ENH board reported that: “Some \$24 million of revenue enhancements have been achieved – mostly via managed care renegotiations. (This figure does not include some \$13 million of additional managed care revenues to participating physicians.) Our net income from operations will go from a budgeted \$4 million to in excess of \$20 million for Fiscal Year 2000.” CX 17 at 1. In addition, “[s]ome \$12 million of cost improvements have been achieved -- mostly from corporate overhead areas.” CX 17 at 1.

465. Neaman’s October 2, 2000 Report reiterated: “As stated previously, none of this could have been achieved by either Evanston or Highland Park alone. The ‘fighting unit’ of our three

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hospitals and 1600 physicians was instrumental in achieving these ends.” CX 17 at 2.

466. None of the initial post-merger price increases obtained by ENH from health plans were reduced in subsequent years, with the exception of a { } Hillebrand, Tr. 1709-10, 1725-26; Neaman, Tr. 960-61, 1269-71.

467. Highland Park could not have raised its prices to health plans absent the merger. According to Chan, all the rates Highland Park had in place in July 1, 1999, were the best that Highland Park could accomplish at that time without threatening termination. Chan, Tr. 820, *in camera*; CX 1099, *in camera*.

468. Spaeth also testified that at the time of the merger Highland Park would not have been successful in raising its rates because the hospital could not sustain a strategy where it kept losing contracts. Spaeth, Tr. 2178-79. Spaeth did not see an opportunity to raise the rates before the merger. Spaeth, Tr. 2172-73.

**(2) Empirical Analysis Establishes that ENH
Prices Rose Relative to Other Hospitals**

(a) Introduction to the Data and Methodology

469. Complaint Counsel’s economic expert, Dr. Deborah Haas-Haas-Wilson, Professor of Economics at Smith College, used four different data sources in her empirical analysis to examine whether whether prices increased at ENH after the merger. The four data sources were: (1) managed care claims data; (2) data from the Universal Dataset from the Illinois Department of Public Health (“IDPH Universal Dataset”); (3) data from the economic consulting consulting firm NERA, submitted to the FTC on behalf of ENH; and

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and (4) data submitted directly by ENH in response to an FTC Civil Civil Investigative Demand (“CID”). Haas-Wilson, Tr. 2495-500.

470. As Noether indicated, however, “there were a number of problems with the data that made the measure of price certainly less than fully accurate.” Noether, Tr. 6051, *in camera*.

471. Noether concluded that analysis of the claims data could be used in “forming [her] opinion and reaching [her] conclusions,” but should be considered “in the context of all the other evidence in the case.” Noether, Tr. 6052, *in camera*.

472. Haas-Wilson also noted the strengths and weaknesses of the four data sources and indicated that she had to “process the data to get it into a form that you can actually use for research.” Haas-Wilson, Tr. 2496-500.

473. Haas-Wilson found that, regardless of the data source that is used or the methodology used to “clean” or manipulate the data, all the evidence shows that following the merger with Highland Park, ENH raised the prices of inpatient acute care hospital services to managed care organizations. Haas-Wilson, Tr. 2500-01.

474. While all experts agree that ENH experienced relative price increases in the 2000 time frame, Respondent’s economic expert, Dr. Jonathan B. Baker, Professor of Law at American University and Senior Consultant, Charles River Associates, contends that the relative price increases were smaller than those calculated by Haas-Wilson. Baker, Tr. 4617-20, 4646, 4795-96, *in camera*; Haas-Wilson, Tr. 2637, *in camera*.

475. Haas-Wilson, further, concluded that the merger eliminated the competition between the two competitors by excluding an alternative provider available to managed care organizations. Haas-Wilson, Tr. 2472-73.

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(i) Relative Price Changes, Not Relative Prices, Is the Appropriate Methodology to Test for Market Power

476. Hospital services are a differentiated product. Haas-Wilson, Tr. 2492-93; Noether, Tr. 5910. Consumers are willing and able to pay higher prices for certain aspects of product differentiation. Because prices can vary in the market for a differentiated service for many different reasons, one may not conclude anything about market power by merely using a cross-sectional analysis of hospital prices at a single point in time. Haas-Wilson, Tr. 2492-93.

477. In contrast, by looking at price changes over time, one can compare the price change at one hospital to the price change at another hospital. Using such an approach, one can conclude that there is a change in market power if there is a price increase after having ruled out the other possible explanations for greater price increases at one hospital versus another. Haas-Wilson, Tr. 2495.

478. Whether ENH's prices increased faster than other hospitals is determined by using a methodology called difference in differences. The first step in the difference in differences analysis is to calculate the difference in price at ENH by subtracting the premerger price at ENH from the post-merger price at ENH, and calling that the "ENH difference." Haas-Wilson, Tr. 2546-47, *in camera*.

479. The second step in the difference in differences analysis is to repeat the process for the comparison hospitals. The difference for the comparison hospitals is called the "control group difference." Haas-Wilson, Tr. 2546-47, *in camera*.

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480. The third step in the difference in differences analysis is to take each difference as the percent of the premerger price, and then examine whether or not the ENH post-merger percentage increase in price is the same or different than the control group post-merger percentage increase in price. Haas-Wilson, Tr. 2546-48, *in camera*.

(ii) Control Groups

481. Haas-Wilson used three control groups: (1) all general acute care hospitals in the Chicago Primary Metropolitan Statistical Area (“PMSA”) (the “Chicago PMSA Hospitals” control group); (2) all general acute care hospitals in the Chicago PMSA, that were not involved with a merger with another hospital between 1996 and 2002 (the “Non-Merging Chicago PMSA Hospitals” control group); and (3) all the general acute care hospitals in the Chicago PMSA that were involved in some teaching activity during the study period (the “Chicago PMSA Teaching Hospitals” control group). Haas-Wilson, Tr. 2548-49, *in camera*.

482. Using multiple control groups provides a “specifications test,” so that if one finds similar results using multiple control groups, that gives one increased confidence in the results. Haas-Wilson, Tr. 2549, *in camera*.

483. It is important that the hospitals in the control groups experience similar changes in cost, regulation, and demand. Haas-Wilson, Tr. 2548, *in camera*.

484. The first control group, the Chicago PMSA Hospitals control group, was chosen because those hospitals should be subject to similar changes in costs, demand, and regulation as ENH. Haas-Wilson, Tr. 2549, *in camera*.

485. The second control group, the Non-Merging Chicago PMSA Hospitals control group, was selected because theory and

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empirical work suggest that cost and pricing might be different at hospitals involved with mergers versus those that are not involved with mergers. Haas-Wilson, Tr. 2549-50, *in camera*.

486. The third control group, the Chicago PMSA Teaching Hospitals control group, was selected because empirical literature suggests that costs and therefore prices might be different at hospitals that are engaged in teaching activity versus those that are not. Haas-Wilson, Tr. 2550, *in camera*. The “Teaching Hospital” control group ended up including nearly fifty hospitals, half of the hospitals in the Chicago PMSA. Noether, Tr. 6110-11, *in camera*.

487. Haas-Wilson rejected the concept of picking hospitals that “looked like” Evanston to use as her control group, because this would have required making arbitrary decisions on which neither theory nor previous empirical work provided guidance. Haas-Wilson, Tr. 2550-51, *in camera*.

488. Any attempt to match hospitals with ENH to form a control group that “looked like” ENH would have to account for the fact that Evanston and Highland Park had different characteristics premerger. A control group that looked like Evanston may not be the appropriate control group to compare post-merger Evanston and Highland Park. Haas-Wilson, Tr. 2550-51, *in camera*.

489. Haas-Wilson’s results were statistically significant. The term “statistically significant” is a term from statistics and econometrics that indicates how much confidence one has in the results of one’s hypothesis test or how much confidence one has in the conclusions one makes based on those results. Haas-Wilson, Tr. 2553, *in camera*.

490. Statistical significance is expressed as levels of significance. One discusses the 1% level or a 5% level or a 10%

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level, where a 1% level would be the highest level of significance. A 5% or 10% level are also quite high levels of significance, but not as high as a 1% level of significance. Haas-Wilson, Tr. 2553-54, 2553-54, *in camera*.

**(b) Claims Data Submitted by Managed
Care Organizations**

491. Although seven managed care organizations produced claims data, the data was only usable for four managed care organizations: United, Blue Cross Blue Shield, Aetna, and Humana. Haas-Wilson, Tr. 2510, *in camera*; Noether, Tr. 6049-50, 6094, 6074, 6055, 6069, *in camera*.

492. The managed care claims data was collected not for research, but to enable managed care insurers to pay hospitals. Therefore, the data had to be processed into a usable form. Haas-Wilson, Tr. 2497-99; *see also* Noether, Tr. 6052-53, *in camera* (data came in a disaggregate fashion).

493. In addition, Haas-Wilson analyzed data from One Health. However, she admitted that this data “does not allow me to look at the total reimbursement to the hospital for inpatient care. It includes only the amount paid to the hospital by the insurance company. It does not include any individual consumer co-pay.” Haas-Wilson, Tr. 2576, *in camera*. Thus, the data could not be compared to the data provided by the other managed care organizations. Haas-Wilson, Tr. 2576-77, *in camera*.

494. The claims data received from One Health does not contain any pre-2000 data points. Noether, Tr. 6050, *in camera*. Haas-Wilson did not testify regarding what time period she used for the premerger period for One Health. Haas-Wilson, Tr. 2511-12, *in camera* (discussing DX 7010). Thus, it is not clear what time period was used by Haas-Wilson to perform her analysis and the One Health data is found to be unreliable.

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495. Haas-Wilson analyzed the managed care claims data by type of plan within payor. According to economic theory and institutional relationships, there was more potential for price increases at some types of plans relative to other types of plans. In particular, when a plan has a more narrow network (including fewer hospitals) that gives the managed care organization a better bargaining position, because there are fewer hospitals in the network and it is easier to exclude hospitals from the network. Haas-Wilson, Tr. 2510-11, *in camera*.

496. Haas-Wilson acknowledged that managed care organizations negotiate trade-offs pertaining to the various plans – *e.g.*, a lower price for the HMO plan in return for a higher price for the PPO plan, and vice versa. Haas-Wilson, Tr. 2853, *in camera*; Mendonsa, Tr. 557, *in camera*; Holt-Darcy, Tr. 1541, 1586-87, *in camera*; Hillebrand, Tr. 1861-62, 2019; RX 844 at ENH JL 2023, *in camera*.

497. The premerger time period varied with each payor, because it was calculated from the beginning of 1998 through the contract effective date (“CED”) of the first contract negotiated by ENH with that payor after the merger. Haas-Wilson, Tr. 2511, *in camera*.

498. Haas-Wilson concluded that “for most payers and plans there were large post-merger price increases at ENH.” Haas-Wilson, Tr. 2518, 2524-25, *in camera*.

(i) United

499. The premerger period for United is from the { } The post-merger period for United is { } Haas-Wilson, Tr. 2511-12, *in camera*.

500. The United data had some limitations including only a sparse number of cases premerger. Baker, Tr. 4621-22, *in camera*. In

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In addition, there were more mothers than newborns in the obstetrics obstetrics claims data, which was about 40% of the claims (the “missing baby” problem). Haas-Wilson used the data as provided while Noether added in babies to make up for the “missing baby” problem. Baker, Tr. 4625-26, 4628, 4806-07, *in camera*; Noether, Tr. Tr. 6053-55, *in camera*. Professor Baker could not fully correct the the obstetrics problem, so he performed his analysis two ways, including obstetrics and excluding obstetrics. Baker, Tr. 4628, *in camera*.

501. Haas-Wilson calculated the post-merger increase in inpatient price per day and per case. She then compared these results to the three control groups. Haas-Wilson, Tr. 2557-59, 61-62, *in camera*; CX 6279 at 3, 8-9, *in camera*.

502. The results are statistically significant unless otherwise noted. CX 6279 at 8-9, 19, *in camera*.

(aa) MO/HMO+

503. For United HMO/HMO+ patients, the post-merger increase in inpatient price per day was { } This means that, according to United’s data, the average price per day across United HMO/HMO+ patients at ENH in the post-merger period was { } more than the average price per day across United HMO/HMO+ patients at Evanston in the premerger period. Haas-Wilson, Tr. 2516, *in camera*; CX 6279 at 3, *in camera*.

504. For United HMO/HMO+ patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2516, *in camera*; CX 6279 at 3, *in camera*.

505. For United’s HMO/HMO+ plan, the price increase at ENH ENH in the price per day was { } greater than the average price price increase across all Chicago PMSA Hospitals. *see* CX 6279 at at 8, *in camera*. For United’s HMO/HMO+ plan, the price increase increase at ENH in the price per case was { } greater than the

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average price increase across all Chicago PMSA Hospitals. *see* CX 6279 at 9, *in camera*.

506. For United's HMO/HMO+ plan, the price increase at ENH in the price per day was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *see* CX 6279 at 8, *in camera*. For United's HMO/HMO+ plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *see* CX 6279 at 9, *in camera*.

507. For United's HMO/HMO+ plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *see* CX 6279 at 8, *in camera*. For United's HMO/HMO+ plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *see* CX 6279 at 9, *in camera*.

(bb) POS/EPO

508. For United POS/EPO (exclusive provider organizations) patients, the post-merger increase in inpatient price per day was { } Haas-Wilson, Tr. 2516, *in camera*; CX 6279 at 3, *in camera*.

509. For United POS/EPO patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2516, *in camera*; CX 6279 at 3, *in camera*.

510. For United's POS/EPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For United's POS/EPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *see* CX 6279 at 9, *in camera*.

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511. For United's POS/EPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For United's POS/EPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

512. For United's POS/EPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For United's POS/EPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

(cc) PPO/Indemnity

513. For United PPO/Indemnity patients, the post-merger increase in inpatient price per day was { } Haas-Wilson, Tr. 2516-17, *in camera*; CX 6279 at 3, *in camera*.

514. For United PPO/Indemnity patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2516-17, *in camera*; CX 6279 at 3, *in camera*.

515. For United's PPO/Indemnity plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For United's PPO/Indemnity plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* Haas-Wilson, Tr. 2558-59, *in camera*; CX 6279 at 9, *in camera*.

516. For United's PPO/Indemnity plan, the price increase at ENH in the price per day was { } greater than the average price

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price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For United's PPO/Indemnity plan, the price increase at ENH in the price per case was { } greater than the the average price increase across Non-Merging Chicago PMSA Hospitals. *See* Haas-Wilson, Tr. 2561-62, *in camera*; CX 6279 at 9, *in camera*.

517. For United's PPO/Indemnity plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For United's PPO/Indemnity plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* Haas-Wilson, Tr. 2561-62, *in camera*; CX 6279 at 9, *in camera*.

(dd) Summary

518. With respect to the United data, Haas-Wilson concluded from her regression analysis that the price increases at ENH were larger than the price increases at comparison hospitals, and that was true no matter how she measured resource intensity or which comparison group she used. Haas-Wilson, Tr. 2626-28, *in camera*; CX 6279 at 19, *in camera*.

519. For United, since the regression results take into account variations in patient mix, customer mix, and teaching intensity across hospitals over time, changes in these variables cannot explain all of the relatively larger price increases at ENH in the post-merger period compared to control group hospitals. Haas-Wilson, Tr. 2627-28, *in camera*; CX 6279 at 19, *in camera*.

520. For United, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases

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increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

521. For United, using the control group of Non-Merging Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

522. For United, using the control group of Chicago PMSA Teaching Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

(ii) Aetna

523. The premerger period for Aetna is from { } The post-merger period for Aetna is from { } Haas-Wilson, Tr. 2512, *in camera*.

524. The results are statistically significant unless otherwise noted. CX 6279 at 8-9, 19, *in camera*.

(aa) HMO

525. For Aetna HMO patients, the post-merger increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

526. For Aetna HMO patients, the post-merger increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

527. For Aetna's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Aetna's HMO plan, the price increase at ENH in the price per

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case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

528. For Aetna's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Aetna's HMO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

529. For Aetna's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For Aetna's HMO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

(bb) PPO

530. For Aetna PPO patients, the post-merger increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

531. For Aetna PPO patients, the post-merger increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

532. For Aetna's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Aetna's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

533. For Aetna's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across

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across Non-Merging Chicago PMSA Hospitals. This result is not statistically significant. *See* CX 6279 at 8, *in camera*. For Aetna's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

534. For Aetna's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. This result is not statistically significant. *See* CX 6279 at 8, *in camera*. For Aetna's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

(cc) Summary

535. For Aetna, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 18, *in camera*.

536. For Aetna, using the control group of Non-Merging Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 18, *in camera*.

537. For Aetna, using the control group of Chicago PMSA Teaching Hospitals, and taking into account changes in patient mix, customer mix and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 18, *in camera*.

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(iii) Humana

538. The premerger period for Humana is from { } The post-merger period for Humana is from { } Haas-Wilson, Tr. 2511-12, *in camera*.

539. Haas-Wilson excluded payments under capitated plans from her analysis. Haas-Wilson, Tr. 2853, *in camera*; Noether, Tr. 6076-77, *in camera*. { } Noether, Tr. 6076, *in camera*.

540. These results are statistically significant unless otherwise noted. CX 6279 at 8-9, 19, *in camera*.

(aa) ASO

541. For Humana ASO (administrative services only) patients, the post-merger percentage increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

542. For Humana ASO patients, the post-merger increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

543. For Humana's ASO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's ASO plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

544. For Humana's ASO plan, the price increase at ENH in the the price per day was { } greater than the average price increase increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's ASO plan, the price increase at at ENH in the price per case was { } greater than the average price

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price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

545. For Humana's ASO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's ASO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

(bb) HMO

546. For Humana HMO patients, the post-merger increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

547. For Humana HMO patients, the post-merger increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

548. For Humana's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's HMO plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

549. For Humana's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's HMO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. This result is not statistically significant. *See* CX 6279 at 9, *in camera*.

550. For Humana's HMO plan, the price increase at ENH in the price per day was { } greater than the average price increase

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increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's HMO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

(cc) PPO

551. For Humana PPO patients, the post-merger increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

552. For Humana PPO patients, the post-merger increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

553. For Humana's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

554. For Humana's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 9, *in camera*.

555. For Humana's PPO plan, the price increase at ENH in the price per day was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 8, *in camera*. For Humana's PPO plan, the price increase at ENH in the price per case was { } greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 9, *in camera*.

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(dd) Summary

556. With respect to the Humana data, Haas-Wilson concluded from her regression analysis that the price increases at ENH were larger than the price increases at comparison hospitals, and that was true no matter how she measured resource intensity or which comparison group she used. Haas-Wilson, Tr. 2626-27, *in camera*; CX 6279 at 19, *in camera*.

557. For Humana, since the regression results take into account variation in patient mix, customer mix, and teaching intensity across hospitals over time, changes in these variables cannot explain all of the relatively larger price increases at ENH in the post-merger period compared to control group hospitals. Haas-Wilson, Tr. 2626-27, *in camera*; CX 6279 at 19, *in camera*.

558. For Humana, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

559. For Humana, using the control group of Non-Merging Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

560. For Humana, using the control group of Chicago PMSA Teaching Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were { } greater than at the average control group hospital. *See* CX 6279 at 19, *in camera*.

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(iv) Blue Cross Blue Shield

561. Blue Cross Blue Shield of Illinois (“Blue Cross Blue Shield”) is the largest insurer in Chicago and accounts for approximately 20% of ENH’s managed care business. Foucre, Tr. 939; Hillebrand, Tr. 1859; Mendonsa, Tr. 481.

562. ENH had less leverage to increase its prices in contract negotiations with Blue Cross Blue Shield than with other payors. CX 67 at 36; Neaman, Tr. 1181-83. Blue Cross Blue Shield had a very strong bargaining position against ENH. Neaman, Tr. 1181-83; Haas-Wilson, Tr. 2638-42, *in camera*.

563. The premerger time period for Blue Cross Blue Shield’s HMO plan is from { } The post-merger period for Blue Cross Blue Shield’s HMO plan is from { } Haas-Wilson, Tr. 2511-12, *in camera*; CX 5046 at 1.

564. { } Haas-Wilson, Tr. 2511-12, *in camera*; CX 5057 at 1, *in camera*.

565. For Blue Cross Blue Shield HMO patients, the post-merger percentage increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

566. For Blue Cross Blue Shield HMO patients, the post-merger percentage increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

567. For Blue Cross Blue Shield POS patients, the post-merger percentage increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

568. For Blue Cross Blue Shield POS patients, the post-merger percentage increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

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569. For Blue Cross Blue Shield PPO patients, the post-merger percentage increase in inpatient price per day was { } CX 6279 at 3, *in camera*.

570. For Blue Cross Blue Shield PPO patients, the post-merger percentage increase in inpatient price per case was { } CX 6279 at 3, *in camera*.

571. The Blue Cross Blue Shield claims data does not show that prices to Blue Cross Blue Shield at ENH rose faster than prices at other hospitals in the Chicago PMSA following the merger between Evanston and Highland Park. CX 6279 at 18, *in camera*.

572. Using the same approach with the Blue Cross Blue Shield data, Haas-Wilson concluded that the price changes at ENH do not appear to be different in most cases than the price changes at the control group hospitals. Haas-Wilson, Tr. 2626, *in camera*.

(c) Data from the IDPH Universal Dataset

573. The Illinois Department of Public Health (“IDPH”) Universal Dataset compiles data from all hospitals in Illinois. The data is very comprehensive. It includes data on all inpatient hospital stays at all hospitals in Illinois, regardless of the managed care organization. Haas-Wilson, Tr. 2500; Haas-Wilson, Tr. 2582-83, *in camera*.

574. The IDPH Universal Dataset includes the hospitals’ list prices for each procedure which reflect each hospital’s chargemaster. The Universal Dataset does not include information on the actual transaction prices, including managed care discounts and patient payments, that hospitals receive. Haas-Wilson, Tr. 2500.

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575. In order to use the data from the IDPH Universal Dataset to calculate prices paid to managed care organizations, Haas-Wilson used a method that has been used by other health care economists to establish prices paid by managed care organizations. Haas-Wilson, Tr. 2527, *in camera*.

576. Haas-Wilson used the IDPH Universal Dataset with other data from the Medicare Cost Reports to derive an estimate of negotiated prices. Haas-Wilson, Tr. 2527-28, *in camera*. Medicare Cost Reports are reports that are required to be submitted by every hospital that participates in Medicare. Haas-Wilson, Tr. 2527, *in camera*. The Medicare Cost Reports show aggregate data on both net payments and gross payments by hospitals for inpatient and outpatient services. Haas-Wilson, Tr. 2529, *in camera*.

577. Using the Medicare Cost Reports, Haas-Wilson constructed a ratio of net receipts to gross billing amounts, and then multiplied that ratio by the billing information in the IDPH Universal Dataset (which is based on list prices) to get an estimate of the actual negotiated price. Haas-Wilson, Tr. 2529, *in camera*.

578. The ratio Haas-Wilson used included both inpatient and outpatient payments. Haas-Wilson, Tr. 2529, *in camera*.

579. While there is potential bias in such an approach, any bias would be small. If there was a bias, “it would work against finding a price increase.” Haas-Wilson, Tr. 2529-30, *in camera*.

580. The IDPH Universal Dataset does not identify the individual managed care organization that paid for a particular patient. Haas-Wilson, Tr. 2531-32, *in camera*. The IDPH Universal Dataset breaks down who paid for a particular patient only by categories of payors, such as: (1) all patients; (2) commercial and self pay; and (3) self administered as well as other categories. Haas-Wilson, Tr. 2532, *in camera*; CX 6279 at 7, *in camera*.

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581. Haas-Wilson used the two calendar years 1998 and 1999 as the premerger period and the two calendar years 2001 and 2002 as the post-merger period in comparing premerger and post-merger prices. Haas-Wilson, Tr. 2530-31, *in camera*.

582. Haas-Wilson compared the price increases estimated from the IDPH Universal Dataset and the Medicare Cost Reports with the change in the Chicago medical care CPI for the period beginning in 1998 to the end of 2002. During that period, the Chicago medical care CPI increased 20.3%. Haas-Wilson, Tr. 2533, *in camera*.

583. Using the IDPH Universal Dataset in conjunction with the Medicare Cost Reports, for any of Haas-Wilson's three control groups, and for any categorization of the different types of patients in the IDPH Universal Dataset, changes in patient mix, customer mix, and teaching intensity do not explain the relative price increases at ENH following the merger with Highland Park, when compared to control groups. All of the results show that the post-merger price increases at ENH were greater than the average price increases at comparison hospitals, even taking into account variations in patient mix, customer mix, and teaching intensity. Haas-Wilson, Tr. 2631-35, *in camera*; see CX 6279 at 20, *in camera*.

584. These results are statistically significant to the 1% level. CX 6279 at 10, 20, *in camera*.

585. Neither theory nor previous empirical research provided guidance on the best way to measure patient mix (capturing differences in resource use from both changes in case mix and severity of illness) across hospitals, so Haas-Wilson measured patient mix four different ways in the regression model: (1) the case case mix and severity of illness measure based on the APRDRGs; (2) the case mix and severity of illness measure based on the

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APRDRGs in combination with a length of stay variable; (3) the case mix measure based on DRG weights; and (4) the case mix measure based on DRG weights in combination with the length of stay variable. Haas-Wilson, Tr. 2622-23, *in camera*.

(i) All Patients

586. For all patients, the post-merger increase in inpatient price per day was 48%. CX 6279 at 7, *in camera*.

587. For all patients, the post-merger increase in inpatient price per case was 30%. CX 6279 at 7, *in camera*.

588. For all patients, the price increase at ENH in the price per day was 34% greater than the average price increase across all Chicago PMSA Hospitals. CX 6279 at 10, *in camera*. For all patients, the price increase at ENH in the price per case was 21% greater than the average price increase across all the Chicago PMSA Hospitals. CX 6279 at 11, *in camera*.

589. For all patients, the price increase at ENH in the price per day was 34% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 10, *in camera*. For all patients, the price increase at ENH in the price per case was 21% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 11, *in camera*.

590. For all patients, the price increase at ENH in the price per day was 34% greater than the average price increase across the Chicago PMSA Teaching Hospitals. *See* CX 6279 at 10, *in camera*. For all patients, the price increase at ENH in the price per case was 21% greater than the average price increase across the Chicago PMSA Teaching Hospitals. *See* CX 6279 at 11, *in camera*.

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591. For all patients in the DPH Universal Dataset, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 14.2 to 16.8% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

592. For all patients in the IDPH Universal Dataset, using the control group of Non-Merging Chicago PMSA Hospitals, and taking into account differences in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 15.2 to 17.0% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

593. For all patients in the DPH Universal Dataset, using the control group of Chicago PMSA Teaching Hospitals, and taking into account differences in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 13.2 to 15.5% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

(ii) Commercial and Self Pay Patients

594. For commercial and self pay patients, the post-merger increase in inpatient price per day was 46%. CX 6279 at 7, *in camera.*

595. For commercial and self pay patients, the post-merger increase in inpatient price per case was 27%. CX 6279 at 7, *in camera.*

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596. For commercially insured and self pay patients, the price increase at ENH in the price per day was 29% greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 10, *in camera*. For commercially insured and self pay patients, the price increase at ENH in the price per case was 15% greater than the average price increase across all Chicago PMSA Hospitals. *See* CX 6279 at 11, *in camera*.

597. For commercially insured and self pay patients, the price increase at ENH in the price per day was 29% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 10, *in camera*. For commercially insured and self pay patients, the price increase at ENH in the price per case was 16% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See* CX 6279 at 11, *in camera*.

598. For commercially insured and self pay patients, the price increase at ENH in the price per day was 26% greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 10, *in camera*. For commercially insured and self pay patients, the price increase at ENH in the price per case was 14% greater than the average price increase across Chicago PMSA Teaching Hospitals. *See* CX 6279 at 11, *in camera*.

599. For commercially insured and self pay patients in the IDPH Universal Dataset, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity the post-merger price increases at ENH were 12.7 to 15.0% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See* CX 6279 at 20, *in camera*.

600. For commercially insured and self pay patients in the IDPH IDPH Universal Dataset, using the control group of Non-Merging Chicago PMSA Hospitals, and taking into account changes in patient

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patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 12.9 to 17.0% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

601. For commercially insured and self pay patients in the IDPH Universal Dataset, using the control group of Chicago PMSA Teaching Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 11.1 to 13.0% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

**(iii) Commercial, Self Pay, Self
Administered, and HMO Patients**

602. For commercial, self pay, self administered, and HMO patients, the post-merger increase in inpatient price per day was 46%. *CX 6279 at 7, in camera.*

603. For commercial, self pay, self administered, and HMO patients, the post-merger increase in inpatient price per case was 26%. *CX 6279 at 7, in camera.*

604. For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per day was 29% greater than the average price increase across all Chicago PMSA Hospitals. *See CX 6279 at 10, in camera.* For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per case was 14% greater than the average price increase across all Chicago PMSA Hospitals. *See CX 6279 at 11, in camera.*

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605. For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per day was 28% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See CX 6279 at 10, in camera.* For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per case was 15% greater than the average price increase across Non-Merging Chicago PMSA Hospitals. *See CX 6279 at 11, in camera.*

606. For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per day was 27% greater than the average price increase across Chicago PMSA Teaching Hospitals. *See CX 6279 at 10, in camera.* For commercially insured, self pay, HMO, and self administered patients, the price increase at ENH in the price per case was 13% greater than the average price increase across Chicago PMSA Teaching Hospitals. *See CX 6279 at 11, in camera.*

607. For commercially insured, self pay, HMO, and self administered patients in the IDPH Universal Dataset, using the control group of all Chicago PMSA Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 13.7 to 15.7% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See CX 6279 at 20, in camera.*

608. For commercially insured, self pay, HMO, and self administered patients in the IDPH Universal Dataset, using the control group of Non-Merging Chicago PMSA Hospitals, and taking taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 14.2 to 17.9% greater than at the average control group hospital. The difference in the price increases at ENH and the control group

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group hospitals is statistically significant. *See* CX 6279 at 20, *in camera*.

609. For commercially insured, self pay, HMO, and self administered patients in the DPH Universal Dataset, using the control group of Chicago PMSA Teaching Hospitals, and taking into account changes in patient mix, customer mix, and teaching intensity, the post-merger price increases at ENH were 11.9 to 13.5% greater than at the average control group hospital. The difference in the price increases at ENH and the control group hospitals is statistically significant. *See* CX 6279 at 20, *in camera*.

610. The IDPH Universal Dataset shows that prices to managed care organizations went up faster at ENH than at other hospitals after the merger with Highland Park. This result does not change with the different control groups and does not change with the different patient groups identified in the IDPH Universal Dataset. F. 591-93, 599-601, 607-09. All of the results show that the post-merger price increases at ENH were greater than the average price increases at comparison hospitals, even taking into account variations in patient mix, customer mix, and teaching intensity. F. 583.

**(d) Data Submitted by the Economic
Consulting Firm NERA on Behalf of ENH**

611. National Economic Research Associates (“NERA”), an economic consulting firm hired by ENH, submitted data to the FTC, on ENH’s behalf. Haas-Wilson, Tr. 2498. The NERA data reported actual negotiated prices for ENH’s fiscal years 1999 through 2001. Haas-Wilson, Tr. 2498.

612. The NERA data includes data on many commercial payors, payors, more payors than there are payors for which there was

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claims data. Haas-Wilson, Tr. 2499; CX 6279 at 4 (showing data for for 13 payors), *in camera*.

613. Haas-Wilson used the fiscal year 1999 as the premerger period and fiscal year 2001 as the post-merger period for the NERA data in comparing premerger and post-merger prices. Fiscal year 2000 was not included in the analysis because it was considered a transition year, a period of time in which ENH was renegotiating many of its contracts with managed care organizations. Haas-Wilson, Tr. 2519, *in camera*.

614. The NERA data contained information only on ENH. It did not contain data on prices at other hospitals to use for comparison. Haas-Wilson, Tr. 2498-99. Therefore, Haas-Wilson compared the price increase per case estimated from the NERA data with the change in the Chicago medical care CPI for the period from the beginning of ENH's fiscal year 1999 through the end of fiscal year 2001. During that period, the Chicago medical care CPI increased 11%. Haas-Wilson, Tr. 2520-22, *in camera*.

615. The NERA findings are reported per adult day and per adult case only. *See* CX 6279 at 4, *in camera*.

616. The NERA data showed "large price increases at ENH post-merger for many payers, and in some cases really large [price increases]." Haas-Wilson, Tr. 2519-20, *in camera*; CX 6279 at 4, *in camera*. For example, Haas-Wilson found that the percentage increase for PHCS using the NERA data was { } Haas-Wilson, Tr. 2522-23, *in camera*; *see also* Ballengee, Tr. 179 ({ }).

(i) First Health

617. For First Health patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

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618. For First Health patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2516, *in camera*; CX 6279 at 4, *in camera*.

(ii) Aetna

619. For Aetna patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

620. For Aetna patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2537, *in camera*; CX 6279 at 4, *in camera*.

(iii) Northwestern Students

621. For Northwestern Student patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

622. For Northwestern Student patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(iv) Blue Cross Blue Shield

623. For Blue Cross Blue Shield patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

624. For Blue Cross Blue Shield patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(v) Cigna

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625. For Cigna patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

626. For Cigna patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(vi) PPONext

627. For PPONext patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

628. For PPONext patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(vii) Humana

629. For Humana patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

630. For Humana patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(viii) MultiPlan

631. For MultiPlan patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

632. For Multiplan patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(ix) Preferred Plan

633. For Preferred Plan patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

634. For Preferred Plan patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

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(x) PHCS

635. For PHCS patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

636. For PHCS patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2522-23, *in camera*; CX 6279 at 4, *in camera*.

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(xi) Unicare

637. For Unicare patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

638. For Unicare patients, the post-merger increase in inpatient price per case was { } CX 6279 at 4, *in camera*.

(xii) United

639. For United patients, the post-merger increase in inpatient price per day was { } CX 6279 at 4, *in camera*.

640. For United patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2522, *in camera*; CX 6279 at 4, *in camera*.

(e) Data Submitted by ENH in Response to a Civil Investigative Demand Issued by the Federal Trade Commission

641. ENH submitted data in response to a CID issued by the Federal Trade Commission. The CID response data was similar to the NERA data. The CID response data reported actual negotiated prices for ENH's fiscal years 1999 through 2002. Haas-Wilson, Tr. 2499-500.

642. The CID response data covered at least fourteen payors. CX 6279 at 5, *in camera*.

643. Haas-Wilson used the fiscal year 1999 as the premerger period and the fiscal year 2002 as the post-merger period for the CID data in comparing premerger and post-merger prices. Haas-Wilson, Tr. 2523, *in camera*. Fiscal years 2000 and 2001 were not included in the analysis, because for this data set they were both considered transition years, a period of time in which

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ENH was renegotiating many of its contracts with commercial payors. Haas-Wilson, Tr. 2523-24, *in camera*.

644. Haas-Wilson compared the price increase per case estimated from the CID data with the change in the Chicago medical care CPI for the period from the beginning of ENH's fiscal year 1999 through the end of fiscal year 2002. During that period, the change in Chicago medical care CPI increased 14.3%. Haas-Wilson, Tr. 2526, *in camera*.

645. The CID data "showed for most commercial payers, there were large price increases at ENH" and "at some payers really large price increases." Haas-Wilson, Tr. 2524-25, *in camera*; CX 6279 at 4-5, *in camera*.

(i) Beech Street/Capp Care

646. For Beech Street/Capp Care patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

647. For Beech Street/Capp Care patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(ii) Cigna

648. For Cigna patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

649. For Cigna patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(iii) First Health

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650. For First Health patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

651. For First Health patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(iv) One Health (Great West)

652. For One Health patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

653. For One Health patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(v) Aetna

654. For Aetna patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

655. For Aetna patients, the post-merger increase in inpatient price per case was { } Haas-Wilson, Tr. 2537, *in camera*; CX 6279 at 5, *in camera*.

(vi) Blue Cross Blue Shield

656. For Blue Cross Blue Shield patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

657. For Blue Cross Blue Shield patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(vii) HFN

658. For HFN patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

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659. For HFN patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(viii) Humana

660. For Humana patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

661. For Humana patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(ix) MultiPlan

662. For MultiPlan patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

663. For MultiPlan patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(x) PHCS

664. For PHCS patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

665. For PHCS patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(xi) Preferred Plan

666. For Preferred Plan patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

667. For Preferred Plan patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

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(xii) State of Illinois

668. For State of Illinois patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

669. For State of Illinois patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(xiii) Unicare

670. For Unicare patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*

671. For Unicare patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(xiv) United

672. For United patients, the post-merger increase in inpatient price per day was { } CX 6279 at 5, *in camera*.

673. For United patients, the post-merger increase in inpatient price per case was { } CX 6279 at 5, *in camera*.

(f) Baker's Analysis

674. Baker defined the premerger time period for his analysis as all observations before January 1, 2000 because that was the effective date of the merger. Baker, Tr. 4635, *in camera*.

675. Baker used the data provided by the managed care organizations to determine post-merger increases in inpatient price per case. Baker then compared these results to the post-merger increases in prices at control groups of eighteen hospitals provided by Noether. Baker, Tr. 4637-38, *in camera*; Haas-Wilson, Tr. 2548-49, *in camera*.

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676. Baker found that, for United patients across all United plans, the raw, unadjusted post-merger increase in inpatient price per case at ENH was { }, while the post-merger price increase for United patients at his control group hospitals was { } Haas-Wilson, Tr. 2564-65, *in camera*.

677. Baker found that, for Aetna patients across all Aetna plans, the raw, unadjusted post-merger increase in inpatient price per case at ENH was { }, while the post-merger price increase for Aetna patients at his control group hospitals was { } Haas-Wilson, Tr. 2566-67, *in camera*; Baker, Tr. 4744-46, *in camera*.

678. Baker found that, for Humana patients across all Humana plans, the raw, unadjusted post-merger increase in inpatient price per case at ENH was { }, while the post-merger price increase for Humana patients at his control hospitals was { } Haas-Wilson, Tr. 2573, *in camera*; see Baker, Tr. 4747, *in camera*.

679. Baker found that the post-merger price increase for Blue Cross Blue Shield was exactly the same as the post-merger price increase for his control group – both were { } Haas-Wilson, Tr. 2569, *in camera*.

680. Baker did not calculate price changes for individual plans of managed care organizations. He looked at prices for the payors as a whole, and also aggregated over all of the payors. Baker, Tr. 4631-32, *in camera*.

681. Baker controlled for case mix variation in his regression differently from Haas-Wilson. Baker Tr. 4648-49, *in camera*. Baker had a length of stay variable in his regression. Baker, Tr. 4800, *in camera*.

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682. Baker used Noether's control groups both for his price change analysis and his price level analysis. Baker, Tr. 4637-38, *in camera*.

683. Baker based his analysis on usable managed care claims data produced during discovery from four managed care organizations. This data reflects the prices actually paid by managed care organizations for ENH's services. Baker, Tr. 4646-47, *in camera*.

684. Baker admitted that the pricing pattern of ENH's prices to Humana, Aetna, and United was consistent with ENH obtaining market power through the merger with Highland Park. Baker, Tr. 4742-43, *in camera*.

685. Baker calculated an average price increase across all four payors whose claims data he used and he found that, for all United, Aetna, Blue Cross Blue Shield, and Humana patients across all plans, the post-merger increase in inpatient price per case at ENH was { }, while the post-merger price increase at his control group hospitals was { } Haas-Wilson, Tr. 2584-85, *in camera*.

686. Baker found that the raw, unadjusted price increase for United, Aetna, Blue Cross Blue Shield, and Humana patients, with inpatient and outpatient combined, at ENH from the premerger period to the post-merger period was { } Baker, Tr. 4639-40, *in camera*.

687. Baker found that ENH's prices for inpatient and outpatient combined increased by { } more than the prices of the control group hospitals, without controlling for patient mix. Baker, Tr. 4640-41, *in camera*.

688. Baker testified that his best estimate of ENH's non-quality non-quality adjusted price increase at the time of the merger, as compared to a control group of hospitals, and adjusted for variation variation in case-mix across hospitals, for inpatient and outpatient

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services combined, is 11 to 12%. Baker, Tr. 4617-19, 4795-96, *in camera*.

689. Baker found that for his four payors combined, the post-merger price increases for inpatient services at ENH were 10.0% higher than the post-merger price increases on average at the comparison hospitals, taking into account the variation in the independent variables that he included in his regression model. Haas-Wilson, Tr. 2636-37, *in camera*; Baker Tr. 4645-46, *in camera*. When Baker excluded obstetrics, the estimated price increases at ENH for inpatient services were 9%. Baker, Tr. 4646, *in camera*.

690. Baker testified that his best estimate of ENH's non-quality adjusted price increase at the time of the merger, as compared to a control group of hospitals, and adjusted for variation in case-mix across hospitals, for inpatient services only, is 9 to 10%. Baker, Tr. 4617-20, 4795-96, *in camera*.

691. There is no record evidence regarding Baker's estimates of price changes at individual managed care organizations that were both case-mix adjusted and compared to a control group of hospitals. Baker, Tr. 4640, *in camera*.

692. Baker testified that examining the overall price changes, rather than looking at any individual managed care organization's price change, is more appropriate because the market alleged by Complaint Counsel was the managed care market as a whole. Baker, Tr. 4648, *in camera*.

(3) Explanations of Price Increases Other than Market Power Ruled Out

(a) Methodology

693. It is not feasible to directly test whether or not market power is the explanation behind the price increases at ENH. Haas-

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Haas-Wilson, Tr. 2482. Because market power cannot be tested for directly, “the best available method is to develop [a] list based on theory and what theory would expect to result in a price increase and then use empirical tests based on available data to be able to either cross these items off the list or, if you’re not able with your empirical test to cross them off, then *see* what you’re left with at the end of the analysis.” Haas-Wilson, Tr. 2482.

694. It is not possible to test for all possible explanations of a price increase, so it is necessary to look for reasonable explanations that are grounded in economic theory. Haas-Wilson, Tr. 2481.

695. Haas-Wilson, drawing upon economic theory, came up with a list of eight potential explanations for the price increases at ENH after the merger other than market power or learning about demand. The “basis for including things in this list was economic theory and what economic theory suggested would be potential explanations for the large post-merger price increase at ENH.” Haas-Wilson, Tr. 2481.

696. The eight plausible explanations of the price increases at ENH, aside from market power or learning about demand, were: (1) cost increases that affect all hospitals; (2) changes in regulations that affect all hospitals; (3) increases in consumer demand for hospital services; (4) increases in quality at ENH; (5) changes in the mix of patients; (6) changes in the mix of customers; (7) increases in teaching intensity; and (8) decreases in outpatient prices. Haas-Wilson, Tr. 2482-88.

697. Haas-Wilson tested whether any of these potential explanations could explain the price increases at ENH and found that they could not. Haas-Wilson, Tr. 2481.

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**(b) Changes in Costs, Regulations,
Consumer Demand, Quality, and
Outpatient Prices Can Be Ruled Out**

698. Economic theory suggests that if there are increases in demand over a time period, one would expect those increases in demand in the Chicago area to increase prices at all hospitals in the Chicago area. Therefore, Haas-Wilson tested for whether increases in demand would explain why ENH's prices increased. Haas-Wilson, Tr. 2484.

699. An example of what could cause an increase in demand that would subsequently affect prices is "[t]o the extent the elderly consume more hospital services than the young, to the extent the population is aging in the Chicago area, that would likely increase demand for hospital services in the Chicago area and could potentially explain, therefore, price increases at all hospitals in the Chicago area." Haas-Wilson, Tr. 2484.

700. In her analysis, Haas-Wilson focused on price increases instead of price levels because the market for hospital services can be characterized as a market for a differentiated product as opposed to a product that would be characterized as homogenous. Consumers are willing and able to pay higher prices for certain aspects of product differentiation, e.g., convenient location or reputation. Thus, because prices can vary in the market for a differentiated service for many different reasons, one may not conclude anything about market power by merely using a cross-sectional analysis of hospital prices at a single point in time. Haas-Wilson, Tr. 2492.

701. In contrast, by looking at price changes over time, one can compare the price change at one hospital to the price change at another hospital. Using such an approach, one can conclude that there is a change in market power if there are price increases after having ruled out the other possible explanations for greater

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price increases at one hospital versus another. Haas-Wilson, Tr. 2495.

702. Haas-Wilson considered whether increases in costs, changes in regulation, and changes in demand for hospital services that would affect all hospitals could have been a possible explanation for the post-merger price increases at ENH. To test this hypothesis, she looked to *see* whether prices increased more at ENH than at comparison hospitals. If they did, general increases in costs, changes in regulation, and changes in demand for hospital services could not be a possible explanation for all of the post-merger price increases at ENH. Haas-Wilson, Tr. 2542-44, *in camera*.

703. Haas-Wilson was able to directly rule out five potential explanations of the price increases at ENH: (1) cost increases; (2) changes in regulations; (3) changes in consumer demand; (4) changes in quality; and (5) declines in outpatient prices. F. 704-26.

(i) Changes in Costs

704. Economic theory suggests that when costs increase in competitive markets, one would expect to *see* prices increase. Therefore, Haas-Wilson tested for whether cost increases in the Chicago area would explain why ENH's prices increased. Haas-Wilson, Tr. 2482.

705. An example of a kind of cost increase that could take place in an area that would lead to a price increase is a shortage of nurses in the area. If a hospital had to pay higher wages in order to hire nurses, that would be an increase in cost that would affect the hospital and all of the other hospitals in the area, and potentially lead to a price increase. Haas-Wilson, Tr. 2482-83.

706. Prices at ENH rose relative to the prices at other hospitals, hospitals, as explained above in Section II.D.1.b.2. These relative price increases rule out cost increases as an explanation of the price

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price increases observed at ENH. Haas-Wilson, Tr. 2562-63, 2565, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

707. The relative price increases rule out any cause of the price increases that would affect all the hospitals in the control groups similarly. Haas-Wilson, Tr. 2562-63, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

(ii) Changes in Regulations

708. Because a change in regulation that affected all hospitals in the Chicago area could potentially explain price increases at all hospitals in the Chicago area, Haas-Wilson tested for whether changes in regulations would explain why ENH's prices increased. Haas-Wilson, Tr. 2483.

709. An example of a change in regulation that could affect the prices at hospitals is taken from California. In California, where they are particularly prone to earthquakes, there are regulations requiring hospitals to make sure their buildings are able to withstand earthquakes of certain levels. Such a regulation clearly would increase costs at all hospitals in California and would be expected to lead to higher prices. Haas-Wilson, Tr. 2483-84.

710. Prices at ENH rose relative to the prices at other hospitals, as explained above in Section II.D.1.b.2. These relative price increases rule out regulatory changes as an explanation of the price increases observed at ENH. Haas-Wilson, Tr. 2562-63, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

711. The relative price increases rule out any cause of the price increases that would affect all the hospitals in the control groups similarly. Haas-Wilson, Tr. 2562-63, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

(iii) Changes in Consumer Demand

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712. Prices at ENH rose relative to the prices at other hospitals, as explained above in Section II.D.1.b.2. These relative price increases rule out cost increases, regulatory changes, and increases in demand as explanations of the price increases observed at ENH. Haas-Wilson, Tr. 2562-63, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

713. The relative price increases rule out any cause of the price increases that would affect all the hospitals in the control groups similarly. Haas-Wilson, Tr. 2562-63, 2565, 2573-74, 2579, 2583, 2586, *in camera*.

(iv) Changes in Quality

714. If quality is increasing in general, that would lead to potentially higher prices at all hospitals. Haas-Wilson, Tr. 2485. If quality is increasing at one hospital relative to other hospitals, and the buyers of hospital services value that increase in quality, then that could potentially explain a greater price increase at the first hospital. Haas-Wilson, Tr. 2485.

715. Haas-Wilson relied upon findings by Complaint Counsel's healthcare quality expert, Dr. Patrick S. Romano, Professor of Internal Medicine and Pediatrics at University of California at Davis, School of Medicine, that the post-merger increase in quality at ENH was not greater than the increases in quality at relevant control hospitals. Haas-Wilson, Tr. 2586-88, *in camera*. See also F. 853-68. Haas-Wilson did not conduct an independent analysis of non-clinical quality. Haas-Wilson, Tr. 2446-47; Haas-Wilson, Tr. 2586, *in camera*.

716. Increases in quality at ENH cannot explain the relatively larger price increases at ENH after the merger when compared to the price increases at other hospitals. Haas-Wilson, Tr. 2587-88, 2615, *in camera*.

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(v) Changes in Outpatient Prices

717. Though economic theory does not predict that decreases in outpatient services prices would lead to increases in inpatient service prices, some managed care payors indicated that they would be concerned about what they paid for all the products that they were purchasing from a hospital. Haas-Wilson, Tr. 2487.

718. To the extent that a managed care organization is concerned about the total price, a managed care organization might be willing to pay higher prices for inpatient services if they were getting outpatient services at a lower price. It might be willing to trade one off for the other. Haas-Wilson, Tr. 2487-88.

719. Because decreases in prices of outpatient services is one of the potential explanations for the price increases that were observed at ENH after the merger, Haas-Wilson analyzed this possibility. Haas-Wilson, Tr. 2607, *in camera*.

720. Haas-Wilson tested whether changes in the prices of outpatient services at ENH differed from the change in prices of outpatient services at control hospitals over the same period of time. Haas-Wilson, Tr. 2607-08, *in camera*. Haas-Wilson used managed care data to test this hypothesis. Haas-Wilson, Tr. 2608, *in camera*.

721. There was no decrease in the prices of outpatient services to managed care organizations at the time of the increases in the prices of inpatient services. Haas-Wilson, Tr. 2614-15, *in camera*.

722. CX 6279 at 17 shows the post-merger increases in price per case of outpatient care at ENH and at control hospitals with more than 100 cases of outpatient care in both the premerger and the post-merger period. The table gives the result by payor and plan type for ENH and the three different groups of control

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hospitals. Haas-Wilson, Tr. 2610, *in camera*; CX 6279 at 17, *in camera*.

723. Based on the empirical analysis, which used the managed care claims data, Haas-Wilson concluded that payors did not accept lower outpatient prices in return for higher inpatient prices. Haas-Wilson, Tr. 2614-15, *in camera*.

724. The finding that outpatient prices did not decline is consistent with Baker's analysis. Baker estimated that the price increases at ENH for four managed care payors, relative to the control group, for inpatient and outpatient services combined was 11 to 12%. Baker, Tr. 4617-18, *in camera*. Looking at just inpatient services, Baker estimated that the price increases at ENH for four managed care payors, relative to the control group, was 9 to 10%. Baker, Tr. 4620, *in camera*. This implies that the price of outpatient services at ENH for Baker's four payors increased more than the price of inpatient services. Baker, Tr. 4797, *in camera*.

725. Baker did not explicitly estimate the price change at ENH for outpatient services, because he could not adjust for case mix variation with the outpatient data. What he did to create an estimate of ENH's price change for inpatient services was find a case mix ratio from the inpatient data, and apply that same ratio to the outpatient data. Baker, Tr. 4642, *in camera*. Baker agrees that the implication of his estimates is that outpatient prices did not decline. Baker, Tr. 4797, *in camera*.

726. Based on her empirical review of the managed care data, Haas-Wilson concluded that changes in the price of outpatient services were not a possible explanation for the post-merger ENH price increase. Haas-Wilson, Tr. 2615, *in camera*.

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**(c) Changes in Patient Mix, Customer Mix,
and Teaching Intensity Can Be Ruled Out
Out****(i) Regression Analysis Methodology**

727. Haas-Wilson developed a multiple regression model to evaluate whether the remaining possible explanations (changes in patient mix, customer mix, or teaching intensity) were responsible for the post-merger ENH price increases. Haas-Wilson, Tr. 2615, *in camera*.

728. Multiple regression analysis is a statistical tool commonly used in econometrics that allows the researcher to study the impact of many variables simultaneously that may have an influence on the dependent variable of interest. Haas-Wilson, Tr. 2616, *in camera*.

729. Haas-Wilson employed a multiple regression model to measure the effect of the merger on the change in prices, while simultaneously taking into account changes in other variables changes in patient mix, customer mix, and teaching intensity. Haas-Wilson, Tr. 2616, 2619, *in camera*.

730. In Haas-Wilson's multiple regression model, prices at ENH and control hospitals were the dependent variables, and patient mix (case mix and severity of illness), customer mix, and teaching intensity were included in the independent variables. Haas-Wilson, Tr. 2619-20, *in camera*.

731. Haas-Wilson used a difference in differences approach to see if the price increases at ENH after the merger were larger than the price increases at a control group of hospitals. Haas-Wilson, Tr. 2620, *in camera*.

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732. Haas-Wilson used the same control groups for her multiple regression model that she used earlier in her difference in differences analysis of whether the price increases at ENH were greater than at the control group hospitals. Haas-Wilson, Tr. 2620, *in camera*.

733. The difference in differences model reported the actual percentage point price difference between the price increases at ENH and at comparison hospitals. So, the regression model reports the number of percentage points by which the prices at ENH exceed the comparison hospitals. Haas-Wilson, Tr. 2621, *in camera*.

734. Haas-Wilson used two data sources for her regression model: (1) the IDPH Universal Dataset in conjunction with the Medicare Cost Reports, and (2) the managed care claims data. Haas-Wilson, Tr. 2621-22, *in camera*. All of the results show that the post-merger price increases at ENH were greater than the average price increases at comparison hospitals, even taking into account variations in patient mix, customer mix, and teaching intensity. Haas-Wilson, Tr. 2631-35, *in camera*; see CX 6279 at 20, *in camera*.

(ii) Changes in Patient Mix

735. Not all inpatient hospital stays require the same resources to treat. Patients with more complex conditions may require more resources than patients with less complex conditions. For two patients with the same condition, one may be sicker, requiring more resources to treat than the patient who is less sick. Haas-Wilson, Tr. 2485.

736. The mix of patients that a hospital has will influence the hospital's prices. If the hospital has patients who require more resources to treat than other hospitals, that will impact the hospital's prices. Haas-Wilson, Tr. 2486.

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737. If a hospital's mix of patients is changing, such that the hospital is getting more complex cases or the patients are arriving sicker, one would expect that the hospital would be using more resources to treat those patients, and that would be a possible explanation for a price increase. Haas-Wilson, Tr. 2589, *in camera*.

738. If case mix or severity of illness is changing similarly across hospitals, it can not be an explanation of a relatively larger price increase at one hospital versus another. But if the mix of patients is changing over time across hospitals differently, then case mix or severity of illness could be a possible explanation of a higher price increase at one hospital versus another. Haas-Wilson, Tr. 2589-90, *in camera*.

739. The case mix index is used by many people who analyze hospital data, and it is a measure of the complexity of the cases that are being treated at particular hospitals. It is constructed based on a system of weights related to diagnostic related groups ("DRG"). Haas-Wilson, Tr. 2594, *in camera*.

740. CX 6279 at 13 is a comparison of the post-merger change in case mix at ENH and at control hospitals using the managed care claims data. Haas-Wilson, Tr. 2592-93, *in camera*; CX 6279 at 13, *in camera*.

741. The managed care claims data suggested the patient mix was changing at ENH after the merger with Highland Park in a manner that may explain, at least in part, price increases at ENH. Haas-Wilson, Tr. 2590, 2595-96, *in camera*. Haas-Wilson used multiple regression to test the extent to which changing patient mix explains the price increases at ENH. Haas-Wilson, Tr. 2619-20, *in camera*.

742. CX 6279 at 14 is a comparison of the post-merger change in case mix at ENH and at control hospitals, using the IDPH

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Universal Dataset. Haas-Wilson, Tr. 2596-98, *in camera*; CX 6279 6279 at 14, *in camera*.

743. The IDPH Universal Dataset suggested the patient mix was changing at ENH after the merger with Highland Park in a manner that may explain, at least in part, the price increases at ENH. Haas-Wilson, Tr. 2598-99, *in camera*. Haas-Wilson used multiple regression to test the extent to which changing patient mix explains the price increases at ENH. Haas-Wilson, Tr. 2619-20, *in camera*.

(iii) Changes in Mix of Customers

744. Mix of customers refers to the different types of organizations that pay for patients at a hospital, whether it is commercial insurance or public health insurance programs, such as the Medicare and Medicaid programs. Haas-Wilson, Tr. 2486.

745. If a hospital has more Medicare and Medicaid patients, that could provide a motivation for the hospital to raise its prices to patients of the managed care organizations, especially when payment under the public programs is reduced. Haas-Wilson, Tr. 2486.

746. Haas-Wilson used the Medicare Cost Reports data showing the percentage of patients receiving care at the hospital that are covered by Medicaid or Medicare. She used the percent of patients covered by Medicare or Medicaid as the measure of the mix of customers. Haas-Wilson, Tr. 2600, *in camera*.

747. Haas-Wilson tested the hypothesis that the change in the mix of customers at ENH and the change in the mix of customers at comparison hospitals over the relevant time period was the same. Haas-Wilson, Tr. 2600, *in camera*.

748. Haas-Wilson found that there were differences in the way the mix of customers was changing over time across hospitals. As a

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a result, she could not, at that point in her analysis, eliminate changes in the mix of customers as a possible explanation for the price increases at ENH. Haas-Wilson, Tr. 2600, 2602-03, *in camera*. Haas-Wilson used multiple regression to test the extent to which changing customer mix explains the price increases at ENH. ENH. Haas-Wilson, Tr. 2619-20, *in camera*.

(iv) Changes in Teaching Intensity

749. Teaching intensity is a measure of how much teaching activity is occurring at a hospital. Some hospitals participate in the training of residents and interns. Haas-Wilson, Tr. 2486-87.

750. There is empirical support for the proposition that hospitals that are involved in teaching activity have higher costs than hospitals that are not involved in teaching activity. Haas-Wilson, Tr. 2487. Therefore, those hospitals involved in more teaching may have higher costs than those involved with lesser amounts of teaching activity. Haas-Wilson, Tr. 2487.

751. Haas-Wilson tested the hypothesis that changes in teaching intensity at ENH over the relevant time period were the same as the changes in teaching intensity over the same time period at comparison hospitals. Haas-Wilson, Tr. 2603-04, *in camera*.

752. Teaching intensity was measured as the number of residents and interns per hospital bed at each hospital. Haas-Wilson, Tr. 2604, *in camera*.

753. Haas-Wilson included any hospital that had at least one intern or one resident. Haas-Wilson, Tr. 2869-70, *in camera*. Haas-Wilson used data from the Medicare Cost Reports to test the hypothesis regarding changes in teaching intensity. Haas-Wilson, Tr. 2604, *in camera*.

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754. Haas-Wilson found that teaching intensity was changing across hospitals differently over time. As a result, she could not, without further analysis, eliminate changes in teaching intensity as a potential explanation for the price increases at ENH. Haas-Wilson, Tr. 2603-04, 2606, *in camera*. Haas-Wilson used multiple regression to test the extent to which changing teaching intensity explains the price increases at ENH. Haas-Wilson, Tr. 2619-20, *in camera*.

755. All of the results show that the post-merger price increases at ENH were greater than the average price increases at comparison hospitals, even taking into account variations in patient mix, customer mix, and teaching intensity. Haas-Wilson, Tr. 2631-35, *in camera*; see CX 6279 at 20, *in camera*.

2. Procompetitive Justifications

a. Learning About Demand

(1) Foundations for the Theory

756. During the due diligence work connected with the merger, Evanston learned about Highland Park's managed care contracts and learned about Highland Park's pricing information. Noether, Tr. 5973-74; Chan, Tr. 660-63, 711-12; Chan, Tr. 825, *in camera*; RX 620 at ENHL TC 17809, *in camera*; RX 652 at BAIN 9.

757. According to Noether, the learning about demand explanation is that before the merger with Highland Park, Evanston had poor information about the true demand for its services. Noether, Tr. 5968. Noether agreed, however, that a hospital merger could lead to market power at the same time the hospital learns more about demand for its services. Noether, Tr. 6142.

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758. Haas-Wilson testified that the “empirical literature . . . suggests that costs and therefore prices ‘might’ be different at hospitals that are engaged in ‘teaching activity’ versus those that are not.” Haas-Wilson, Tr. 2550, *in camera*.

759. Respondent’s experts testified that premerger, Evanston priced itself more like a community hospital, rather than a major teaching hospital. Noether, Tr. 5968; Baker, Tr. 4654-55, *in camera*.

760. Respondent’s experts’ learning about demand theory proposes that once Evanston learned about the demand for its services, it modified its pricing to reflect this greater understanding and to price itself more like a teaching hospital. Noether, Tr. 5968-69; Baker, Tr. 4654-55, *in camera*.

(2) ENH’s Contract Negotiations in the 1990’s

761. Jack Sirabian handled Evanston’s managed care contracting negotiations from approximately 1990 to 2000. Sirabian, Tr. 5697-98. Sirabian reported to Hillebrand with respect to managed care contracting. Sirabian, Tr. 5728-29; Hillebrand, Tr. 1700.

762. During the period in which Sirabian was responsible for contracting, he received positive evaluations from both Neaman and Hillebrand for his work at ENH. Sirabian, Tr. 5728.

763. When Bain provided contract negotiation advice in 1999 to Evanston, neither Bain nor Evanston management informed Sirabian that any of Evanston’s rates that were perceived to be unfavorable were the result of Sirabian’s poor contract negotiations in the 1990’s. Sirabian, Tr. 5762.

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764. Bain advised ENH that it “should recognize its position and not be afraid to ask to be paid fair market value” for its services. RX 2047 at 39-40 (Ogden, Dep.).

765. Sirabian received a bonus after the merger in 2000. Neaman, Tr. 1265-66; CX 31 at 1.

766. Hillebrand had and continues to have general oversight and supervisory responsibility for managed care contracting. Hillebrand, Tr. 1701-02; Neaman, Tr. 1220.

767. Hillebrand testified that Evanston’s negotiating stance with managed care organizations was equally aggressive before and after the merger. Hillebrand, Tr. 1731, 1733.

768. ENH’s CEO believes Hillebrand to be an effective negotiator, with a good understanding of the marketplace and ENH’s relationships with managed care organizations. The CEO never criticized Hillebrand about ENH’s premerger managed care contracts. Neaman, Tr. 1220.

769. Hillebrand was never accused of being soft or of not bargaining hard with managed care organizations. Hillebrand, Tr. 1727.

770. Hillebrand received a bonus after the merger in 2000. Neaman, Tr. 1221.

771. After the merger, Theresa Chan, who had negotiated contracts with managed care organizations on behalf of Highland Park, resigned and was not asked to remain. Hillebrand, Tr. 1730, 2044.

(3) Testimony of Managed Care Organizations

772. In its contract negotiations, ENH did not indicate to managed care organizations that ENH was attempting to match

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academic teaching hospitals' pricing. Ballengee, Tr. 193-94 (PHCS); (PHCS); Neary, Tr. 621; Dorsey, Tr. 1447 (One Health).

(a) One Health

773. In negotiating with hospitals to be in its network, One Health makes judgments about the hospitals' level of services. Neary, Tr. 622.

774. One Health views academic teaching hospitals as teaching facilities that train physicians and as institutions that are part of a medical school. Such hospitals are on the cutting edge of medical technology, performing services that other general acute care facilities and community hospitals do not perform, such as transplant services, burn units, and higher levels of cardiac services. Neary, Tr. 622; Dorsey, Tr. 1443.

775. One Health believes academic hospitals in the Chicago area are: the University of Chicago, Rush-Presbyterian-St. Luke's, Northwestern Memorial, Loyola University, and University of Illinois. Dorsey, Tr. 1443-44; Neary, Tr. 623.

776. One Health does not view any of the hospitals in ENH (Evanston, Glenbrook, and Highland Park) as academic teaching hospitals. Neary, Tr. 621; Dorsey, Tr. 1444.

(b) PHCS

777. PHCS categorizes hospitals as community, tertiary, and advanced teaching hospitals. Advanced teaching hospitals offered the really high-level procedures, such as transplants, burn units, and hyperbaric centers. Ballengee, Tr. 159.

778. Premerger, PHCS viewed Highland Park as in the community hospital group and Evanston as a community and tertiary tertiary hospital, spanning both groups. Post-merger, PHCS

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continued to view ENH as both a community and tertiary hospital. Ballengee, Tr. 158-59.

779. PHCS views the advanced teaching hospitals in the Chicago area as Northwestern Memorial, Rush-Presbyterian-St. Luke's, University of Chicago, Loyola University, and University of Illinois. Ballengee, Tr. 189.

780. PHCS does not view ENH as an advanced teaching hospital. Ballengee, Tr. 189.

(c) United

781. United views an academic hospital as one that has a medical school as part of the hospital. Foucre, Tr. 935.

782. United believes Loyola University, University of Chicago, Northwestern Memorial, and Rush-Presbyterian-St. Luke's are all academic hospitals. Foucre, Tr. 936.

783. United does not believe that Evanston, Glenbrook, and Highland Park are academic hospitals. Foucre, Tr. 936.

**(4) Evanston Could Not Have Learned
Anything Significant About Demand from
Highland Park**

**(a) Differences Between Highland Park and
Evanston**

784. Evanston and Highland Park were different in a number of dimensions. Premerger, Highland Park was a community hospital, and Evanston had elements of both a community and tertiary hospital. Ballengee, Tr. 159.

785. Evanston offered a number of services that Highland Park did not. While Evanston and Highland Park offered many of

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the same services, about 11.6% of the patients at Evanston in 1999 1999 were being treated for DRGs for which Highland Park did not not treat four or more patients in a year. RX 1912 at 44, *in camera. camera.*

786. Evanston Hospital/ENH has been named by one publication as a top 15 teaching hospital and a top 100 hospital in the country. Neaman, Tr. 1197, 1290-91.

**(b) Premerger, Highland Park Charged
Lower Actual Prices Than Evanston**

787. Sirabian testified that in approximately one third of thirty-five or forty contracts with managed care organizations, Highland Park had higher contract rates than Evanston. Sirabian, Tr. 5717.

788. The negotiated rates that one observes in contracts typically are not the actual prices that health plans would pay to hospitals. Haas-Wilson, Tr. 2645, *in camera.*

789. Rates are just one factor that goes into determining prices. There are multiple factors in hospital contracts that determine the actual price or the reimbursement per case. Haas-Wilson, Tr. 2647, *in camera.*

790. In addition to per diem rates, contracts also specify stop loss provisions, which specify at what point the per diem no longer applies and instead the hospital gets reimbursed on a different basis specified in the contract. Haas-Wilson, Tr. 2647, *in camera.*

791. The contract itself also shows nothing about the hospital's hospital's chargemaster. Thus, if two hospitals have contracts that specify a 10% discount off charges, without knowing the respective respective chargemasters, knowing the discount off charges does not

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not show which hospital had higher prices. Haas-Wilson, Tr. 2647-2647-48, *in camera*.

792. The hospital with the higher negotiated rates is not necessarily the hospital with the higher prices. Haas-Wilson, Tr. 2645, *in camera*.

793. Evanston's chargemaster was higher than Highland Park's premerger. Chan, Tr. 743. *See also* CX 1373 at 14, *in camera*; RX 620, *in camera* ("The same contract terms that may be more favorable to [Highland Park] based on [Highland Park's] charge data may turn out to be less favorable to ENH if rates were to apply to ENH's charge data.").

794. For each of the four managed care organizations that were covered in Noether's back-up materials, the prices at Evanston were higher than the prices at Highland Park. Haas-Wilson, Tr. 2646, *in camera*.

795. Baker calculated the percentage price increase following the merger for four health plans, Aetna, Blue Cross, Humana, and United. He did the calculations in two ways: (1) comparing Evanston and Glenbrook's premerger prices to the ENH post-merger prices; and (2) comparing Evanston, Glenbrook, and Highland Park's combined premerger prices (Baker's "constructed prices") to the ENH post-merger prices. Baker, Tr. 4633, *in camera*.

796. When Baker's constructed price (which includes the premerger prices at Highland Park) showed a larger price increase than his calculation for the price increase for just Evanston and Glenbrook, that necessarily means that the prices at Highland Park were lower than the prices at Evanston and Glenbrook premerger. *See* Baker, Tr. 4744-46, *in camera*.

797. Baker testified that looking at the prices actually paid by Aetna, Humana, and Blue Cross Blue Shield for inpatient services,

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services, the actual prices paid by those managed care organizations organizations to Highland Park were lower than the prices paid to Evanston in the premerger period. Baker, Tr. 4744-47, *in camera*.

(5) Noether's Control Groups Are Flawed

798. Noether looked at price levels and relied on a comparison of the price levels at ENH with the price levels of several major teaching hospitals in the Chicago area and with the price levels of community hospitals. Noether, Tr. 5991-92, 6000.

799. Noether drew conclusions about the manner in which ENH's prices increased above the prices of her selected community hospitals toward the prices of her selected academic hospitals. *See* Noether, Tr. 6060, *in camera*.

800. The comparisons performed by Noether depend upon the hospitals that Noether selected for her two groups of hospitals. If the control group selected by Noether is not appropriate, the analysis using that control group could lead to a biased result. Haas-Wilson, Tr. 2697, *in camera*.

(a) Noether Began with an Arbitrary Group of Twenty Hospitals

801. Noether began with her list of twenty hospitals (eighteen plus Evanston and Highland Park) to develop what she called her academic hospital and community hospital control groups. Noether, Tr. 6154-55.

802. Noether testified that to determine the list of twenty hospitals, she selected hospitals after she "reviewed the evidence from a variety of sources in the record and developed a list based on [her] analysis of the information," including hospitals which Noether testified were "in some way competitors to Evanston and/or Highland Park." Noether, Tr. 5913-14, 6149-50.

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803. There were no specific criteria or journal articles in economic literature used by Noether to decide which hospitals to include on her list of hospitals. Noether, Tr. 6149-50.

804. There was no single document that listed the hospitals as competitors. Noether made the decisions to pick and choose which hospitals she would include. Noether, Tr. 6149.

805. Noether's academic hospital control group consists of six hospitals, in addition to Evanston: Advocate Lutheran General, Advocate Northside, Northwestern Memorial, Rush-Presbyterian-St. Luke's, Loyola, and University of Chicago. Noether, Tr. 6000; RX 1912 at 60.

806. Noether's community hospital group consists of twelve hospitals, in addition to Highland Park: Alexian Brothers, Louis A. Weiss, Northwest Community, Resurrection, St. Francis, Rush North Shore, Condell, Holy Family, Lake Forest, Swedish Covenant, Vista Health Saint Therese, and Vista Health Victory Memorial. Noether, Tr. 6000; RX 1912 at 60.

**(b) Noether's Division of Her List of Hospitals
into an Academic Hospital Group and a
Community Hospital Group Is Arbitrary**

807. There is no official government designation of what hospitals are community hospitals or academic hospitals. Noether, Tr. 6155.

808. Noether used three criteria to select which of the twenty hospitals to include in her academic control group: teaching intensity (rate of residents to beds), number of staffed beds, and breadth of services (number of Diagnosis Related Groups ("DRGs")). Noether, Tr. 5993-95.

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809. Medicare Payment Advisory Commission (“MedPAC”) is an advisory body to Congress on Medicare reimbursement criteria. MedPAC defines a major teaching hospital as a hospital with at least .25 residents per bed. Noether, Tr. 5995.

810. The MedPAC criteria for classification as a major teaching hospital have nothing to do with the number of DRGs that a hospital offers. Noether, Tr. 6155.

811. In determining the number of DRGs to use as a criterion to include hospitals in her academic control group, Noether counted a hospital as offering a DRG only if the hospital offered it four or more times in a year, an arbitrary cut-off. Noether, Tr. 5914-15.

812. Using Noether’s criterion of four cases, even a change from looking at a fiscal year as opposed to looking at a calendar year can cause the number of DRGs that Noether counts to change. For example, in fiscal year 1999 Highland Park was found to offer 208 DRGs, but in calendar year 1999 Highland Park was found offering 212 DRGs. RX 1912 at 44, *in camera*; RX 1912 at 60.

813. Noether listed the hospitals in order of the number of DRGs that they offered, and took the top third of the hospitals as having enough DRGs to be classified as academic hospitals, so that she only included hospitals with more than 370 DRGs. Noether, Tr. 6164-65.

814. There is no basis in the health care literature to require a hospital to be above a certain number of DRGs in order to be considered an academic hospital. Noether, Tr. 6165-66.

815. Only after considering evidence describing the different hospitals on her list and after looking over the list of hospitals, did Noether decide to include the top third, instead of the top quarter or

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or top half of the hospitals as having enough DRGs to be included as an academic hospital. Noether, Tr. 6166-67.

816. The last hospital to be included as having enough DRGs to be considered as an academic hospital was Rush-Presbyterian-St. Luke's. Noether, Tr. 6167-68. Rush-Presbyterian-St. Luke's is one of the four highest priced hospitals in Noether's list of twenty hospitals. *See* RX 1912 at 147-52, *in camera*.

817. Similarly, the MedPAC criteria defining a major teaching hospital do not rely on size. Noether, Tr. 6155. All of the hospitals in Noether's academic control group have more beds than ENH, some of them, significantly more (e.g. Advocate Northside, with 663 beds). Haas-Wilson, Tr. 2708-09, *in camera*; RX 1912 at 60. *See* F. 829.

818. Noether's academic group included four of the most expensive hospitals in Chicago: { } RX 1912 at 147-52, *in camera* (Average Reimbursement per Case) RX 1912 at 147-49, *in camera* and (Average Reimbursement per Case, Excluding Obstetrics); RX 1912 at 150-52, *in camera*. Noether's academic group of hospitals are priced higher than her community group of hospitals. RX 1912 at 60; RX 1912 at 147-52, *in camera*.

819. Noether's academic control group excluded less expensive hospitals even though many of those excluded can handle most of the patients Evanston treated and treat more complex cases than ENH. *See* RX 1912 at 60; RX 1912 at 147-52, *in camera*.

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**(c) Noether's Academic Control Group Is Not
Not an Appropriate Control Group**

820. Noether's academic control group is not an appropriate control group from the scientific perspective. Haas-Wilson, Tr. 2698, *in camera*.

(i) Case Mix and Services Provided

821. There is a difference between the case mix of four of the six hospitals included by Noether in her academic control group and the case mix at ENH. { } all have case mix indexes that are much higher than ENH's case mix index. Haas-Wilson, Tr. 2698-2700, *in camera*.

822. Quaternary services are different from other inpatient hospital services. These services, which include solid organ transplants and treatment for severe burns, require very specific human capital, specially trained nurses and doctors and very specialized physical capital. Haas-Wilson, Tr. 2701-02, *in camera*.

823. ENH differed from the hospitals in Noether's academic control group in terms of quaternary services. ENH provides no solid organ transplants and no extensive burn cases, while four of the six hospitals in Noether's academic control group offer solid organ transplants, and two of the six hospitals treat extensive burn injuries. Haas-Wilson, Tr. 2702, *in camera*; CX 6282 at 7-8, *in camera*; Neaman, Tr. 1378.

824. Each of the hospitals in Noether's academic control group offers a broader range of services than ENH. The hospitals in Noether's academic control group offer the following number of DRGs that ENH does not offer: { } RX 1912 at 44, *in camera*.

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825. Noether excluded from her academic control group some hospitals that treated, on average, more complex cases than ENH, including: { } Haas-Wilson, Tr. 2594, *in camera*; Noether, Tr. 6168-72; RX 1912 at 25.

(ii) Teaching Intensity

826. Teaching intensity, as measured by the number of interns and residents per bed, is one way to *see* which hospitals are comparable to ENH. Haas-Wilson, Tr. 2708, *in camera*.

827. Four of the six other hospitals that Noether has in her academic control group have significantly more residents per bed than Evanston. Evanston has .3386 residents per bed, while Loyola University has .6060 residents per bed, Northwestern Memorial has .5670 residents per bed, Rush-Presbyterian-St. Luke's has .7606 residents per bed, and University of Chicago has .7938 residents per bed. RX 1912 at 60.

828. The combined ENH has .29 residents per bed. O'Brien, Tr. 3542.

829. Size, in terms of number of beds, is a characteristic that one could use to compare other hospitals to ENH to *see* if they are similar. All of the hospitals in Noether's academic control group have more beds than ENH, some of them, significantly more (e.g. Advocate Northside, with 663 beds). Haas-Wilson, Tr. 2708-09, *in camera*; RX 1912 at 60.

830. Noether excluded from her academic control group some hospitals that meet MedPAC's definition of a teaching hospital (more than .25 residents per bed), including: Louis A. Weiss and St. Francis. Norther, Tr. 6170; RX 1912 at 60.

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**(d) ENH Compared to Noether's Proposed
Geographic Market**

831. Noether compared ENH's prices to prices charged by other hospitals. Noether, Tr. 5992-93, 6000; RX 1912 at 146-50, *in camera*. { } RX 1912 at 147-52, *in camera*. { } RX 1912 at 147-52, *in camera*.

832. { } RX 1912 at 148, 151, *in camera*.

833. { } RX 1912 at 147, *in camera*.

834. { } RX 1912 at 149, 152, *in camera*.

835. { } RX 1912 at 149, 152, *in camera*.

836. { } RX 1912 at 149, 152, *in camera*.

837. { } RX 1912 at 148, 151, *in camera*.

b. Quality of Care**(1) Price Increases to Managed Care Were Not
Related to Improvements at Highland Park**

838. The economic testimony in this case appears to view quality as part of the cost/price continuum. Baker testified that "quality improvements need to be considered in evaluating competitive effects because if quality gets better, the quality-adjusted price to the buyers declines." Baker, Tr. 4604. Baker agreed that there is no need to adjust for quality of care if quality of care is changing at the same rate as other hospitals. Baker, Tr. 4799, *in camera*.

839. Haas-Wilson testified that "[i]f quality is increasing in general, that would lead to potentially higher prices at all hospitals,

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hospitals, and if quality is increasing more at one hospital than at others, then that could potentially explain a greater price increase at at one hospital over others in the case where the buyers of hospital hospital services value that quality enhancement.” Haas-Wilson, Tr. 2484-85.

840. ENH did not justify its price increases to managed care based on improvements being made at Highland Park. F. 842-47.

841. Respondent did not present an explanation of how to value the “improvements” or how to compare them to the price increases. Chassin, Tr. 5447-48.

842. ENH’s COO, Hillebrand, admitted that he did not tell managed care organizations that the higher prices were justified by quality changes. Hillebrand, Tr. 1784.

843. ENH’s CEO, Neaman, admitted that he never saw any documents correlating the higher prices with the quality changes at Highland Park. Neaman, Tr. 1241-42.

844. The One Health representative testified that the topic of quality changes simply never came up during negotiations. E.g., Neary, Tr. 624.

845. The PHCS representative testified that even after implementing the changes, ENH did not advertise them to managed care organizations. Ballengee, Tr. 188, 200-03.

846. The PHCS representative testified that Highland Park’s quality of care has remained the same from before the merger to after the merger. Ballengee, Tr. 187.

847. The United representative testified that she had not been shown any evidence that the quality of care improved at Highland Park. Foucre, Tr. 926-27.

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848. Simultaneous with the execution of the Letter of Intent, on June 30, 1999, Evanston and Highland Park sent a press release to managed care organizations, area employers, elected officials, and the press describing the goals of the merger: “The merger will result in significant additional investments in clinical services at the Highland Park Hospital campus Our intent is to strengthen Highland Park Hospital’s capabilities in key clinical growth areas such as oncology, cardiac services, obstetrics, fertility, home health, behavioral health,” and listed specific projects such as the Kellogg Cancer Care Center. RX 563 at ENH TH 1568-76; Hillebrand, Tr. 1857-58.

849. The PHCS representative testified that managed care organizations will pay more to select hospitals that offer more complex services and with reputations for higher quality. Ballengee, Tr. 163-64.

850. Highland Park management and outside observers believed that the quality of care of Highland Park was “very good, if not excellent” at the time of the merger. Newton, Tr. 376.

851. Highland Park was also described as a “pretty good community hospital” that “delivers basic services at a very high level” and was perceived as an “excellent community hospital.” Neaman, Tr. 1306; Spaeth, Tr. 2098; CX 1868 at 7, 10.

852. Evanston and Highland Park “were both very good hospitals.” Ballengee, Tr. 160.

**(2) No Evidence of Improvement in Overall
Quality of Care Relative to Other Hospitals**

853. In 1999, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) evaluated hospitals including Highland Park and Evanston. *See* Spaeth, Tr. 2148-49. In 1999, Highland Park received a preliminary score of 95 and a final score

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of 96 out of 100. Spaeth, Tr. 2122, 2148-49; CX 96 at 1; CX 2304 at 3; RX 412 at ENHL PK 17794, *in camera*. In 2002, Highland Park received a score of 94 as part of ENH's JCAHO survey. RX 1380 at ENH JH 11480.

854. Evanston received a preliminary score of 94 in 1999 and a final score of 95 in 2000. Neaman, Tr. 1198, 1231; CX 871 at 4; CX 6 at 5; RX 1380 at ENH JH 11480.

855. Most hospitals in this country use JCAHO scores to look at quality of care. Spaeth, Tr. 2154.

856. JCAHO scores are based on about 1200 very specific aspects of hospital activities that are called elements of performance. Chassin, Tr. 5156-57.

857. JCAHO is the nationally accepted norm for healthcare accreditation organizations. Other quality measurement tools are in their infancy and not viable options for managed care organizations to compare hospital quality. Ballangee, Tr. 186-87.

858. JCAHO accreditation is necessary to qualify for Medicare and many managed care plans. Ballengee, Tr. 151; Newton, Tr. 385.

859. Complaint Counsel's expert testified that starting in the late 1990's, there has been a nationwide trend of improved quality, with one major study finding an average per state inpatient improvement rate of 12% through 2001. Romano, Tr. 3000-01. Other studies also show that hospitals were improving their quality during the time from 1997 through 2004. Romano, Tr. 2999-3000; *see also* Noether, Tr. 6011.

860. The U.S. Agency for Healthcare Research and Quality (AHRQ) is the lead federal agency that is responsible for developing and promoting methods for quality of care research in the United States. Romano, Tr. 2969.

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861. Complaint Counsel's expert, Romano, using AHRQ measures found { } at Highland Park relative to a control group. Romano, Tr. 3093-95, 3210-12, *in camera*; see also DX 7034A at 1.

862. Using the JCAHO measure, Romano found evidence of { } at Highland Park, although that evidence was not statistically significant. Romano, Tr. 3217, *in camera*; see also DX 7034A at 2.

863. In obstetrics, using the AHRQ measures, Romano found evidence of { } under the JCAHO measures. Romano, Tr. 3226-29, *in camera*; see also DX 7034A at 10-11.

864. JCAHO measure uses the more typical kind of risk adjustment process, which is logistic regression while the AHRQ measure uses a cruder risk adjustment based on DRGs. Chassin, Tr. 5184.

865. Press Ganey does survey work in hospitals regarding patients perception of their care, in the form of patient satisfaction surveys. Neaman, Tr. 1227; Romano, Tr. 2982-83; Romano, Tr. 3098, *in camera*.

866. Many of the Press Ganey questions concern amenities. Spaeth, Tr. 2093-94; Romano, Tr. 3339-40, 3342.

867. The response rate of the Press Ganey data is unclear. Romano, Tr. 3344-46. Respondent's healthcare quality expert, Dr. Mark R. Chassin, Edmond A. Guggenheim Professor of Health Policy, Chairman of the Department of Health Policy of the Mount Sinai Medical School, made a rough estimate that the response rate was about twenty percent, which Romano admitted would be suboptimal. Romano, Tr. 3346; Chassin, Tr. 5244.

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868. Complaint Counsel's expert, Romano, was not aware of the Press Ganey survey methodology. Romano, Tr. 3344-45.

**(3) ENH's Non-Merger Specific Improvements
to Highland Park**

869. In its 1998 Strategic Plan for Highland Park 1999-2002, Highland Park's parent company, planned to: maximize the Northwestern Healthcare affiliation; implement a cardiovascular surgery program; implement a comprehensive oncology program; recruit physician specialists; enhance physician leadership throughout the organization with improved communication forums; promote a work environment that facilitates strong associate relations, open communication, teamwork, involvement, and standards of excellence; and improve workflow and scheduling systems in all departments with particular focus on radiology, cardiology, laboratory, and physical medicine to increase patient satisfaction. CX 1868 at 12-14, 17.

870. Recognizing the need to improve quality, on March 23, 1999, Lakeland's strategic plan for 1999-2003, included among its goals to: enhance its core clinical competencies (cardiac surgery, oncology and specialty surgery); implement a cardiovascular surgery program; implement a comprehensive oncology program; identify and promote selected physician clinical leaders and enhance physician leadership; provide documented and measurable outcomes of quality which exceed those of the competition and establish national standards and provide a continuum of care for the patient across the delivery system including providing the highest quality clinical and non-clinical services; utilize the latest technology to support patient care; and promote a work environment that facilitates strong associate relations, open communication, teamwork, involvement, and standards of excellence to achieve success. CX 1908 at 9, 12-13, 18-20, 23.

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871. Highland Park recognized the need for improvements as early as 1998 and in March of 1999, before the merger, outlined a strategic plan to improve its quality of care. CX 1868; CX 1908.

872. In March 1999, Highland Park's finance committee approved more than \$100 million for new projects through 2003. CX 1055 at 2; CX 1903 at 2-3; CX 545 at 3.

873. Highland Park's long range capital budget identified \$43 million for investment in strategic initiatives and master plan items such as cardiology services, ambulatory services, oncology, assisted living, and facility expansion and \$65 million for hospital construction, routine capital, and information technology. CX 545 at 3.

874. The finance committee concluded that based on growth through new clinical services and existing cash and investments and cash flow, the hospital could "generate sufficient cash" to "restore the profitability" of Highland Park and fund the improvements. CX 1903 at 1; CX 545 at 4.

875. Prior to the merger, Highland Park always had the latest piece of equipment and if it needed to invest in new technology, it made those routine investments and purchased new technology. Newton, Tr. 384.

(a) Obstetrics and Gynecological Services

876. At the time of the merger the Obstetrics and Gynecological ("Ob/Gyn") department was the largest patient care area at Highland Park. Chassin, Tr. 5196

877. ENH instituted nighttime and weekend coverage by obstetricians in Highland Park's Ob/Gyn department. Chassin, Tr. 5204; Silver, Tr. 3779-80, 3783-84.

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878. ENH installed a full-time chair for the Ob/Gyn department in the Spring of 2001. Chassin, Tr. 5204-05; Silver, Tr. 3841.

879. Nurse training models of care were improved. This process began before the merger and continued after the merger. Chassin, Tr. 5205.

880. ENH provided multidisciplinary clinical care at Highland Park, so that doctors, nurses, and all of the participants in the obstetric services worked together as a team. Chassin, Tr. 5206-07.

881. ENH instituted an Ob/Gyn preoperative surgery review program at Highland Park. Chassin, Tr. 5206; Silver, Tr. 3780-81.

882. ENH instituted physician discipline against a few of Highland Park's Ob/Gyn physicians. Chassin, Tr. 5206-07; Silver, Tr. 3882-83, 3886, *in camera*.

883. Prior to the merger, Highland Park had invited the { } review of the hospital as part of its ongoing effort to improve quality of care. Romano, Tr. 3152-54, *in camera*; Spaeth, Tr. 2114-15; Chassin, Tr. 5498; RX 324 at ENHL PK 29688-89, *in camera*.

884. { } made a number of recommendations to improve the { } Romano, Tr. 3154-55, *in camera*; RX 324 at ENHL PK 29689, *in camera*.

885. Many changes were made in reaction to the { }, including the hiring of a { } in 1998. Romano, Tr. 3155, *in camera*; Spaeth, Tr. 2114-15; CX 98 at 2.

886. Highland Park's efforts to implement { } recommendations were subsequently recognized by the Chicago Hospital Risk Pooling Program after a site visit and report issued in

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in November of 1999. Romano, Tr. 3155-58, *in camera*; CX 6265, *in camera*.

887. The Chicago Hospital Risk Pooling Program made additional recommendations for improvement. CX 6265 at 17-30, *in camera*.

(b) Quality Assurance Programs

888. ENH changed the structure within the clinical departments of how oversight of physicians was conducted by replacing part-time and private practice chairs with full-time ENH clinician chairs. Chassin, Tr. 5211, 5224-25; Spaeth, Tr. 2253-54.

889. ENH took disciplinary action against a number of Highland Park physicians. Chassin, Tr. 5225-26.

890. ENH reviewed physician practices during periodic recredentialing. Chassin, Tr. 5226-27.

891. There were post-merger changes made in error reporting and adverse events reporting, although these changes took a fair amount of time to play out. Chassin, Tr. 5227-29.

892. Highland Park, premerger, had regularly initiated disciplinary actions against its physicians, including suspension, reduction, or removal of staff privileges. Newton, Tr. 382-83.

893. There are a number of examples of Highland Park's review of adverse events prior to the merger. Chassin, Tr. 5514; RX 251 at ENHL PK 17839, *in camera*; RX 346 at ENHL PK 24708-11, *in camera*; CX 6296 at 3-6, *in camera*.

894. The { } was requested because of an adverse event in the { } Krasner, Tr. 3733-34.

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895. The quality assurance improvements made by ENH at Highland Park after the merger reflect an emerging consensus in the field of quality assurance. Romano, Tr. 3159, *in camera*.

(c) Quality Improvement Programs

896. After the merger, the critical pathways at ENH were aligned with the care maps being used at Highland Park, improving both. O'Brien, Tr. 3559-60; Chassin, Tr. 5257; CX 6286 at 4 (King, Dep.).

897. Critical pathways and care maps are protocols identifying the best practices for the treatment of patients. Romano, Tr. 3167-68, *in camera*; Silver, Tr. 3803-04.

898. Prior to the merger, Highland Park conducted an internal review of quality programs which highlighted areas for improvement. Chassin, Tr. 5256; RX 417.

899. Nothing in the record suggests that ENH's critical pathways were better than the care maps used by Highland Park before the merger or that Highland Park would not have continued to develop other care maps after 1999 on its own. Silver, Tr. 3839; Romano, Tr. 3170-71, *in camera*.

900. The evidence does not clearly show whether the critical pathways are always being followed. Romano, Tr. 3170, *in camera*.

901. Critical pathways are always being revised and improved. O'Brien, Tr. 3561-62.

902. The quality improvements made by ENH at Highland Park after the merger reflect an emerging consensus in the field of quality improvements. Romano, Tr. 3159, *in camera*.

(d) Nursing Staff

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903. ENH improved communication and teamwork between nurses and physicians. Chassin, Tr. 5239-40.

904. After the merger, nurse training improved, some nurses received training at ENH, and nurse managers were rotated through all ENH hospitals. Chassin, Tr. 5239; O'Brien, Tr. 3535; Krasner, Tr. 3725-26; RX 1445 at ENHL PK 51620.

905. ENH eventually improved recruiting, vacancy, and turnover rates. RX 1445; O'Brien, Tr. 3671-72, *in camera*; Krasner, Tr. 3722-24.

906. Highland Park had intergenerational nursing where grandmothers, mothers, and daughters were all nurses at the hospital. Newton, Tr. 383.

907. Highland Park had a "high quality nursing staff" in the 1990's. Newton, Tr. 383.

908. In 1999, Highland Park adopted a comprehensive initiative to train, retain, and reward its nurses. CX 1908 at 23; CX 6264 at 1; Krasner, Tr. 3721; Newton, Tr. 410-11.

909. The nursing culture at Highland Park underwent a transition from a punitive and dysfunctional culture to a much more effective culture over a period of years beginning before the merger and continuing until 2004. Chassin, Tr. 5239, 5478-79; O'Brien, Tr. 3536-37.

910. The improvements to the nursing culture was an evolutionary process that took many years. Chassin, Tr. 5478-79.

(e) Physical Plant

911. ENH built a new ambulatory care center which opened in February 2005, and which houses radiation medicine, nuclear

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medicine, the Kellogg Cancer Care Center, and a new breast imaging Center. O'Brien, Tr. 3497-98; Chassin, Tr. 5288-89.

912. ENH built a new cardiac cath lab to support the interventional cardiology program; renovated and expanded the emergency department and psychiatry units; and added modern equipment in a variety of areas. Chassin, Tr. 5288-89.

913. ENH replaced the Highland Park patient care building's electrical distribution and ventilation systems, plumbing, and waste pipes. Hillebrand, Tr. 1982.

914. ENH built a new central plant at Highland Park, including a new power plant that houses utilities such as electrical generators, backup generators, boilers, and air ventilation equipment. Hillebrand, Tr. 1979; O'Brien, Tr. 3514-15; CX 6304 at 14 (Livingston, Dep.).

915. ENH added an additional boiler, new air handlers for the ventilation system, replaced the electrical generator, and added a second emergency electrical generator. Hillebrand, Tr. 1979-80.

916. ENH began remodeling all of its patient units in December of 2003. O'Brien, Tr. 3511-12; Neaman, Tr. 1351-52. The process of remodeling patient rooms is continuing and scheduled at least through 2006. O'Brien, Tr. 3513.

917. ENH added a new parking garage and made improvements to the lobby corridor and entrance to Highland Park. O'Brien, Tr. 3513-15; Hillebrand, Tr. 1920-21, *in camera*; CX 6304 at 14 (Livingston, Dep.).

918. On April 15, 1999, the Illinois Department of Public Health Health and Healthcare Financing Administration conducted a survey survey of Highland Park's physical plant and identified 144 physical physical plant deficiencies which needed to be corrected to continue

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continue to participate in Medicare. Chassin, Tr. 5285-86; RX 1379 1379 at ENH LH 11544.

919. On August 26, 1999, 26 items were removed from the list and 3 were added for a total of 121 deficiencies. RX 1379 at ENH LH 11544.

920. On December 9, 1999, a reinspection was conducted and 88 additional items were removed from the list leaving a total of 33 items. The plan for correction of these remaining items was submitted by Highland Park on December 28, 1999, prior to the merger, and these remaining items were corrected by ENH by August 1, 2000. RX 1379 at ENH LH 11544; Spaeth, Tr. 2258-59.

(f) Oncology Service

921. Through the Kellogg Cancer Center at Highland Park, ENH implemented a multidisciplinary approach that brought together an oncology team consisting of the physician oncologist, nurse, pharmacist, psychologist, social workers, and nutritionists who were available to patients in one location. Chassin, Tr. 5369-70; Dragon, 4391.

922. ENH brought subspecialty oncologists to Highland Park so that patients would not have to travel for their consultations. Chassin, Tr. 5369-70.

923. The Kellogg Cancer Center moved into a new section of the ambulatory care center in March 2005. Dragon, Tr. 4389-90.

924. Before the merger, Highland Park already had undertaken numerous initiatives in ontology services and had a variety of options other than the merger to achieve these same ends. Spaeth, Tr. 2224-25; CX 91 at 2; CX 1869 at 4; Neaman, Tr. 1243.

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925. Highland Park had considered joint comprehensive oncology programs with organizations other than ENH. CX 1868 at 13; CX 99 at 2; CX 1866 at 1, 5; Newton, Tr. 420.

926. In the 1990's, Highland Park had created centers of excellence for oncology and breast cancer that it was continually improving until the time of the merger. CX 91 at 2; CX 1869 at 4; Newton, Tr. 291-92, 419-20.

927. These centers of excellence already had access to the necessary technology, physicians, and research protocols in place to develop a comprehensive oncology program, and Highland Park merely needed to develop the community perception of excellence. Newton, Tr. 291-92, 419-20.

928. To this end, Highland Park could have expanded its oncology services and research activities through an affiliation agreement with hospitals other than ENH and, in fact, it was exploring these options before the merger, including the possibility of a joint venture with ENH or another hospital for oncology services. Newton, Tr. 340-42, 417-20; Neaman, Tr. 1243; Hillebrand, Tr. 2044-45.

(g) Radiology, Radiation Medicine, and Nuclear Medicine

929. ENH purchased a linear accelerator for Highland Park. O'Brien, Tr. 3500.

930. ENH added two new CT scanners in Highland Park's radiology department, upgraded radiation therapy equipment, and purchased a simulator. O'Brien, Tr. 3496, 3501-02; Chassin, Tr. 5362-63; RX 1896 at ENHL MO 7109.

931. ENH purchased a CT pet, which is a diagnostic tool, for the nuclear medicine department. O'Brien, Tr. 3496, 3501-02.

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932. ENH extended RADNET, its radiology imaging system and PACS, its filmless radiology imaging system, to Highland Park. O'Brien, Tr. 3494; Romano, Tr. 3184-85, *in camera*.

933. ENH added additional radiology staff to improve turnaround times for reading radiology reports. O'Brien, Tr. 3493.

934. Highland Park had a premerger budget of \$9.5 million to improve radiology services. CX 545 at 20.

(h) Emergency Care

935. ENH improved both the physical layout and service components of Highland Park's emergency department. Chassin, Tr. 5333-34.

936. ENH invested in a major facility expansion, improved physician and nurse staffing, and improved the fast track procedures in the emergency department. Harris, Tr. 4213-14; Newton, Tr. 470; Hillebrand, Tr. 1980-81.

937. Prior to the merger, the emergency department at Highland Park was "very good," and was "on par, if not better" than Highland Park's peers. Newton, Tr. 394-95.

938. Throughout the 1990's, Highland Park had continually made improvements to its emergency care: it had implemented a fast-track program to improve turnaround times; it had added physician assistants to the emergency room; it had streamlined the radiology process; and it had reduced the time that it took for a patient to receive an EKG. Harris, Tr. 4266-70.

939. Highland Park planned to "expand the Emergency Department from a facilities standpoint." Newton, Tr. 394; Harris, Tr. 4289-90; CX 98 at 2.

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940. Highland Park could have made the changes to the emergency department absent the merger: for example, most emergency departments at hospitals like Highland Park are staffed through contracts with physician groups, and Highland Park simply could have “demanded” higher staffing of the emergency room as a condition of its contract. Romano, Tr. 3111-12, *in camera*; Harris, Tr. 4204-07.

(i) Laboratory Medicine

941. Prior to the merger, Highland Park operated Consolidated Medical Labs (“CML”), a joint venture with Lake Forest that consisted of a main lab located between the two hospitals with satellite labs at Highland Park and Lake Forest. Victor, Tr. 3638-40.

942. After the merger, ENH decided to close CML and expand the on-site laboratory at Highland Park, although certain tests are sent to the laboratory at Evanston. O’Brien, Tr. 3507-09; Victor, Tr. 3591-92.

943. ENH constructed new histology and cytology laboratories on-site, installed over \$1 million in state-of-the-art lab equipment, and introduced more stringent quality controls. Victor, Tr. 3615-17, 3619-20.

944. CML afforded Highland Park’s lab “greater volume,” “access to greater human pathology,” and the “opportunity to provide a greater benchmark in terms of [the lab’s] performance.” Newton, Tr. 396-97. The lab operated “actually exceptionally well.” Newton, Tr. 396.

945. Highland Park could have easily implemented further changes in its laboratory in the absence of the merger. Romano, Tr. 3178, *in camera*.

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946. Many of the changes that ENH made after the merger were simply consistent with updates that all hospital laboratories made during that period in order to meet licensing and accreditation standards. Romano, Tr. 3179, *in camera*.

(j) Pharmacy

947. ENH installed approximately twenty Pyxis automated drug distribution machines at Highland Park in 2000. Kent, Tr. 4851, 4854-55.

948. ENH has decentralized the pharmacists. RX 1697 at ENHL PK 51635; Kent, Tr. 4864-65.

949. ENH added an additional pharmacist to dispense medications at night in the summer of 2003. Kent, Tr. 4846, 4849; RX 1697 at ENHL PK 51635.

950. The Pyxis system did not become available to hospitals until the late 1990's, when there was a "trend" in which pharmaceuticals and medications were decentralized to be located in the unit itself. Newton, Tr. 397-98.

951. Pyxis costs about \$20,000 per machine, and Highland Park could have installed the machines on its own. Newton, Tr. 399; Romano, Tr. 3180, *in camera*.

(k) Cardiac Surgery

952. ENH opened a cardiac surgery program at Highland Park in June of 2000. Spaeth, Tr. 2275-76; Neaman, Tr. 1381; RX 879 at ENH GW 3252.

953. Cardiac surgery is a necessary component of a full-service cardiology program. Chassin, Tr. 5290.

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954. Cardiac surgery procedures include coronary artery bypass grafting, valve procedures, and surgery on the aorta. Rosengart, Tr. 4452.

955. Before the merger, Highland Park already had plans to open a cardiac surgery program with Evanston or another hospital. CX 1868 at 13; CX 1867 at 1; CX 91 at 2; CX 1869 at 4; Newton, Tr. 335-38.

956. Highland Park also considered a joint cardiac surgery program with Northwestern Memorial or Advocate Lutheran General. Newton, Tr. 338.

957. ENH runs successful joint cardiac surgery programs with Swedish Covenant and Louis A. Weiss. Romano, Tr. 3075, *in camera*; Rosengart, Tr. 4443-44.

958. Highland Park and Evanston had executed a contract for a joint cardiac surgery program before the merger. Newton 335-36; CX 2094.

959. The Certificate of Need Application for the Highland Park cardiac surgery program indicates that the collaboration necessary to implement the program did not depend on the merger. *See* CX 413 at 5.

(I) Interventional Cardiology

960. Interventional cardiology refers to the treatment of obstructions in coronary arteries (coronary disease) by dilating the plaques obstructing the arteries and inserting little wire tubes called stents to keep the arteries open. Chassin, Tr. 5303.

961. After the merger, ENH established an interventional cardiology program at Highland Park. Chassin, Tr. 5304-05.

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962. ENH built a new cardiac catheterization lab at Highland Park that performs both diagnostic and interventional procedures such as angioplasties. Hillebrand, Tr. 1980; O'Brien, Tr. 3490.

963. Highland Park's medical staff included physicians with the expertise to perform interventional cardiac procedures. Newton, Tr. 466.

964. Highland Park planned to expand the diagnostic capabilities of its existing cardiac catheterization lab and to provide emergent angioplasty in conjunction with the planned cardiac surgery program or even "without open heart on-site." Newton, Tr. 337, 416-17.

(m) Psychiatry

965. Before the merger and through the spring of 2001, Highland Park and Evanston each had separate inpatient psychiatric units that treated both adult and adolescent patients. O'Brien, Tr. 3516; RX 1754 at ENH RS 3086.

966. In the spring of 2001, ENH consolidated the adolescent inpatient services at Highland Park and the adult inpatient services at Evanston. O'Brien, Tr. 3517; Chassin, Tr. 5339; Neaman, Tr. 1358-59; RX 1080 at ENHL PK 55405.

967. ENH hired several adolescent psychiatrists to staff the Highland Park adolescent unit. O'Brien, Tr. 3518.

968. ENH remodeled the psychiatric unit in December 2003, to include private patient rooms with a keyless entry system and secure furniture. O'Brien, Tr. 3518-19.

969. The post-merger segregation of psychiatric patients (adolescents at Highland Park and adults at Evanston) is a structural

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structural change which has not been shown in the medical literature literature to improve outcomes. Romano, Tr. 3115-16, *in camera*.

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(n) Intensivist Program

970. ENH added an intensivist program to Highland Park after the merger. Ankin, Tr. 5041; RX 1099 at ENHE F35 340; O'Brien, Tr. 3529-30; Chassin, Tr. 5328.

971. An intensivist is a physician who specializes in the care of intensive care patients and who has more experience dealing with the complications of these critically ill people. Ankin, Tr. 5035-36; O'Brien, Tr. 3529.

972. Intensivists also have an administrative role in overseeing and coordinating the medical and nursing staff that provide care to critically ill patients. Ankin, Tr. 5036.

973. Intensivist programs in hospitals like Highland Park became popular only after 2000. Romano, Tr. 3113-14, *in camera*; Ankin, Tr. 5078.

974. Pulmonary Physicians of the North Shore, which provides the intensivist coverage at Highland Park, does so through a contractual arrangement. Ankin, Tr. 5103-04, *in camera*; CX 2176 at 1, *in camera*.

975. Pulmonary Physicians of the North Shore would consider contracting with a new owner of Highland Park. Ankin, Tr. 5104-05, *in camera*.

(4) ENH's Merger Specific Changes to Highland Park**(a) Electronic Medical Records**

976. In 2001, ENH decided that its current medical records system was not sufficient to meet its needs and ENH began its search for a better system. Wagner, Tr. 3964.

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977. In June 2001, the EPIC clinical information system was selected from a group of finalists. Wagner, Tr. 3965.

978. EPIC is a software system for managing patient records for both hospital and physicians and was selected, in part, for its ability to work with physician offices. Wagner, Tr. 3966-67.

979. EPIC includes a computerized physician order entry system and clinical decision support systems. O'Brien, Tr. 3520; Chassin, Tr. 5365.

980. The EPIC system was implemented at all three hospitals, at the faculty practice medical group, and at all the affiliated physician practices that were willing to participate. Wagner, Tr. 3967.

981. EPIC became functional at Highland Park in December 2003. Wagner, Tr. 4069- 70; Neaman, Tr. 1251.

982. ENH spent approximately \$14 million to implement EPIC at Highland Park. O'Brien, Tr. 3523; Hillebrand, Tr. 1984; Neaman, Tr. 1355.

983. Comprehensive medical records systems like EPIC are an emerging technology and very few hospitals had such a system before 2000. Romano, Tr. 3161-62, *in camera*.

984. There are a number of electronic medical records systems other than EPIC, including Meditech and McKesson. Wagner, Tr. 4067-69.

985. Meditech, as deployed at Highland Park, was not paperless, could not be accessed remotely, and lacked ambulatory capability. O'Brien, Tr. 3521; Wagner, Tr. 4061-62.

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986. Meditech, the computer program used by Highland Park before the merger, was and is an “excellent” system that other hospitals continue to use today. Romano, Tr. 3165-66, *in camera*; Newton, Tr. 333-34.

987. The federal government has established a national initiative to develop universally accessible electronic healthcare records systems for all citizens. In 2004, the Office of National Healthcare Information Technology was created. Wagner, Tr. 3957; RX 1701 at 1.

(b) Medical Staff Integration and Academic Involvement

988. Family medicine is the only department at Highland Park that has residents and at the time of trial, there were only 6 residents. O’Brien, Tr. 3539; Romano, Tr. 3125, *in camera*.

989. Since the merger, physicians in pathology, radiology, emergency medicine, cardiology, cardiac surgery, and some parts of anesthesiology rotate through all three campuses. Chassin, Tr. 5598; O’Brien, Tr. 3540-41.

990. Following the merger, about sixty Highland Park physicians were able to obtain appointments at Northwestern Medical School. Chassin, Tr. 5376; O’Brien, Tr. 3540.

991. ENH provides Highland Park physicians with a \$4,000 continuing medical education stipend. Harris, Tr. 4253.

992. The merger did not transform Highland Park into an academic hospital. Romano, Tr. 3117-18, *in camera*.

993. Merely being owned by a teaching hospital has not been shown in previous studies to be associated with improved processes and outcomes of care. Romano, Tr. 3118, *in camera*. There

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There is no evidence that Highland Park benefitted simply by being being owned by a teaching hospital. Romano, Tr. 3124, *in camera*. *camera*.

c. Nonprofit Status**(1) Respondent's Nonprofit Status Did Not Affect Its Approach to Post-Merger Price Increases**

994. As part of the merger with Highland Park, ENH decided to renegotiate contracts with the managed care organizations in 2000. Neaman, Tr. 1031; *see* F. 355-64.

995. When ENH set prices for the 2000 contract renegotiations with health plans, the fact that it was a non-profit entity did not weigh in as a reason not to take actions toward higher prices. Neaman, Tr. 1032-33.

(2) Respondent's Nonprofit Status Did Not Affect Incentives for Management

996. On June 29, 1999, shortly before the letter of intent to merge was signed, Highland Park's senior executives entered into enhanced compensation agreements that replaced their previous agreements. The new agreements "offered additional retention bonuses as well as enhanced severance agreements" at a cost of \$8 million. CX 534 at 3.

997. ENH's managers were given bonuses for meeting revenue targets from operations, giving managers the incentive to set supra competitive prices. Simpson, Tr. 1629.

998. ENH management planned to benefit from some of the money derived from raising hospital prices post-merger. The president of ENH proposed adding an additional \$3 million into the the 2000 bonus pool attributable to the merger integration activities.

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activities. The board reduced this amount to \$1 million, which ultimately was the amount distributed to the top fifty people. Neaman, Tr. 1263-64; CX 31 at 1.

999. Several of ENH's senior executives received merit increases in their salaries in the range of 5 to 6% in 1998 to 1999 and a 10% increase from fall of 2000 to fall of 2001. These increases in compensation coincided with the completion of the merger integration efforts. Neaman, Tr. 1265-67; CX 2099 at 2-3.

1000. Various ENH executives also received substantially higher awards at the end of 2000 compared to the awards in 1998 and 1999. Neaman, Tr. 1267-69; CX 2099 at 8-9.

1001. ENH's compensation contracts did not align management's interests with consumers on the issue of price. Simpson, Tr. 1629.

**(3) Respondent's Board Did Not Get Involved
in Pricing Issues**

1002. ENH's Board contains community representatives who provide oversight to the organization. Simpson, Tr. 1639. Approximately three-quarters of ENH's Board are outside directors chosen from the community. Simpson, Tr. 1639. In addition to the ENH Board, the Healthcare Foundation of Highland Park also monitors ENH's activities, specifically its commitments to Highland Park and the Highland Park community. RX 2037 at HFHP 1364; Styer, Tr. 4971, 4985.

1003. The ENH board did not actively monitor the pricing decisions of hospital management and did not try to ensure that price was set at a competitive level. Simpson, Tr. 1622, 1629.

1004. Spaeth attended meetings of the Highland Park board before the merger and of the ENH board after the merger. Spaeth, Tr.

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Tr. 2215. Over the years, including after the merger, Spaeth has never heard a board member or Neaman say that ENH should lower its rates to managed care organizations or make any comment regarding the rate at which the hospital was contracting with a particular payor. Spaeth, Tr. 2218-19.

1005. The ENH board is not involved in negotiations with managed care organizations, does not review contracts, and is not informed in advance of negotiating strategies. CX 6304 at 17-18 (Livingston, Dep.).

(4) Highland Park Healthcare Foundation

1006. In December 1999, Evanston Hospital and the Highland Park Foundation signed the agreement creating the Healthcare Foundation of Highland Park. RX 2037; Styer, Tr. 4977-78. The Healthcare Foundation of Highland Park came into being on January 1, 2000, as a result of the merger. Styer, Tr. 4951, 4971; Belsky, Tr. 4894; Spaeth, Tr. 2281.

1007. The Healthcare Foundation of Highland Park started with a corpus of roughly \$100 million. Neaman, Tr. 1260. As of March 2005, the Healthcare Foundation had an \$85 million corpus, down from its original \$100 million, due to poor performance of investments in 2000 and 2001 and because the Foundation has given away more than \$28 million. Styer, Tr. 4979-80.

1008. During the merger negotiations, Evanston attempted to minimize the amount of funds that Highland Park would contribute to the post-merger foundation. Kaufman, Tr. 5863.

1009. The Foundation Agreement establishing the Healthcare Foundation of Highland Park describes the Foundation's mission as being to support Highland Park and healthcare in the general Highland Park community. RX 2037 at HFHP 1356; Styer, Tr. 4951, 4979; Neaman, Tr. 1373.

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1010. The Foundation Agreement creating the Healthcare Foundation of Highland Park obliged the Foundation to send to ENH the greater of 100% of its investment earnings or \$8 million in 2000, the greater of 75% of its investment earnings or \$6 million in 2001 and 2002, and the greater of 50% of its investment earnings or \$4 million for every year thereafter. RX 2037 at HFHP 1362; Styer, 4980-81; Spaeth, Tr. 2281; Neaman, Tr. 1261; Belsky, Tr. 4898. The Foundation Agreement, in turn, obliges ENH to use the money it gets from the Healthcare Foundation to offset the costs of uncompensated care and other clinical programs at Highland Park selected at ENH's discretion. RX 2037 at HFHP 1362; Styer, Tr. 4981.

1011. The majority of the Healthcare Foundation's funds sent to ENH are used to support indigent or uncompensated care at Highland Park. Styer, Tr. 4981; H. Jones, Tr. 4179-80.

1012. The Healthcare Foundation of Highland Park also dispenses grants to charities in the Highland Park area. Styer, Tr. 4987-88. Since its creation, the Healthcare Foundation of Highland Park has given roughly \$26 million back to Highland Park and another \$3 to 4 million to organizations within the greater Highland Park community. Styer, Tr. 4974.

1013. In 2002, the Healthcare Foundation awarded \$500,000 to the Lake County Health Department to establish a community healthcare clinic in the Highland Park/Highwood area to improve access to healthcare for underserved populations in southeast Lake County. RX 1238 at HFHP 2565.

d. Ease of Entry

1014. Illinois has a state Certificate of Need ("CON") Law that governs future hospital entry or expansion. D. Jones, Tr. 1653-54, 1655; Spaeth, Tr. 2167.

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1015. CON approval from the state's Planning Board is required if a health care facility is going to engage in a transaction that is clinical in nature and exceeds either the capital expenditure or the major medical equipment threshold. D. Jones, Tr. 1655.

1016. The Planning Board, when reviewing a CON application for additional beds, considers whether the proposed beds are actually needed at the facility. D. Jones, Tr. 1656.

1017. Bed need is calculated with need formulas established by the board in its administrative rules. The Division of Health Statistics compiles the data and variables necessary to compute those bed needs for the Division of Health Systems Development. D. Jones, Tr. 1664.

1018. Based on the Planning Board's current addendum to its inventory, there is no need for beds in the Evanston, Glenview, and Highland Park areas for services in medical/surgical, pediatrics, or intensive care units. D. Jones, Tr. 1665-66.

1019. If someone were to submit a CON application for the construction of a new hospital in Evanston today, the Department of Public Health's report would most likely issue a negative finding regarding the bed need for a new facility by referencing the existing providers in the Evanston area, referencing the current bed need calculation for that area, and determining that additional beds are not needed based on the Planning Board's inventory. D. Jones, Tr. 1666-67.

1020. The state CON Board has denied hospitals beds where there is no bed need. If an area is overbedded, the likelihood that the State of Illinois would approve additional beds is minimal. Further, other hospitals might intervene to oppose the CON application. Spaeth, Tr. 2168-69.

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1021. There have been no CON applications for the construction of new hospitals in the area around Highland Park, Evanston, or Glenbrook over the past five years. D. Jones, Tr. 1664.

1022. In addition to a Certificate of Need, a person would need to get approval from other state agencies and local governments to build a new hospital. The Illinois Department of Health reviews facility plans, and a city council may need to provide zoning approval for the new hospital. Spaeth, Tr. 2169.

1023. The Illinois CON law is scheduled to be repealed on July 1, 2006. D. Jones, Tr. 1685. Unless the Illinois CON law is extended or new laws are enacted, the CON process will cease to exist in July 2006. D. Jones, Tr. 1685.

1024. Irrespective of the CON law, it takes about two and a half to three years to build a new hospital. Spaeth, Tr. 2169.

1025. In 1999, Condell filed a CON application for a major modernization and expansion of its hospital facilities, including its inpatient, ancillary and support services. RX 755 at CMC 5978. Since the merger, the Illinois Health Facilities Planning Board granted Condell Medical Center permits to add ten medical/surgical beds, eight ICU beds, and ten obstetric beds. D. Jones, Tr. 1683-84.

1026. In 2003, the Illinois Health Facilities Planning Board granted Lake Forest a permit to increase the number of medical/surgical beds by 10 beds. D. Jones, Tr. 1684.

1027. Since Evanston's merger in 2000 with Highland Park, there has been no new hospital entry in the North Shore area (D. Jones, Tr. 1664), even though Evanston has raised prices. *See* F. 347-755.

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e. Failing Firm

(1) Highland Park Could Have Continued As a Stand Alone Competitor Without the Merger

(a) Highland Park's Management and Board Believed That Highland Park Was Financially Strong

1028. On March 23, 1999, Lakeland's finance and planning committee approved the 1999-2003 Strategic Plan and Financial Plan. Spaeth, Tr. 2146; CX 1055 at 3.

1029. At the March 23, 1999 meeting, when members posed the question of the long-term financial viability, the Lakeland finance and planning committee concluded that Highland Park "can remain financially strong over the foreseeable future." CX 1055 at 3; Newton, Tr. 432-34; Spaeth, Tr. 2147.

1030. Highland Park's 1999-2003 financial plan set forth a "long range capital budget" that included \$43 million for "strategic initiatives and master plan items," including "ambulatory, assisted living and facility expansion." The plan also set aside \$65 million for "[h]ospital construction, routine capital and information technology" investments, and a small amount for Lakeland Health Ventures. The combined budget was in excess of \$100 million. Newton, Tr. 430-31; CX 545 at 3; CX 1055 at 2.

1031. According to Highland Park's 1999-2003 financial plan, "[c]ash and investments are forecasted to grow from \$238 million in 1998 to \$323 million in 2003." CX 1055 at 3.

1032. Highland Park also forecasted that its investments would generate a return of \$28 million in incremental net revenues in 2003. CX 1055 at 2.

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1033. The 1999-2003 Highland Park financial plan emphasized that “[e]xisting cash and investments are available to fund strategic initiatives and generate new programs.” CX 545 at 3.

1034. At the April 30, 1999 Highland Park board meeting, the board members approved the 1999-2003 Strategic Plan and Financial Plans. CX 96 at 4; Spaeth, Tr. 2155. The board members did not express doubt about Highland Park’s ability to generate the \$100 million required to fund the projects. Newton, Tr. 430-32.

1035. Highland Park’s 1999-2004 Financial Plan projected that cash and investments would increase by \$48 million from 1999-2004, and that long-term debt would be reduced by \$24.3 million, excluding amortization. CX 1903 at 1.

1036. Highland Park’s 1999-2004 Financial Plan projected that it had sufficient cash flow for both the planned capital expenditures and the strategic initiatives. CX 1903 at 1.

1037. Highland Park’s 1999-2004 Financial Plan included planned capital expenditures of \$79 million. These expenditures were comprised of “primarily routine capital for equipment and facility improvements, construction for renovation of patient care areas, information system enhancements and physician development.” CX 1903 at 1.

1038. Highland Park’s 1999-2004 Financial Plan also included an additional \$28 million in planned expenditures for “Strategic/Master Plan Initiatives.” These initiatives included development of a cath lab, additional parking, and additional facilities for oncology and radiation therapy. CX 1903 at 1, 3.

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(b) Highland Park Had a Strong Balance Sheet

1039. Kenneth Kaufman is managing partner of Kaufman Hall & Associates, a financial consulting firm primarily servicing hospital systems. Kaufman, Tr. 5773. Kaufman and his firm provided financial and strategic consulting services to Highland Park prior to its merger with ENH and served as transaction counsel to Highland Park during the ENH merger negotiations. Kaufman, Tr. 5774, 5777-78.

1040. Kaufman advised the Highland Park board and management that “the financial condition of Highland Park was such that it did not require a financial reason to go forward with the merger.” Kaufman, Tr. 5840; CX 1923 at 2.

1041. At the end of 1998, Highland Park had a strong balance sheet. Kaufman, Tr. 5860.

1042. At the end of 1998, Highland Park had 444 days of cash on hand. CX 1912 at 1; Newton, Tr. 427-28. This was the equivalent of being able to run a fully functional hospital for 444 days without a penny of additional revenue. Kaufman, Tr. 5859-60. The 444 days of cash on hand did not include any premerger foundation assets. Kaufman, Tr. 5860.

1043. At the end of 1998, Highland Park had \$133.6 million in cash assets available to contribute to the merged ENH. Kaufman, Tr. 5842; CX 1912 at 2. This \$133.6 million did not include the premerger Highland Park Foundation’s assets. Kaufman, Tr. 5842; CX 1912 at 2-3.

1044. At the end of 1998, Highland Park and its affiliated corporations had a total of about \$235 million in cash and unrestricted investments. The components of this total were the \$102 million earmarked for the independent, post-merger foundation and \$133.6 million in cash and unrestricted investments

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investments that Highland Park planned to contribute to the merged merged ENH. Kaufman, Tr. 5842, 5844.

1045. At the end of 1998, Highland Park and the foundation had \$120 million in long-term debt. Kaufman, Tr. 5844; CX 1912 at 1. Highland Park's bond issues in the 1990's accounted for this long-term debt. Kaufman, Tr. 5844. The assets of the obligated groups (the foundation and the hospital) backed up the long-term debt. Kaufman, Tr. 5846; CX 413 at 120.

1046. At the end of 1998, Highland Park had a debt service coverage ratio of 1.8 and a debt to capitalization ratio of 61%. CX 1912 at 1.

1047. When Kaufman calculated the debt indicators set forth in his February 1999 memorandum to Stearns and Spaeth, Kaufman did not include the assets of the foundation. Kaufman, Tr. 5846. Including the entirety of the obligated group's assets in the financial calculations would cause the debt indicators to improve compared to indicators that only utilized the hospital's assets. Kaufman, Tr. 5858.

1048. Highland Park projected that by 2003 the debt service coverage ratio would improve to 3.1 and the debt to capitalization ratio to 39%. CX 413 at 119.

1049. Highland Park and its affiliated corporations experienced a decline in long-term debt and an increase in cash and unrestricted investments position from 1998 to 1999. In particular, long-term debt declined from \$120.5 million to \$116.7 million. CX 693 at 17. Cash and unrestricted investments increased from \$217.8 million to approximately \$260 million. CX 693 at 16.

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1050. At the end of 1999, Lakeland Health, Highland Park's parent, had \$140 million more in cash and unrestricted investments than long-term debt. CX 693 at 16-17.

1051. In 1999, Kaufman advised Highland Park that the hospital "has always Supported its credit position through exceptional liquidity." CX 1912 at 2.

**(c) Highland Park Was Backed by its
Foundation's Assets**

1052. Premerger, Highland Park, through its parent, Lakeland Health, was backed by the assets of its foundation. These funds were available to support the hospital. Styer, Tr. 4954. The post-merger, independent foundation was established in order to compensate the local community of Highland Park for the loss of control following Highland Park's merger with Evanston. Kaufman, Tr. 5855.

1053. The premerger Highland Park Foundation was "responsible for fund raising for and on behalf of Lakeland Health Services, Inc. ("Lakeland"), the Hospital [Highland Park] and their affiliates." CX 6321 at 61.

1054. These raised funds were available to Highland Park. The foundation "maintains the funds received and distributes the funds based upon the needs of the affiliates, or, if restricted to a specific purpose, the directions of the donor." CX 6321 at 61. As the former chairman of the premerger foundation testified, "[t]he funds from the premerger Foundation went to support the hospital, to fulfill needs." Styer, Tr. 4954.

1055. Premerger, Highland Park executives "would bring [the foundation board] various projects that were ongoing in the hospital," and the foundation members would select specific projects to fund, such as improvements to the hospital's dialysis center. Styer, Tr. 4959-60.

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(d) No Financial Need to Merge

1056. In the fall of 1998, Highland Park contemplated both a merger strategy as well as an independent, stand alone growth strategy. CX 1869 at 5-6; Spaeth, Tr. 2145-46 (plans set forth goals for “going forward without a merger”).

1057. Highland Park was prepared to proceed with the status quo, unaffiliated option if the ENH merger talks failed. Kaufman, Tr. 5838.

1058. Steams, Highland Park’s Chairman of the Board, testified that he believed that Highland Park was not in danger of exiting the market for at least ten years. CX 6305 at 5 (Steams, Dep.).

1059. If the merger with ENH had not closed, Highland Park had “the financial wherewithal to sustain [itself].” Highland Park management and board believed that “[t]here was no urgency to have an alternative immediately available.” CX 6305 at 11 (Steams, Dep.).

1060. Highland Park believed pursuing the stand alone, independent option in 1998-99 “was absolutely a viable alternative for Highland Park.” Newton, Tr. 319-20.

1061. Highland Park could remain independent due to a variety of factors. It had a quality medical staff with significant coverage over a range of about forty-five specialties. It had a broad primary care network and it was efficient in managed care activities. Newton, Tr. 320.

1062. At a March 23, 1999 meeting, the Lakeland finance and planning committee concluded that based on the 1999 strategic and financial plans, Highland Park “can remain financially strong over the foreseeable future.” CX 1055 at 3; Spaeth, Tr. 2147. These

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These plans were “developed assuming no affiliation with another provider were to occur.” CX 1055 at 1; Spaeth, Tr. 2145-46.

1063. Highland Park proposed a year 2000 budget in October 1999. The budget was prepared assuming no merger with ENH would take place; “therefore, no merger-related impact [was] included.” CX 397 at 1. The proposed budget for 2000 anticipated “dramatic improvement over 1999’s results.” CX 397 at 1. For example, the budget projected net revenue increases of more than \$6.3 million in 2000 for the hospital. CX 397 at 3.

1064. The Highland Park board had assessed the financial position of the hospital and felt it was acceptable. Highland Park was not planning to file for bankruptcy before the merger. It never considered filing for bankruptcy. Spaeth, Tr. 2308.

**(2) Highland Park Was an Attractive Candidate
for Other Merger Partners**

1065. Highland Park viewed itself as an attractive partnership candidate and considered other partners besides ENH. In the fall of 1998, Highland Park contemplated a number of potential merger partners, besides Evanston, including Northwest Community, Lake Forest, and Condell. CX 1869 at 6.

1066. Highland Park had a strong balance sheet (F. 1039-51), was backed by its foundation’s assets (F. 1052-55), had an “attractive service area” (F. 339, 1069), and had no financial need to merge (F. 1056-64).

1067. If the ENH merger had not closed, Highland Park was prepared “to continu[e] to explore other options,” meaning “other partnership options.” CX 6305 at 11 (Stearns, Dep.).

1068. According to Highland Park’s chairman of the board, Highland Park “had at least some contact with other institutions and and . . . would have pursued those more aggressively had this -- the

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the merger with Evanston not gone through.” CX 6305 at 11-12 (Stearns, Dep.).

1069. Highland Park had “an attractive service area,” and therefore, it “would be attractive to other partnership candidates.” CX 6305 at 12 (Stearns, Dep.).

III. ANALYSIS AND CONCLUSIONS OF LAW

A. Preliminary Issues

1. Jurisdiction

The Complaint charges Respondent with violating Section 7 of the Clayton Act, 15 U.S.C. § 18. Section 7 of the Clayton Act states:

No person ... shall acquire, directly or indirectly, the whole or any part of the stock or other share capital ... of another person ... 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 tend to create a monopoly.

15 U.S.C. § 18. The word “person” includes corporations and associations existing under or authorized by the laws of any state. 15 U.S.C. § 12(a). Section 7 of the Clayton Act applies to asset acquisitions by nonprofit hospitals. *FTC v. University Health, Inc.*, 938 F.2d 1206, 1209 (11th Cir. 1991).

Respondent Evanston Northwestern Healthcare Corporation (“ENH”) is a nonprofit corporation organized, existing, and doing business under the laws of Illinois. F. 1. ENH owns and operates three acute care hospitals: Evanston Hospital (“Evanston”), Glenbrook Hospital (“Glenbrook”), and Highland Park Hospital

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(“Highland Park”). Prior to the merger, ENH was comprised of Evanston, Glenbrook, ENH Medical Group, ENH Research Institute, Institute, and ENH Homecare Services. F. 2. Throughout this Initial Decision, except where noted, the premerger Glenbrook and Evanston hospitals are referred to as “Evanston.” Prior to the merger, Highland Park was a nonprofit hospital and a subsidiary of of Lakeland Health Services (“Lakeland”), a nonprofit corporation existing under the laws of Illinois. F. 18-19.

In the merger agreement, finalized on October 29, 1999, the parties agreed that Lakeland and Highland Park would be merged into ENH and that Lakeland and Highland Park would no longer exist as separate corporations. F. 83-84. The merger was consummated on January 1, 2000. F. 85.

The Commission has express jurisdiction under Section 11 (b) of the Clayton Act to determine the legality of a corporate acquisition under Section 7. 15 U.S.C. § 21(b); *United States v. Rockford Memorial Corp.*, 898 F.2d 1278, 1280 (7th Cir. 1990) (Commission’s jurisdiction to enforce the prohibitions of the Clayton Act includes the hospital industry); *see also Hospital Corp. of Am. v. FTC*, 807 F.2d 1381, 1386 (7th Cir. 1986). The Commission’s jurisdiction allows it to adjudicate the lawfulness of acquisitions that have already been completed. *In re Chicago Bridge & Iron Co.*, 2005 WL 120878, Dkt. No. 9300, at 90 (Op. of FTC Comm’n January 6, 2005) (*available at* <http://www.ftc.gov/os/adjpro/d9300/index.htm>); *In re Coca-Cola Co.*, 117 F.T.C. 795, 911 (June 13, 1994). *See also United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 597 (1957) (“[T]he Government may proceed at any time that an acquisition may be said with reasonable probability to contain a threat that it may lead to a restraint of commerce or tend to create a monopoly of a line of commerce.”).

Accordingly, the Commission has jurisdiction over Respondent and the subject matter of this proceeding, pursuant to Sections 7 and 11 of the Clayton Act.

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2. Burden of Proof and Statutory Framework

The parties' burdens of proof are governed by Commission Rule 3.43(a), Section 556(d) of the APA, and case law. Federal Trade Commission Rules of Practice, Interim rules with request for comments, 66 Fed. Reg. 17,622, 17626 (April 3, 2001). 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). The APA establishes preponderance of the evidence as the standard of proof for formal administrative adjudicatory proceedings. *Steadman v. SEC*, 450 U.S. 91, 102 (1981). The preponderance of the evidence standard is also used in federal antitrust cases. *E.g.*, *Herman & McLean v. Huddleston*, 459 U.S. 375, 389-90 (1983); *Ramsey v. United Mine Workers*, 401 U.S. 302, 308 (1971).

"To establish a *prima facie* case under Section 7 of the Clayton Act, [the government] must first define the relevant market, and then establish that the proposed merger will create an appreciable danger of anticompetitive consequences." *California v. Sutter Health Sys.*, 130 F. Supp. 2d 1109, 1118 (N.D. Cal. 2001) (citing *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 362 (1962)). "[T]he test of a violation of § 7 is whether, at the time of the suit, there is a reasonable probability that the acquisition is likely to result in the condemned restraints." *E.I. du Pont*, 353 U.S. at 607. "Congress used the words 'may be substantially to lessen competition' to indicate that its concern was with probabilities, not certainties." *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 (1962). "Thus, to satisfy section 7, the government must show a reasonable probability that the proposed transaction would substantially lessen competition in the future." *University Health*, 938 F.2d at 1218.

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Under the framework established by the courts and the Commission, Complaint Counsel must first establish a *prima facie* case that the acquisition is unlawful. “Typically, this has been accomplished by showing that the transaction will significantly increase market concentration, which in turn establishes a ‘presumption’ that the transaction is likely to substantially lessen competition.” *Chicago Bridge & Iron*, Dkt. 9300, at 7 (citing U.S. DOJ and FTC, *Horizontal Merger Guidelines*, § 1.51 (1992, as amended 1997), reprinted in 4 Trade Reg. Rep. (CCH) ¶ 13, 104 (hereinafter “*Merger Guidelines*”)); *FTC v. H.J. Heinz, Co.*, 246 F.3d 708, 715 (D.C. Cir. 2001); *United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982 (D.C. Cir. 1990). “[S]tatistics concerning market share and concentration are not conclusive indicators of anticompetitive effects, but they provide a meaningful context within which to address the question of the merger’s competitive effects.” *FTC v. Warner Communications, Inc.*, 742 F.2d 1156, 1163 n.1 (9th Cir. 1984). “That the government can establish a *prima facie* case through evidence on only one factor, market concentration, does not negate the breadth of this analysis. Evidence of market concentration simply provides a convenient starting point for a broader inquiry into future competitiveness.” *Baker Hughes*, 908 F.2d at 984. Post-acquisition evidence goes “directly to the question of whether future lessening of competition [is] probable,” and thus is appropriate to rely upon. *United States v. General Dynamics, Corp.*, 415 U.S. 486, 506 (1974). Accordingly, Complaint Counsel may establish a *prima facie* case with concentration data and may introduce other types of evidence relating to market conditions to bolster their concentration data. *Chicago Bridge & Iron*, Dkt. 9300, at 7.

If the government successfully establishes a *prima facie* case, “[t]he burden of producing evidence to rebut this presumption then shifts to the defendant.” *Baker Hughes*, 908 F.2d at 982. Respondent “may rely on ‘nonstatistical evidence which casts doubt on the persuasive quality of the statistics to predict future anticompetitive consequences,’” such as: ease of entry into the

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market, the trend of the market either toward or away from concentration, the continuation of active price competition, and weakness of the acquired firm. *University Health*, 938 F.2d at 1218 (quoting *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1341 (7th Cir. 1981)). In addition, evidence of improvements that benefit competition, and hence, consumers, may overcome the presumption arising from a *prima facie* case. See *University Health*, 938 F.2d at 1223. If the respondent successfully rebuts the presumption of anticompetitive effects, “the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times.” *University Health*, 938 F.2d at 1218-19 (quoting *Baker Hughes*, 908 F.2d at 983); *Sutter Health*, 130 F. Supp. 2d at 1118.

Accordingly, the proper “application of the burden-shifting approach requires the court to determine (1) the ‘line of commerce’ or product market in which to assess the transaction; (2) the ‘section of the country’ or geographic market in which to assess the transaction; and (3) the transaction’s probable effect on competition in the product and geographic markets.” *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1110-11 (N.D. Cal. 2004); *FTC v. Libbey, Inc.*, 211 F. Supp. 2d 34, 44-45 (D.D.C. 2002); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1072 (D.D.C. 1997); see also *United States v. Phillipsburg Nat’l Bank & Trust Co.*, 399 U.S. 350, 359-66 (1970); *United States v. Marine Bancorporation*, 418 U.S. 602, 618-23 (1974).

B. Relevant Market

Section 7 of the Clayton Act explicitly refers to “any line of commerce” and “any section of the country.” 15 U.S.C. § 18. 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.’” *E.I. du Pont*,

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Pont, 353 U.S. at 593 (citation 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. Accordingly, an analysis of the antitrust implications of a challenged merger and whether a transaction violates Section 7 begins with an assessment of the appropriate relevant market. *FTC v. Freeman Hosp.*, 69 F.3d 260, 268 (8th Cir. 1995).

Complaint Counsel bears the burden of proving a relevant market within which anticompetitive effects are likely as a result of the acquisition. *FTC v. Tenet Health Care Corp.*, 186 F.3d 1045, 1052 (8th Cir. 1999); *In re Adventist Health Sys./West*, 117 F.T.C. 224, 289 (April 1, 1994). Indeed, Complaint Counsel must “show the rough contours of a relevant market” even when market power is established through direct evidence of anticompetitive effects. *Republic Tobacco Co. v. North Atlantic Trading Co., Inc.*, 381 F.3d 717, 737 (7th Cir. 2004). As set forth below, substantial evidence in this case establishes that the relevant product market is general acute care inpatient services sold to managed care organizations and that the relevant geographic market encompasses the following hospitals: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis.

1. Product Market

Complaint Counsel contends that the relevant product market is general acute care inpatient services sold to managed care organizations, which includes primary, secondary, and tertiary inpatient services, but excludes quaternary and outpatient services. CCB at 52-53. Respondent argues that because hospitals’ primary customers, managed care organizations, negotiate for all acute care hospital services, including both inpatient and outpatient services, the relevant product market also includes outpatient services. RB at 16-17.

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a. Reasonable Interchangeability

The relevant product or service market is “composed of products that have reasonable interchangeability for the purposes for which they are produced – price, use and qualities considered.” *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 404 (1956). This “cross elasticity of demand” represents product substitutability and the customer’s ability to choose among competing products. *Id.* at 393; *H.J. Heinz*, 246 F.3d at 718. The courts rely on various factors to determine how closely the products at issue compete. *E.g.*, *H.J. Heinz*, 246 F.3d at 718-19; *FTC v. Swedish Match*, 131 F. Supp. 2d 151, 158-59 (D.D.C. 2000). “An element for consideration as to cross-elasticity of demand between products is the responsiveness of the sales of one product to price changes of the other.” *E.I. du Pont*, 351 U.S. at 400.

The *Merger Guidelines* delineate a product market by asking whether a hypothetical monopolist of the proposed product market could impose a “small but significant and nontransitory increase in price” (“SSNIP”) and not lose so much of its sales to alternative products that the price increase would be unprofitable. *Merger Guidelines* § 1.11; *Swedish Match*, 131 F. Supp. 2d at 160 (relevant question is whether the increase in the price of product B will induce substitution to product A to render product B’s “price increase unprofitable”). The SSNIP test typically utilizes a 5% price increase. *Merger Guidelines* § 1.11; *Staples*, 970 F. Supp. at 1076 n.8. Although the *Merger Guidelines* are not binding, courts have often adopted the standards set forth in the *Merger Guidelines* in analyzing antitrust issues. *Sutter Health*, 130 F. Supp. 2d at 1120.

In order to define a relevant product market, a court must determine what services or products the customer, if faced with a price increase, could or would reasonably substitute for the products in question. *H.J. Heinz*, 246 F.3d at 718 (citing *Merger*

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Guidelines § 1.0); *Eastman Kodak Co. v. Image Technical Services, Services, Inc.*, 504 U.S. 451, 481-82 (1992) (relevant market determined by the choices of products or services available to customers). The customers in this case are the managed care organizations that contract with hospitals for services. F. 110; *see infra* at Section III.B.2.a.

b. Hospital Context

Inpatient hospital services may be treated as a “cluster of services” comprising acute inpatient care, rather than in terms of any individual service. *Sutter Health*, 130 F. Supp. 2d at 1119. This is necessary given a hospital’s chargemaster which, in this case, contains up to 20,000 individual service items and related procedures offered to patients. F. 176. “While the treatments offered to patients within this cluster of services are not substitutes for one another (for example, one cannot substitute a tonsillectomy for heart bypass surgery), the services and resources that hospitals provide tend to be similar across a wide range of primary, secondary, and tertiary inpatient services.” *Sutter Health*, 130 F. Supp. 2d at 1119. The cluster market concept has been accepted generally as the most realistic way to assess the actual competitive effects of hospital activity.

Courts reviewing hospital mergers consistently recognize acute inpatient care as the appropriate product market in hospital merger cases. *E.g.*, *Freeman Hosp.*, 69 F.3d at 268; *University Health*, 938 F.2d at 1210-11; *Rockford Memorial*, 898 F.2d at 1284; *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1290-91 (W.D. Mi. 1996); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 139 (E.D.N.Y. 1997). *See also In re Hospital Corp. of Am.*, 106 F.T.C. 361, 464-66 (Oct. 25, 1985), *aff’d*, *Hospital Corp. of Am. v. FTC*, 807 F.2d 1381 (7th Cir. 1986). The rationale for this conclusion is simply that “most hospital services cannot be provided by non-hospital providers; as to these, hospitals have no competition from other providers of medical care.” *Hospital Corp. of Am.*, 807 F.2d at 1388.

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In Section 7 hospital merger cases, the relevant market determination is restricted to acute inpatient care services, and not expanded to include outpatient services. *E.g.*, *Rockford Memorial*, 898 F.2d at 1284; *Butterworth Health Corp.*, 946 F. Supp. at 1290-91. As explained by the Court of Appeals for the Seventh Circuit in *Rockford Memorial*:

For many services provided by acute-care hospitals, there is no competition from other sorts of provider. If you need a kidney transplant, or a mastectomy, or if you have a stroke or a heart attack or a gunshot wound, you will go (or be taken) 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. If you need your hip replaced, you can't decide to have chemotherapy instead because it's available on an outpatient basis at a lower price.

898 F.2d at 1284.

The evidence presented in this case is no less persuasive. The record establishes that, as a matter of medical practice and provision of services, there is an inherent inability to substitute outpatient services for inpatient services. F. 204-11. If a physician decides that a patient requires inpatient care, managed care organizations and hospitals do not and cannot switch the patient to outpatient care. F. 206. ENH's expert concedes that inpatient and outpatient services are not functionally interchangeable. F. 211.

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The evidence in this case also demonstrates that prices for inpatient services are not restrained by prices for outpatient services. F. 207-08. ENH set inpatient rates independent of its outpatient rates and without concern that patients would switch to outpatient services. F. 209. Managed care organizations cannot substitute outpatient services for inpatient services if prices for the latter increase significantly. F. 208. Consistent with the decisions in *Rockford Memorial*, 898 F.2d at 1284 and *Butterworth Health Corporation*, 946 F. Supp. at 1291, and which excluded outpatient services because a price increase in inpatient services would not cause consumers to substitute services, there is not substantial evidence in this case to indicate that an increase in the price of inpatient care services would drive consumers to purchase outpatient services.

In defining the relevant product market, the Court acknowledges that some inpatient services can also be performed by specialized hospitals which may be located in the same geographic market. *See Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1477 (9th Cir. 1997). Such facilities might include psychiatric hospitals, rehabilitation hospitals, veterans' hospitals, military hospitals, children's and women's hospitals, and nursing homes. *See Hospital Corp.*, 106 F.T.C. at 436; *Tenet Health Care*, 186 F.3d at 1048 (excluding a veterans' hospital from the product market). In this case, both parties agree that specialty hospitals, that may be specialized either in a particular service or for a particular category of patients, are excluded from the market. Complaint Counsel Proposed Order at M; RFF 380. There is no substantial evidence in this case that such speciality facilities were adequate to restrain the exercise of market power in the primary, secondary, and tertiary acute inpatient care markets. As such, they are properly excluded from the relevant product market.

c. Demand Analysis

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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. RB at 17. In the case on which Respondent primarily relies, *FTC v. Staples*, the relevant product market was determined by looking at the availability of substitute commodities and the responsiveness of sales of one product to price changes of another, and not just by whether customers demanded all the products sold by the merging parties. 970 F. Supp. at 1074-75. Indeed, the merging parties, Staples and Office Depot, each sold both consumable office supplies (products that consumers buy recurrently) and other office products, including business machines, computers, and furniture. *Id.* at 1069. The product market, however, was found to be the sale through office supply stores of only consumable office supplies; it did not include other products (e.g., computers, furniture) also sold by Staples and Office Depot. *Id.* at 1074. Thus, although the hospitals in the instant case sell services besides inpatient services, just as in *Staples*, those other services (outpatient) are not included in the relevant product market.

Further, the 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 Court in *Rockford Memorial* held that inpatient and outpatient “services are not in the same product market merely because they have a common provider.” *Rockford Memorial*, 898 F.2d at 1284. The reasoning of the Seventh Circuit in *Rockford Memorial* applies with equal force here. Simply because the merging parties provide both inpatient and outpatient services does not compel a finding that outpatient services are included in the product market.

d. Summary

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Although managed care organizations negotiate for all acute care hospital services, including both inpatient and outpatient services (RB at 16-17), the evidence clearly demonstrates that managed care organizations cannot substitute outpatient services for inpatient services. As such, outpatient services are not included in the relevant market. The evidence also demonstrates that quaternary services, which require the use of very specialized doctors, nurses, and equipment, and which are not offered at ENH (F. 200, 203), are also not included in the relevant market. Accordingly, Complaint Counsel has met its burden and demonstrated that the relevant product market is general acute care inpatient services sold to managed care organizations, which includes primary, secondary, and tertiary inpatient services.

2. Geographic Market**a. Impact of Managed Care**

As a result of the restructuring of market forces, changing government policies, and technological innovations, the last two decades have brought tremendous change to the health care industry. *Tenet Health Care*, 186 F.3d at 1050; *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 124-25. During this transformation, hospital systems, previously unaffected by the influences of other markets, have begun to experience the competitive dynamics of the market place. *United States v. Mercy Health Serv.*, 902 F. Supp. 968, 973-75 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997). During the 1990's, these economic motivations led to a substantial wave of consolidations, forcing hospitals to reduce excess capacity while striving to improve the quality of care for patients. *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 124-25. These changes have also substantially affected the antitrust analysis of hospital mergers.

Until the early 1980's, most health insurance plans were "indemnity plans." F. 153. Under indemnity plans, insurers routinely contracted with all hospitals for services using the same

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formula for all contracts. The patient (or patient's physician) had virtually complete discretion in choosing the hospital at which the patient would seek services. F. 155. The introduction of managed care, however, constituted a significant change from traditional indemnity insurance. *See Mercy Health Serv.*, 902 F. Supp. at 973. One common feature of all managed care organizations is that – unlike indemnity insurers – a managed care organization exercises discretion in choosing the providers with which it contracts. F. 109, 109, 156. Managed care organizations thus introduced price competition among hospitals, and the managed care company – not not the doctor or patient – became the hospital's customer for the terms, including price, under which managed care is delivered. F. 109-110; *see also Sutter Health*, 130 F. Supp. 2d at 1129; *University University Health*, 938 F.2d at 1213 n.13.

Complaint Counsel's economic expert, Dr. Deborah Haas-Wilson, refers to the price competition found in negotiations between hospitals and the managed care organizations as "first stage" competition. F. 106. In Haas-Wilson's framework, second stage competition occurs when hospitals compete, primarily on non-price factors, to attract patients to their hospitals. F. 111. Thus, hospitals initially engage in price competition in order to be included in a managed care organization's hospital network. F. 109. The ultimate patient is not affected by price because the patient's contribution, or co-payment, is generally the same regardless of which hospital in the hospital network is selected. F. 104. Second, hospitals compete with other hospitals in these networks through non-price factors, such as quality of care and amenities, in order to attract patients. F. 123.

In this case, the government challenges the merger because of its probable effects on price, i.e., on first stage managed care competition. Accordingly, it is the first stage managed care market that is of critical concern to the antitrust analysis, and it is the review of this market which will determine whether Respondent has market power to raise its prices to anticompetitive levels.

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b. Overview

The proper determination of geographic market is of critical importance in hospital merger cases and is a “necessary predicate” to ascertaining market concentration levels in the relevant market. *E.I. du Pont*, 353 U.S. at 593. Determination of the geographic market is highly fact sensitive and must be done on a market to market basis. *Tenet Health Care*, 186 F.3d at 1052; *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 140; *see also Brown Shoe*, 370 U.S. at 336 (“Congress prescribed a pragmatic, factual approach to the definition of the relevant market and not a formal, legalistic one.”); *Freeman Hosp.*, 69 F.3d at 271 n.16 (“The Supreme Court has repeatedly emphasized that the definition of a geographic market is highly fact-driven and therefore different in each case.”). This determination must be based on a dynamic, “forward looking” analysis which considers not only where consumers have gone in the past for hospital services, but what “practical alternatives” they would have in the future. *Freeman Hosp.*, 69 F.3d at 268-69; *see also Tenet Health Care*, 186 F.3d at 1055; *Mercy Health Serv.*, 902 F. Supp at 978.

The Supreme Court has defined the relevant geographic market market as “the ‘area of effective competition . . . in which the seller seller operates, and to which the purchaser can practicably turn for for supplies.’” *Philadelphia Nat’l Bank*, 374 U.S. at 359 (quoting *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961)). A (1961)). A geographic market has also been described as the area “in “in which the antitrust defendants face competition.” *Freeman Hosp.*, 69 F.3d at 268. “A properly defined market includes potential suppliers who can readily offer consumers a suitable alternative to the defendants’ services.” *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 136 (quoting *Butterworth Health Corp.*, 946 F. F. Supp. at 1290). The properly defined market excludes those potential suppliers whose product is sufficiently differentiated or too too far away and who are unlikely to offer a suitable alternative. *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 136 (citation omitted).

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omitted). Courts do not compel “scientific precision” in defining the geographic market, although they do insist that any such market be “well-defined.” *Sutter Health*, 130 F. Supp. 2d at 1120; *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 49 (D.D.C. 1998). Consequently, “[t]he geographic market selected must, therefore, both ‘correspond to the commercial realities’ of the industry and be economically significant.” *Brown Shoe*, 370 U.S. at 336-37.

c. Positions of the Parties

Complaint Counsel contends that the relevant geographic market is the area adjacent or contiguous to the three ENH hospitals. CCB at 53-55, *see also* Attachment 1 (DX 8173, map). Relying on the *Merger Guidelines*, Complaint Counsel argues that after the merger, ENH demanded large price increases – well above the 5% SSNIP test. *See Merger Guidelines* § 1.21. Complaint Counsel relies on evidence that managed care organizations tried to avoid ENH price increases through alternative hospital networks that did not include the ENH hospitals; that one managed care organization went so far as to terminate its contract with ENH but was later forced by market realities to negotiate a contract with ENH; and that managed care organizations found that they had to accept ENH’s price increases because they could not satisfy their customers, employers, without ENH in their networks. CCB at 54. In addition, Complaint Counsel points to testimony by ENH’s CEO and COO that when they approved price increases after the merger, managed care organizations’ ability to exclude the ENH hospitals from managed care plans was not a factor in their pricing decisions. CCB at 55. Complaint Counsel thus asserts that these market realities demonstrate that managed care organizations cannot “practicably” turn outside the ENH geographic triangle for substitute hospitals, and that ENH can raise prices by more than a SSNIP without losing so much in sales to hospitals outside its geographic triangle as to make the price increase unprofitable. CCB at 54-55.

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Respondent argues that the relevant geographic market should, at a minimum, include the three ENH hospitals plus Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, Condell, and Resurrection. RB at 23. Respondent also contends that other hospitals outside this geographic market, such as Northwestern Memorial, Swedish Covenant, Holy Family, and the Vista hospitals, also place a competitive constraint on ENH. RB at 23, RFF ¶ 489. In determining her proposed geographic market, Respondent's economic expert, Dr. Monica G. Noether, considered: geographic proximity; patient travel patterns; physician admitting patterns; and market participants' views on competition. RB at 23. In addition, Respondent points to the rather expansive definitions of geographic market found in previous hospital merger cases. RB at 18.

d. Prior Case Law

Both parties acknowledge the string of government losses in hospital merger cases over the last decade. CCB at 57; RB at 18. In many of those cases, the government's failure to prove a relevant geographic market within which a hospital merger would have anticompetitive effects was determinative. *E.g.*, *Tenet Health Care*, 186 F.3d at 1053 (characterizing the FTC's failure to produce sufficient evidence of a well-defined relevant geographic market as fatal to the government's claim); *Freeman Hosp.*, 69 F.3d at 272 (describing the FTC's failure to meet its burden of establishing the relevant geographic market as dispositive); *Mercy Health Serv.*, 902 F. Supp. at 987 ("The government has failed to establish the relevant geographic area and hence has failed to establish that the merger . . . will likely result in anticompetitive effects."). These hospital merger challenges are distinguishable because they were decided in the context of prospective mergers, without the benefit of post-acquisition evidence.

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At issue in these prior hospital merger cases was the probable anticompetitive effect of the merger, specifically whether managed care organizations could practicably defeat a price increase by eliminating the merged entity from their hospital networks and switching to a lower-cost alternative hospital network configuration, through steering or selective contracting. In *Tenet Health Care*, the court doubted that managed care organizations would “unhesitatingly accept a price increase rather than steer their subscribers to hospitals [outside the geographic market].” 186 F.3d at 1054 (managed care’s “economic interests” would be to resist a price increase). *See also Sutter Health*, 130 F. Supp. 2d at 1132 (managed care organizations likely to “steer” members away from merged entity’s price increases to other hospitals); *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 130, 144 (managed care representatives testified that if confronted with twenty percent price increase by merged entity, they would “drop” the hospital from their networks, as they had done in comparable situations). As noted, the courts in these cases made certain assumptions regarding managed care organizations’ behavior which depended in large part upon the competitive dynamics existing in each individual market.

The post-merger evidence in this case, however, demonstrates that when ENH raised prices more than 5% after the merger, managed care organizations did not utilize alternative hospital network configurations to avoid the price increases. F. 372. Managed care organizations’ inability to selectively contract or steer patients to more distant hospitals to avoid ENH’s price increases is powerful evidence that a local market for hospital services exists in the geographic market and that patients want a local hospital in their managed care plan. F. 398, 408, 414, 446, 455. Given these business and economic realities, managed care testimony is more credible because their post-merger actions, prior to initiation of legal investigation or proceedings, support their testimony.

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Prior cases have traditionally relied on the Elzinga-Hogarty test and patient flow data to establish the geographic market for hospital services. *E.g.*, *Freeman Hosp.*, 69 F.3d at 264; *Sutter Health*, 130 F. Supp. 2d at 1120-21; *Adventist Health Systems/West*, 117 F.T.C. at 257, 292. The Elzinga-Hogarty test was developed by Kenneth G. Elzinga and Thomas F. Hogarty in the 1970's to analyze patterns of consumer origin and destination and to identify relevant competitors of merging entities. *Freeman Hosp.*, 69 F.3d at 264; Elzinga & Hogarty, *The Problem of Geographic Market Delineation Revisited: the Case of Coal*, 23 Antitrust Bull. 1 (1978); Elzinga & Hogarty, *The Problem of Geographic Market Delineation in Antitrust Suits*, 18 Antitrust Bull. 45 (1973). The test was developed for the beer and coal industries prior to the development of the *Merger Guidelines*. F. 212. In the hospital context, the Elzinga-Hogarty test has been used to examine current market behavior through an analysis of hospital service areas and historical patient flow data. *Sutter Health*, 130 F. Supp. 2d at 1120-21; F. 215. Dr. Kenneth G. Elzinga testified as Complaint Counsel's expert at trial, however, that his Elzinga-Hogarty test is not appropriate for determining the relevant geographic market for hospital services. F. 216.

Indeed, neither party relies on the Elzinga-Hogarty test, although Respondent argues that patient-flow data remains relevant to a geographic market determination. CCB at 53-55; RB at 18-31. As explained by Elzinga, the first problem with use of patient flow data and the Elzinga-Hogarty test is the "payor problem," which recognizes that, in the hospital industry, managed care organizations pay for hospital services, but their enrollees are the ones who use the services. F. 217. Because patients do not set the price of hospital services, their willingness to travel tells us nothing about their sensitivity to price changes by the merging hospitals. F. 218. In other words, patient flow data is relevant to second stage competition for patients, but provides no useful information about first stage competition for managed care contracts.

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The second problem with patient flow analysis is that it incorrectly assumes that if some patients are willing to travel to distant hospitals, then others will also travel in response to a change in hospital prices, thereby incorrectly suggesting a broader geographic market. F. 219. Actually, a “silent majority” of people will not travel in response to a change in hospital prices, and those people can be subject to an anticompetitive price increase. F. 220. Similarly, based on perceptions of hospital services and quality in large urban centers from patients living in surrounding areas, the Elzinga-Hogarty test may overestimate the geographic market to include hospitals in surrounding towns, when in fact, few urban patients are willing to travel to surrounding hospitals for services. *See* F. 251, 257.

Patient flow data is used by managed care organizations and by hospitals themselves to determine service areas and core service areas. F. 221. Indeed, patient flow data may provide reliable information for hospitals engaging in second stage (non-price) competition for patients because it shows which hospitals patients actually utilize for services. F. 214. However, the question of which hospitals patients ultimately utilize for treatment is a different question than which hospitals patients want available in their managed care organizations’ hospital networks. Therefore, evidence regarding patient flow data, service areas, and the Elzinga-Hogarty test are not probative in determining the relevant geographic market.

A key issue in determining the geographic market in this case is identifying which hospitals managed care organizations need to have in their hospital networks in order to establish viable, competitive networks. This situation is similar to that in *Republic Tobacco*, where the ultimate consumer was not the purchaser. 381 F.3d at 738-39. In *Republic Tobacco*, the parties sold cigarette papers to distributors and wholesalers, not to retailers and customers. *Id.* The Seventh Circuit noted that “the evidence presented regarding where wholesalers can practicably sell their

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products (or in other words, where customers and retailers practicably turn for alternative sources of [the product]) is beside the the point when it comes to [geographic] market definition.” *Id.* Here, Here, the evidence establishes that people select managed care plans plans that include a local hospital – that is, a hospital that is close geographically and in travel time and a hospital where their physician admits patients. F. 226-28, 251, 253-54, 257, 261.

Thus, patient flow data and service areas are not reliable in determining substitutability in first stage (price) competition for managed care contracts and are not considered in determining the geographic market. The factors utilized by Respondent’s expert are appropriate, with the exception of patient flow data, which most likely overestimates the geographic market to include certain outlying hospitals not otherwise shown to constrain ENH’s pricing to managed care. Therefore, factors such as market participant views, geographic proximity, travel times, and physician admitting patterns are considered in making the geographic market determination.

e. Market Participant Views

Views of market participants are relevant to a determination of the proper geographic market, although they may not be sufficient, sufficient, alone, to establish the geographic market. *Freeman Hosp.*, *Hosp.*, 69 F.3d at 270; *see also Tenet Health Care*, 186 F.3d at 1054. 1054. Hospital services are a highly differentiated product. F. 102. The commercial realities of the highly competitive health insurance industry in Chicago are that managed care organizations believe that they cannot successfully market a managed care plan without a local hospital. F. 226-27. For example, one managed care care representative stated that people “do not like to drive by a local local hospital and have to go to another hospital.” F. 226. Although Although all of the managed care representatives who testified indicated that selective contracting is used, most managed care plans plans only exclude a small minority of hospitals in the Chicago

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market. F. 158-65. The fact that patients may ultimately travel great great distances for medical care does not alter the analysis. Thus, although patients may use hospitals outside of the geographic market, the evidence demonstrates that, in this market, these outlying hospitals do not constrain Respondent's pricing and they are not hospitals to which managed care organizations can turn to construct viable hospital networks.

The inclusion of local hospitals in this particular geographic market is critical to hospital networks because, as ENH officials proclaimed, this is an area populated by "senior executives and decision-makers" and it would be "real tough" for any managed care organization and employer "whose CEOs either use [Evanston or Highland Park] to walk from [ENH] and 1700 of their doctors." F. 227. Many executives live within this geographic market who "make decisions about health benefits for their employers, employees," and have "immense influence and power with the health plans." F. 227. According to Elzinga, this testimony is consistent with economic literature which finds that affluent consumers may be less willing to travel because they "impute a higher value to their time and consequently travel becomes more costly to them in the opportunity cost sense." F. 228.

Prior to the merger, managed care organizations viewed Evanston and Highland Park as substitutes and price constraints for for purposes of building viable hospital networks in the local area. F. F. 229-33. Managed care representatives described the two hospitals hospitals as each other's "main" competitors or "primary" alternative, thereby permitting managed care organizations to "trade "trade off one for the other" or "work them against each other" in contract negotiations. F. 229. Aetna could constrain Evanston's prices by utilizing Highland Park (and others) in its network as an alternative (and vice-versa). F. 230. Unicare could exclude Evanston Evanston and satisfy the needs of local customers by offering a network that consisted of Highland Park and other hospitals offering offering services comparable to Evanston (and vice-versa). F. 234.

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PHCS knew that if rate negotiations were not “going well” at either either Evanston or Highland Park, PHCS could turn to the other as as the alternative and use this fact to work the negotiations favorably favorably its way. F. 231. The Unicare representative testified that she could have a viable network comprised of Highland Park, Advocate Lutheran General, Rush North Shore, and St. Francis or Evanston and Lake Forest. F. 234.

Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis were the hospitals most consistently included by managed care organizations in their lists of hospitals that compete with ENH. F. 233-42. Aetna’s representative testified that Evanston competed locally with Rush North Shore and St. Francis and that Highland Park competed locally primarily with Lake Forest. F. 235. PHCS’s representative testified that premerger, Advocate Lutheran General, Rush North Shore, and St. Francis were significant competitors to Evanston, that Lake Forest was a significant competitor to Highland Park, and that for purposes of developing its network, she viewed the service and quality of Advocate Lutheran General, possibly Rush North Shore, and possibly Advocate Northside to be comparable to Evanston. F. 236-37. Great West’s representative testified that the main alternatives to ENH were: Advocate Lutheran General, St. Francis, Condell, and Northwestern Memorial. F. 239. Unicare’s representative testified that ENH competes with Lake Forest, Rush North Shore, St. Francis, and Advocate Lutheran General to varying degrees. F. 241. United’s representative testified that Evanston competes with Advocate Lutheran General, Rush North Shore, and St. Francis and that Highland Park primarily competes with Lake Forest and Condell. F. 242.

Moreover, contemporaneous documents from two of the managed care organizations are relevant in informing the Court’s geographic market determination. Contemporaneous documents are are entitled to significant weight. *See United States v. United States States Gypsum Co.*, 333 U.S. 364, 396 (1948); *see also United States*

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States v. International Business Machines Corp., 1974 WL 899, * 2 2 (S.D.N.Y. 1974); *In re Adolph Coors Co.*, 83 F.T.C. 32, 326 (July (July 24, 1973). When PHCS notified its customers about the merger, it identified “other contract providers within the same geographical area as that of Highland Park Hospital and Evanston,” including: Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, and Holy Family Medical Center. F. F. 238. Great West provided its subscribers with a list of hospitals that were in its network that could be alternatives to ENH, including: including: Lake Forest, Advocate Lutheran General, St. Francis, and and to the north, St. Therese and Victory Memorial (now the Vista hospitals). F. 240.

Highland Park, prior to the merger, considered its closest or primary competitor to be Lake Forest, although it was also “reasonably close” to Evanston, Advocate Lutheran General, Rush North Shore, and Condell. F. 244. Highland Park’s president indicated that he believed that managed care organizations could exclude Highland Park from a network and substitute: Evanston, Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, and/or Condell. F. 245.

At trial, the CEO of Evanston testified that Condell and Lake Forest were competitors of Evanston, but testified that Highland Park was not a substantial competitor of Evanston. F. 243. This testimony by an interested party, however, is contrary to contemporaneous evidence which clearly demonstrates that Evanston considered Highland Park as a significant competitor throughout the premerger period. F. 243, 247. As such, his testimony on this point is accorded little, if any, weight. *Gypsum Co.*, 333 U.S. at 396.

The contemporaneous evidence and market participants’ views views thus clearly demonstrate that managed care organizations cannot develop a viable managed care plan in this market without: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, or St. Francis in their hospital

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hospital network. F. 233-42. As previously noted, although patients may use hospitals outside of the geographic market, the evidence demonstrates that those hospitals do not constrain Respondent's pricing to managed care organizations and are not hospitals to which managed care organizations can realistically turn to construct their local hospital networks.

**f. Geographic Proximity, Travel Times, and
Physician Admitting Practices**

The evidence demonstrates that geographic realities matter to competition. Managed care organization testimony indicates that the distance an employee must travel is a critical component for employers who are evaluating health care benefit plans. F. 226-27. Because managed care organizations typically market their health care plans to employers, who are concerned about where their employees want to seek hospital care, managed care organizations themselves take into account patient preferences concerning hospital geography when building their hospital networks. F. 111, 114. Consequently, to the extent that employees value convenience, there is a derived demand by managed care organizations for hospitals that are convenient to their enrollees. F. 114-15, 118.

Prior hospital merger cases recognize the relevance of patient travel patterns. *Tenet Health Care*, 186 F.3d at 1053-55 (patient travel patterns a relevant factor in defining geographic market and practical alternatives to the merged hospital); *Butterworth Health Corp.*, 946 F. Supp. at 1292-93 (relying on travel patterns to define geographic market and identify competitors). In addition to accounting for the physical distance between locations, courts routinely find travel times – which are affected by roads, traffic patterns, and natural impediments such as rivers or mountains – relevant to geographic market definition. *See, e.g., Sutter Health*, 130 F. Supp. 2d at 1126 (travel time is relevant to a dynamic analysis of the geographic market); *J&S Oil, Inc. v. Irving Oil Corp.*,

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Corp., 63 F. Supp. 2d 62, 68 (D. Me. 1999) (“Simply put, the geographic market for retail gasoline depends on how far individuals are willing and able to travel to purchase the product.”). product.”).

According to a 2001 Lake Forest customer survey report, consumers are willing to travel, on average, up to 16 minutes for emergency care and 35 minutes for an overnight hospital stay. F. 257. It is thus reasonable to presume that, when selecting a managed care plan, these customers would select a plan that includes a local hospital, ideally one within 16 minutes of their home or work. Although this may not be a scientific survey, it does give a glimpse into what consumers in this market consider to be reasonable travel times when selecting a managed care plan.

As part of her proposed geographic market, Respondent’s expert, expert, Noether, computed the driving times from Evanston and Highland Park to other area hospitals. F. 256. These distance and driving time components of Noether’s methodology are appropriate factors to utilize to determine the relevant geographic market. The actual driving time will vary for each patient, depending depending on where he or she lives or works, and may be longer than Noether’s estimates. F. 256; *see* Attachment 1 (DX 8173, map). map). Adopting Noether’s methodology, it is clear that the hospitals included in the geographic market (discussed below), are the closest hospitals to the triangle formed by Evanston, Glenbrook, and Highland Park, in both mileage and driving time: Lake Forest, 6.1 miles (13 minutes) from Highland Park; Advocate Advocate Lutheran General, 10.2 miles (21 minutes) from Evanston; Evanston; Rush North Shore, 3.7 miles (9 minutes) from Evanston; Evanston; and St. Francis, 3.0 miles (8 minutes) from Evanston. F. 266, 272, 281, 287. Together, the average driving distance of these these hospitals is 5.75 miles from the closer of Evanston or Highland Highland Park, while the average driving time is 13 minutes. F. 258. 258. With respect to the two hospitals that Noether proposed for inclusion in the geographic market, but which are found to be outside of the geographic market, Condell and Resurrection, the

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average distance from the closer of Evanston or Highland Park is 12.4 miles, while the average driving time is 24.5 minutes. F. 259.

Another component of Noether's methodology, physician admitting practices, is relevant to establishing the geographic market. The record demonstrates that when the merger was announced, several physicians who had been admitting patients primarily to Highland Park shifted "a lot" of their patients to Lake Forest. F. 269. Managed care organizations, therefore, would want a hospital network that includes Highland Park or Lake Forest for patients of physicians with admitting privileges at both hospitals. *See* F. 270-71. Such evidence is highly relevant to a dynamic analysis of the geographic market. There is insufficient evidence in the record, however, regarding physician admitting practices at the other relevant hospitals.

g. Hospitals Included in the Geographic Market

The evidence does not support Complaint Counsel's contention that the geographic market should be comprised exclusively of the three merging ENH hospitals and that no additional hospitals could constrain ENH's pricing. However, the evidence also does not support the inclusion of all nine hospitals that Respondent's expert selected for her proposed geographic market. Establishing a geographic market for a differentiated product such as hospital services is challenging. As Respondent's expert stated "in the context of a differentiated product, it's difficult to draw a bright line that hospitals inside the bright line are all competitors to each other, and then as soon as you cross that line, there's no competitive pressure that's exerted." F. 103; *see also E.I. du Pont*, 351 U.S. at 392-93. Thus, neither party has proposed a geographic market which fully (and persuasively) addresses the particular market structure characteristics that define competition in this market.

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The Court must identify the market which best comports with the totality of the relevant evidence. Upon review of the record, it has therefore determined that the geographic market should properly include a total of seven hospitals: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. This determination encompasses the three merging hospitals, as proposed by Complaint Counsel, plus an additional four hospitals. F. 262-92. This market includes seven of the nine hospitals, including ENH, in Respondent's proposed geographic market, but excludes Condell and Resurrection. F. 293-303.

The geographic market reflects the market reality, noted by the Seventh Circuit, that hospital services are essentially local. *Rockford Memorial*, 898 F.2d at 1284-85 ("For highly exotic or highly elective hospital treatment, patients will sometimes travel long distances, of course. But for the most part hospital services are local. People want to be hospitalized near their families and homes, in hospitals in which their own – local – doctors have hospital privileges."). It is highly probable that the four non-ENH hospitals in the geographic market would have the ability to constrain prices at ENH, either now or in the future, and could be utilized by managed care organizations to create alternate hospital networks. These hospitals comprise the "area of effective competition" (*Philadelphia Nat'l Bank*, 374 U.S. at 359) to ENH and provide suitable alternatives for managed care organizations in building and marketing their health plan networks in the geographic market.

The three ENH hospitals, Evanston, Glenbrook and Highland Park, have been described as forming a geographic triangle in the North Shore area of Chicago. The evidence establishes that the actual geographic market forms a parallel, but larger, triangle, proximal to and encompassing the ENH triangle. *See* Attachment 1 1 (DX 8173, map). Should ENH hospitals be excluded from a payor's hospital network, a patient living within the ENH triangle would only have to drive past one hospital to reach a hospital within

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within the geographic market. The rationale for each hospital's inclusion in the geographic market determination is discussed more fully below.

(1) Evanston

Evanston Hospital, located in Evanston, Illinois, has more than 400 beds. F. 1, 5. Evanston Hospital provides a wide array of inpatient and outpatient services, from basic hospital services (such as obstetrics) to more intensive services (such as cardio-angiogenesis). F. 8. Evanston also offered obstetrical services, pediatric services, a skilled nursing facility, psychiatric care, neurosurgery, radiation therapy, cardiology services, orthopedics, trauma centers, and the Kellogg Cancer Care Center. F. 7. Evanston had .34 residents per bed in 1999. F. 6.

(2) Glenbrook

Glenbrook, located in Glenview, Illinois, is a community hospital that was developed, built, and opened by Evanston in 1977. F. 9. Glenbrook is located 12.6 miles and 26 minutes west of Evanston. F. 10. Glenbrook has approximately 125 to 150 beds. F. 11. Glenbrook has a Kellogg Cancer Care Center, center of excellence in orthopedics, and does a significant amount of work in neurology, particularly movement disorders. F. 13. Glenbrook Hospital provides inpatient and outpatient services, but it does not provide obstetrics services. F. 12.

(3) Highland Park

Highland Park, located in Highland Park, Illinois, has approximately 150 to 200 beds. F. 20, 22. Highland Park is located located 13.7 miles and 27 minutes north of Evanston, along Lake Michigan. F. 21. Prior to the merger, Highland Park offered obstetrical services, including a level II perinatal center, pediatric services, diagnostic services, a skilled nursing facility, a fertility

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center, psychiatric care, neurosurgery, radiation therapy, cardiology cardiology services, including an adult cardiac catheterization lab, an oncology program, and a level II trauma center. F. 24. Highland Highland Park had a medical staff of 562 physicians in 1999. F. 23. 23.

(4) Lake Forest

Lake Forest is located 6.1 miles and 13 minutes northwest of Highland Park. F. 266. Lake Forest is a 142 bed hospital that does not provide any tertiary care and had no residents per bed in 1999. F. 267-28. It therefore provides similar services to those provided at Highland Park. In addition, there was a substantial overlap of physicians who had privileges and admitted patients to both Highland Park and Lake Forest prior to the merger. F. 269. Once the merger was announced, a number of these physicians actually shifted a significant volume of their admissions from Highland Park to Lake Forest. F. 269. Lake Forest was identified in contemporaneous PHCS and Great West correspondence to patients as a viable alternative to ENH. F. 270. Managed care representatives identified Lake Forest as a significant competitor to ENH. F. 271. The evidence thus strongly demonstrates that Lake Forest is a significant competitor to ENH and is appropriately included in the geographic market.

(5) Advocate Lutheran General

Advocate Lutheran General is located 10.2 miles and 21 minutes minutes west and slightly south of Evanston. F. 272. Advocate Lutheran General is a 521 bed tertiary care hospital that is the largest largest hospital in the Advocate system. F. 273. Advocate Lutheran Lutheran General has a teaching relationship with University of Illinois at Chicago Health Services Center. F. 274. Advocate Lutheran Lutheran General had .36 residents per bed in 1999. F. 275. In terms terms of range of services, Advocate Lutheran General is similar to to Evanston. F. 276. United's representative stated that: "Lutheran General is the most comparable facility [to Evanston] from type of

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of services, quality of services, size of facility; however, it is the furthest away. It's got a bit of geographical disadvantage, but it's not not terribly far away." F. 276. Before the merger, patients who went to the emergency room at Highland Park or Lake Forest with a heart attack were referred to Advocate Lutheran General for more advanced care. F. 277. It is significant that ENH, during contract negotiations with PHCS, suggested giving a better rate to PHCS if PHCS excluded Advocate Lutheran General from its hospital network. F. 278. Moreover, Advocate Lutheran General was identified in contemporaneous PHCS and Great West correspondence to patients as an alternative to ENH. F. 279. Managed care representatives identified Advocate Lutheran General as a significant competitor to ENH. F. 280. Thus, under the the relevant criteria, Advocate Lutheran General – although a little little further away than the other hospitals in the geographic market – is similar enough in range of services, according to predominant payors' views, that it is considered a significant competitor to ENH and is appropriately included in the geographic geographic market.

(6) Rush North Shore

Rush North Shore, owned by the Rush system, is located 3.7 miles and 9 minutes southwest of Evanston. F. 281. Rush North Shore has 150 to 200 beds and, as of February 2005, it was affiliated affiliated with Rush-Presbyterian-St. Luke's. F. 282. The Rush-Rush-Presbyterian affiliation improved the breadth, quality, and the the perception of services offered at Rush North Shore. F. 282. Rush Rush North Shore is geographically close to Evanston, but does not not have the same tertiary facilities that exist at Advocate Lutheran Lutheran General. F. 283. Rush North Shore had .12 residents per bed in 1999. F. 284. Rush North Shore was identified in contemporaneous PHCS correspondence to patients as an alternative alternative to ENH. F. 285. Managed care organizations identified Rush North Shore as a significant competitor to ENH. F. 286. Given Given this evidence and the fact that Rush North Shore's future

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competitive position may increase as a result of its affiliation with the Rush-Presbyterian system, a dynamic, forward looking analysis analysis of its position in the market indicates that it is and will continue to be a significant competitor to ENH and is appropriately appropriately included in the geographic market.

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(7) St. Francis

St. Francis is located 3 miles and 8 minutes south of Evanston on the same street. F. 287. St. Francis has 300 to 400 beds and, as of February 2005, was part of the Resurrection System. F. 288. St. Francis's services range from cardiology and obstetrics to general surgery. F. 288. St. Francis is geographically close to Evanston, but does not have the same tertiary facilities that Advocate Lutheran General has and has less of a reputation as an equivalent facility. F. 289. St. Francis had .36 residents per bed in 1999. F. 290. St. Francis was repeatedly identified in contemporaneous PHCS and Great West correspondence to patients as an alternative to ENH. F. 291. Moreover, managed care organizations identified St. Francis as a competitor to ENH. F. 292. Thus, St. Francis is considered a significant competitor to ENH – geographically close, and a competitor on primary and secondary services, although without the same level of tertiary services available at Evanston, and is appropriately included in the geographic market.

h. Hospitals Excluded from the Geographic Market

The geographic market in this case has been described as a “moving target.” RB at 19. Indeed, neither party's proposed geographic market is supported with scientific precision. The Complaint describes the geographic market as: “the densely populated corridor that runs for about 15 miles north-south along the the shore of Lake Michigan, and extends roughly ten miles west of of the Lake.” Complaint ¶ 17. Complaint Counsel later suggested that, hypothetically, the geographic market could be “expanded to encompass a larger geographic area in which additional hospitals are located, such as Holy Family Medical Center, St. Francis Hospital, Lake Forest Hospital, Advocate Lutheran General Hospital, and Rush North Shore Hospital.” Complaint Counsel Interrog. Answers at 20. However, Complaint Counsel now contends

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contends that the geographic market should only include the three ENH hospitals. CCB at 9, 54.

Similarly, Respondent proposed a minimum geographic market of nine hospitals, but qualified that determination with a list of additional hospitals that “could potentially” be in the market. Respondent argues that Holy Family, Swedish Covenant, the two Vista hospitals, and even teaching hospitals such as Northwestern Memorial should also be considered for inclusion in the geographic market. RB at 23. As noted, the Court adopts Respondent’s proposed minimum market, with the exception of Condell and Resurrection. F. 262-92.

Complaint Counsel’s proposed geographic market, comprised only of the three ENH hospitals, is found to be too limited and not sufficiently forward-looking. The Court is mindful that during the last three years ENH has been under investigation by the Commission, which may have acted as a constraint against ENH imposing even further price increases on managed care organizations. The geographic market recognizes that in the face of such future increases, there are alternate providers to which managed care organizations could turn for hospital services.

Each of the hospitals proposed for the geographic market by the parties but found by the Court to be outside the geographic market are discussed in detail below.

(1) Condell

Condell was included by Respondent in its proposed geographic market and some market participants mentioned Condell as generally competing with ENH. Condell is a 163 bed hospital and had no residents in 1999. F. 294, 296. The evidence as a whole does not warrant its inclusion in the geographic market. The market participants who commented specifically on Condell mentioned significant proximity issues, stating that it was “further west” than Lake Forest, which is the principal competitor

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north of Highland Park. F. 297. Condell is 12.7 miles and 24 minutes minutes (driving time) northwest of Highland Park. F. 293. Thus, the the drive time to Condell is substantially beyond the 16 minute drive drive time noted in the informal Lake Forest survey that people living within the area are willing to travel for emergency care. F. 257. Moreover, Condell does not offer any additional services which which are unavailable at Highland Park and Lake Forest. *See* F. 295. 295. Accordingly, Condell is not included in the geographic market. market.

(2) Resurrection

Resurrection was also included in Respondent's proposed geographic market. Resurrection is 12.1 miles or 25 minutes (driving time) southwest of Evanston Hospital. F. 298. Like Condell, the drive time to Resurrection is substantially beyond the 16 minute drive time noted in the Lake Forest survey that patients within the area are willing to travel for emergency care. F. 257. Resurrection had 350 staffed beds and .17 residents per bed in 1999. F. 299-300. The Resurrection system includes St. Francis, which is included in the geographic market, and there is conflicting testimony regarding whether the Resurrection system negotiated all of its hospitals as one contract or separately. F. 302. The Resurrection system is large and was described by one managed care organization as a "system which we really need to keep." F. 301. Therefore, managed care organizations may value Resurrection Medical Center only because they value the system. In addition to significant proximity and travel time issues, none of the managed care representatives testified that Resurrection was a significant competitor to ENH. Thus, there is insufficient evidence to support including Resurrection in the geographic market.

(3) Holy Family

Holy Family is 11.3 miles or 23 minutes (driving time) from Evanston Hospital. F. 305. Holy Family has 260 staffed beds and .02

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.02 residents per bed. F. 305. Although PHCS contemporaneous correspondence mentions Holy Family as an alternative to Evanston Evanston (F. 305), there is virtually no evidence in the record, including testimony of managed care representatives, which would indicate that Holy Family constrains the prices of Evanston or or is in any way a significant competitor. F. 305. Moreover, as is the the case with Condell and Resurrection, proximity and travel times times mitigate against Holy Family being a significant competitor to to ENH. Given these substantial limitations, the evidence does not support including Holy Family in the geographic market.

(4) Swedish Covenant

Swedish Covenant is 6.8 miles or 19 minutes (driving time) south of Evanston, and as of February 2005, had 324 beds. F. 306. In 1999, Swedish Covenant had .13 residents per bed. F. 306. The managed care representatives did not mention Swedish Covenant as a significant competitor to ENH, nor is there sufficient evidence from ENH that it considered Swedish Covenant as a viable competitor or that Swedish Covenant otherwise constrained ENH's prices. F. 306. The evidence does not, therefore, support including this hospital in the geographic market.

(5) Vista Hospitals

The Vista hospitals include Vista Health St. Therese and Vista Health Victory Memorial, both located in Waukegan in northern Illinois, with Victory Memorial located "almost up to Wisconsin." F. 307. The Vista hospitals are an average of 15.9 miles or 30 minutes (driving time) north of Highland Park. F. 307. Although Great West lists the Vista hospitals as an alternative in contemporary correspondence (F. 240, 307), given the outlying proximity issues of distance and travel times, and the almost complete lack of payor testimony and evidentiary support as to their competitive constraint on ENH, there is no foundation to include these northern Illinois hospitals in the geographic market.

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(6) Teaching Hospitals

Teaching hospitals in downtown Chicago, such as Northwestern Memorial, Rush-Presbyterian-St. Luke's, and the University of Chicago, may compete with ENH for more sophisticated or tertiary services. F. 242, 248, 308. However, as previously noted, when selecting a managed care plan, employees and employers want a plan that includes a local hospital. This is true even though patients may be willing to travel further for "exotic" services. *Rockford Memorial*, 898 F.2d at 1284-85. The court in *Long Island Jewish Medical Center* concluded that there were two relevant geographic markets – one for primary and secondary care and the other for tertiary care – to account for evidence that "patients prefer to receive health care treatment relatively close to their homes," but also that patients are willing to travel further for certain services such as specialty tertiary care. *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 141. Thus, although teaching hospitals may compete with ENH in the second stage for patients with more complex needs, they do not constrain ENH's first stage prices to managed care organizations, and are thus not properly considered as part of the geographic market.

i. Summary

The evidence establishes that when employers select a managed managed care plan, they prefer a plan that provides the most choice choice – specifically the choice, or option, of using a local hospital. hospital. F. 115, 118. Therefore, to create a viable hospital network, network, managed care organizations in this market must include local hospitals. The Court, guided by relevant case law, has defined defined the geographic market on the principle that such determination must undergo a dynamic "forward looking" approach approach to Clayton 7 analysis which considers the probable competitive responses from competing hospitals, managed care organizations, and, ultimately, consumers. *Freeman Hosp.*, 69 F.3d F.3d at 268; *Mercy Health Serv.*, 902 F. Supp. at 978. Based on the

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the evidentiary record, it seems reasonable that in the face of probable, future anticompetitive pricing, managed care organizations could create a network excluding the ENH hospitals and including the next proximal set of geographically close hospitals where consumers could go to seek “practical alternative” alternative” acute care inpatient hospital services. *Freeman Hosp.*, 69 F.3d at 268-69. Thus, the hospitals included in the geographic market are: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. This geographic market determination best comports with the market realities and the evidentiary record.

C. Probable Effects on Competition

“The Supreme Court has adopted a totality-of-the- circumstances approach to [Section 7], weighing a variety of factors to determine the effects of particular transactions on competition.” *Baker Hughes*, 908 F.2d at 984. The “Supreme Court and appellate courts acknowledge the need to adopt a flexible approach in determining whether anticompetitive effects are likely to result from a merger.” *Oracle Corp.*, 331 F. Supp. 2d at 1111. Courts require that the merger be “functionally viewed, in the context of its particular industry” and “only a further examination of the particular market – its structure, history and probable future – can provide the appropriate setting for judging the probable anticompetitive effect of the merger.” *Brown Shoe*, 370 U.S. at 321, 322 n.38; *In re Weyerhaeuser Co.*, 106 F.T.C. 172, 278 (Sept. 26, 1985).

1. Anticompetitive Effects

Having determined the relevant product and geographic markets, markets, the Court now turns to an analysis of the competitive effects of the merger. In doing so, it first undertakes a structural analysis of the probable anticompetitive effects of the merger, specifically an examination of market concentration in the relevant

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relevant market. Then, the evidence of contemporaneous and post-post-merger price increases is reviewed.

a. Market Concentration

Market concentration under the *Merger Guidelines* is measured by the Herfindahl-Hirschman Index (“HHI”). *Merger Guidelines* § 1.5. “The HHI is the most prominent method of measuring market concentration, commonly used by the Justice Department, the FTC and the courts in evaluating proposed mergers.” *Butterworth Health Corp.*, 946 F. Supp. at 1294. The HHI is calculated by summing the squares of the market shares of every firm in the relevant market. *University Health*, 938 F.2d at 1211 n. 12; *Merger Guidelines* § 1.5. “For example, in a market with six firms with market shares of 25%, 20%, 20%, 15%, 10%, and 10%, the HHI is 1850 ($25^2 + 20^2 + 20^2 + 15^2 + 10^2 + 10^2 = 1850$).” *University Health*, 938 F.2d at 1211 n. 12; *Merger Guidelines* § 1.51 n.17. Under the *Merger Guidelines*, a market in which the post-merger HHI is above 1800 is considered “highly concentrated,” and a merger in a highly concentrated market that increases the market’s HHI by over 100 is presumed to be “likely to create or enhance market power or facilitate its exercise.” *University Health*, 938 F.2d at 1211 n. 12; *Butterworth Health Corp.*, 946 F. Supp. at 1294; *Merger Guidelines* § 1.51.

The geographic market, as proposed by Complaint Counsel’s expert, Haas-Wilson, included only the ENH hospitals (Evanston, Glenbrook, and Highland Park), giving ENH a monopoly in the provision of inpatient services sold to managed care organizations. CCB at 55. Under Complaint Counsel’s proposed market, the HHI would be 10,000, the highest possible HHI number. *Merger Guidelines* § 1.51 n.17. Complaint Counsel asserts that even using Respondent’s proposed geographic market, market, the post-merger HHI level corresponds to a market that is “highly concentrated,” and the merger is “presumed” likely to

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“create or enhance market power.” CCB at 55-56. Complaint Counsel further argues that ENH cannot demonstrate that the market market share and market concentration figures give an “inaccurate account” of the merger’s effects, where the large post-merger price increases show that the anticompetitive effects predicted by the the market structure analysis are accurate. CCB at 56.

Alternatively, Complaint Counsel argues that Respondent’s market share can be determined based on Evanston’s contemporaneous estimation of its combined core service area (“CCSA”) to compute an HHI of 3426, with a corresponding increase of over 1000. CCB at 9. In 1999, ENH identified the market share in its CCSA as: Evanston, 44%; Highland Park, 11%; Lake Forest, 3%; Advocate Lutheran General, 7%; Rush North Shore, 14%; St. Francis, 7%; downtown teaching hospitals, 7%; and other, 7%. F. 325. Respondent contends that ENH’s “core service area” is not the same as an appropriately defined geographic market and that the information contained in these documents is an unscientific, unverified, and much less accurate form of patient flow data. RRB at 21 n.16. The Court agrees with Respondent that service areas are not the same as geographic market, in part because they are based upon patient flow data which, as previously noted, is more relevant to stage two competition for patients. *See Tenet Health Care*, 186 F.3d at 1052. Thus, use of ENH’s estimate of a 55% market share in its CCSA is not an appropriate method for determining HHI concentration levels.

Respondent argues that Complaint Counsel’s proposed market of only the merging parties and Complaint Counsel’s use of ENH’s ENH’s estimation of its CCSA to determine HHI statistics are incorrect. RB at 19; RRB at 55. Respondent’s expert, Noether, computed a post-merger HHI of 1919, an increase of 222 from premerger levels, based on Respondent’s proposed geographic market. F. 314, 323. In addition, Respondent argues that the HHI statistics give an inaccurate account of the merger’s probable effects effects on competition because the evidence shows that: the quality

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quality of care at Highland Park has improved, and is continuing to to improve, dramatically; there are currently several hospitals both both within and outside of the relevant geographic market that are viable alternatives to ENH and which exercise a constraint on ENH's pricing; and existing hospitals have been repositioning to expand their existing services and add new ones. RRB at 55-56; *see also* RB at 20-28, 56-59, 67-107.

As described in section III.B.2 *supra*, the geographic market is larger than Complaint Counsel's proposed three hospital market, yet smaller than Respondent's proposed nine hospital market. The Court's determination of relevant geographic (and product) market yields an HHI calculation which lies between the parties' estimates. Adopting and utilizing Respondent's net inpatient revenue determinations, but excluding Condell and Resurrection hospitals from the calculation, leads to a post-merger HHI of 2739, with an increase of 384. F. 316-19.

The HHI figure of over 2700 is calculated using Respondent's expert's market share figures. Noether acknowledged that she was not able to calculate exact market shares given the available data. F. 309. Noether did, however, calculate proxy shares using the best best available information, contained in the Medicare Cost Reports, Reports, without substantive critique by Complaint Counsel. F. 309; 309; CCRFF ¶¶ 508-14. The Medicare Cost Reports provide information on total net revenues, both inpatient and outpatient, across all managed care organizations for each hospital. F. 309. Noether provided revenues for inpatient services combined with outpatient services and for inpatient services alone. F. 309. Only the the inpatient revenues are used, to conform with the appropriate product market previously established. *See supra* Section III.B.1. Noether properly treated St. Francis and Resurrection as separate hospitals, although the hospitals had merged in the late 1990's. F. 311. Indeed, both Advocate Lutheran General and Rush North Shore are part of larger systems, but it would be improper to include include revenue from other hospitals in those systems in the

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determination of market shares, as such other hospitals are not in the the relevant geographic market. The post-merger HHI of over 2700 2700 is substantially above the *Merger Guidelines*' threshold of 1800 to consider a market "highly concentrated," and the increase of of over 350 far exceeds the *Merger Guidelines*' threshold of 100 to to presume that the merger is "likely to create or enhance market power or facilitate its exercise." *Merger Guidelines* § 1.51.

In 1999, within the relevant geographic and product market, Evanston and Highland Park had a combined market share of approximately thirty-five percent. F. 317, 322, 324. Lake Forest had a market share of { }, Advocate Lutheran General had a market share of { }, Rush North Shore had a market share of { }, and St. Francis had a market share of { } F. 322. Respondent's post-merger market share increased to approximately forty percent by 2002, with the other four hospitals in the geographic market all losing some market share in the three year period from 1999 to 2002. F. 322. These statistics demonstrate not only that this was a concentrated market in 1999, but that, over time, while ENH's concentration level has been steadily increasing, ENH's competitors have lost market share.

Courts have traditionally considered the market share of the combined firm to determine whether the merger is likely to cause anticompetitive effects. Under *Philadelphia National Bank*, a post-merger market share of thirty percent or higher presents the threat of undue concentration. *Philadelphia Nat'l Bank*, 374 U.S. at 364; see also *Oracle*, 331 F. Supp. 2d at 1110. Here, ENH's post-merger market share of thirty-five percent in 1999, which increases to forty percent in 2002, is well above the thirty percent threshold established in *Philadelphia National Bank*. F. 317, 324. Thus, all of the available methods for determining market concentration lead to the same conclusion – that this is a highly concentrated market and that the merger is likely to create or enhance ENH's market power or facilitate its exercise. This presumption is further supported by the post-merger evidence of ENH's price increases.

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Complaint Counsel has demonstrated sufficient market concentration to predict probable anticompetitive effects. Because this is a consummated merger case, however, Complaint Counsel was also able to provide contemporaneous and post-acquisition evidence regarding the merger's impact on ENH's prices to managed care.

b. Contemporaneous and Post-Acquisition Evidence**(1) Introduction**

Section 7 of the Clayton Act was intended to arrest the anticompetitive effects of market power in their incipency. *Brown Shoe*, 370 U.S. at 317. As previously noted, the test of a violation of § 7 is whether, at the time of suit, there is a "reasonable probability" that the acquisition is likely to result in the condemned restraints. *E.I. du Pont*, 353 U.S. at 607. Section 7 "requires not merely an appraisal of the immediate impact of the merger upon competition, but a prediction of its impact upon competitive conditions in the future." *Philadelphia Nat'l Bank*, 374 U.S. at 362. There "is no requirement that the anticompetitive power manifest itself in anticompetitive action before § 7 can be called into play. If the enforcement of § 7 turned on the existence of actual anticompetitive practices, the Congressional policy of thwarting such practices in their incipency would be frustrated." *FTC v. Procter & Gamble, Co.*, 386 U.S. 568, 577 (1967). Indeed, the Supreme Court in *Procter & Gamble* stated that the appellate court "misapprehended . . . the standards applicable in a § 7 proceeding" where the appellate court found that the post-post-acquisition evidence did "not prove anti-competitive effects of of the merger." *Procter & Gamble*, 386 U.S. at 576. *See also Hospital Corp. of Am.*, 807 F.2d at 1389 ("Section 7 does not require require proof that a merger or other acquisition has caused higher prices in the affected market. All that is necessary is that the merger merger create an appreciable danger of such consequences in the

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future.”). Accordingly, Complaint Counsel is not required to provide evidence of actual anticompetitive post-merger effects, only only evidence that anticompetitive effects are probable.

It is well settled that contemporaneous and post-acquisition evidence may properly be considered in determining whether the probable effect of a merger will be a substantial lessening of competition. *E.g.*, *Purex Corp. v. Procter & Gamble Co.*, 664 F.2d 1105, 1108 (9th Cir. 1981); *United States v. Falstaff Brewing Corp.*, 383 F. Supp. 1020, 1025 (D.R.I. 1974); *see also FTC v. Consolidated Foods Corp.*, 380 U.S. 592, 598 (1965). The Supreme Court, in *E.I. du Pont*, relied upon “the plain implications of the contemporaneous documents” to determine the motives of the acquisition. *E.I. du Pont*, 353 U.S. at 602; *see also University Health*, 938 F.2d at 1220 n.27 (evidence from defendants’ premerger documents evincing an intent to eliminate competition through the proposed acquisition can help establish the government’s *prima facie* case.). Similarly, post-acquisition evidence is appropriately considered where it “tends to confirm, rather than cast doubt upon, the probable anticompetitive effect” of a merger. *Consolidated Foods*, 380 U.S. at 598. However, post-acquisition evidence that can be manipulated by the party seeking to use it is entitled to little weight, in part because the actions may have been taken to “improve [the defendant’s] litigating position.” *Hospital Corp. of Am.*, 807 F.2d at 1384; *see also General Dynamics*, 415 U.S. at 504-05.

With respect to the post-acquisition evidence, Respondent argues that its expert’s analysis shows a smaller price increase relative to other hospitals than Complaint Counsel’s expert’s analysis; that not all viable competitively benign explanations have been ruled out; and, that Respondent’s price increases are a result of its learning about demand for its services and that its premerger prices at Evanston were, on average, below market. RB at 34. In addition, Respondent argues that Evanston and Highland Park were not close substitutes and therefore, ENH, the combined entity, could not have had greater bargaining power than the

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hospitals did before the merger. RB at 35. As discussed more fully below, the Court finds these arguments without merit.

Complaint Counsel has presented contemporaneous and post-acquisition evidence which establishes that ENH exercised its enhanced post-merger market power and obtained post-merger price increases substantially above its premerger prices and significantly larger than price increases obtained by other comparison hospitals. F. 326-755. This evidence confirms the predictive assessments made by the structural market analysis. F. 309-25. Complaint Counsel presented contemporaneous documents, testimony of managed care organizations, and empirical analysis to establish the post-merger price increases.

In the hospital services market, determination of relative prices must take into account a variety of factors. First, approximately half of ENH patients are covered by government insurance through Medicare or Medicaid. F. 135. For these patients, hospitals are reimbursed at a rate set by the government. F. 128. Second, managed care organizations negotiate contracts that include fixed rates (per case or per day) and discount off charges rates. F. 173-80. Thus, contract rates cannot be directly compared with each other because they arise through different payment methodologies. Third, relative prices vary depending on patient mix because not all inpatient hospital stays require the same resources for treatment. F. 735-37. Some patients, even those with the same condition, may be sicker and may require more treatment resources than the patient who is less sick. F. 735. Fourth, data on hospital prices is not maintained in a consistent or complete fashion. Indeed, only four managed care organizations provided usable data for analysis in these proceedings and even that data had limitations. F. 491-94, 500.

Respondent's expert, Noether, relied only on data provided by managed care organizations. As Noether indicated, "there were a number of problems with the data that made the measure of price

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certainly less than fully accurate.” F. 470. Noether concluded that the claims data provided by managed care organizations could be used in “forming [her] opinion and reaching [her] conclusions,” but but cautioned that her findings should be considered “in the context context of all the other evidence in the case.” F. 471. Recognizing the limitations of all of the data, Complaint Counsel’s expert, Haas-Haas-Wilson, provided an analysis which utilized four different data data sources. F. 469-692. Reviewing the evidence, the Court concludes that Haas-Wilson’s conclusions are more reliable, in part part because they present more detailed and consistent findings which were validated throughout each of the different data sources. sources. F. 469-692. In addition, contemporaneous documents and testimony of managed care organizations affirm the conclusions of of Haas-Wilson and provide evidentiary support for her empirical analysis. F. 328-468. Given the breadth and variety of this evidence, evidence, Complaint Counsel’s expert’s conclusions on relative price price increases are found credible and persuasive.

The merger violates the Clayton Act because the merger reduced reduced competition in the relevant market and enhanced ENH’s market power, regardless of whether ENH’s prices have yet risen to to a supra competitive level. Since the enactment of the Hart-Scott-Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. § U.S.C. § 18a), most enforcement actions are initiated prior to the proposed merger. Therefore, there are very few recent cases which have examined post-merger evidence and there is relatively little case law regarding the proper analysis of price changes in a consummated merger under Clayton 7. Courts have indicated that, consistent with the *Merger Guidelines*’ SSNIP test, a 5% price increase is an appropriate value against which to judge a merger. *Sutter Health*, 130 F. Supp. 2d at 1129; *Mercy Health Serv.*, 902 F. Supp. at 980-81; *see also CF Industries, Inc. v. Surface Transp. Bd.*, *Bd.*, 255 F.3d 816, 823-24 (D.C. Cir. 2001). Analysis of relative price increases in the consummated merger context is fact intensive intensive and depends upon the economic realities of each market. Thus, the focus of this analysis rests, by necessity, on the quality of of the factual evidence presented by the parties. As discussed below,

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below, the evidence in this case is more than sufficient for the Court Court to reach its conclusions.

Respondent contends that “in order to utilize evidence of price increases to prove that a firm possesses market power, that evidence must be accompanied by proof that the price increased above a competitive level and can be sustained at that level over a period of time, or is associated with a reduction of output.” RB at 36. In support of this contention, Respondent cites no Section 7, Clayton Act cases. RB at 36 n.23. Complaint Counsel responds that it is not required to demonstrate a decrease in output, but even if it were, output decreased as a result of ENH’s higher prices including the temporary loss of its contract with One Health and the patients who lost coverage due to the increased cost of health care. CCRB at 19-20.

The evidence indicates, but does not conclusively establish, that Respondent’s prices were supra competitive. Indeed, Complaint Counsel did not attempt to compare ENH’s prices to a competitive level, instead focusing on ENH’s price increases relative to other hospitals’ price increases. CCB at 44-45; F. 469-97. ENH’s expert, Noether, compared ENH’s inpatient and outpatient prices to inpatient and outpatient prices charged by other hospitals. F. 798, 831. { } F. 831-35. { } F. 831, 833. Thus, Respondent’s own expert’s analysis indicates that ENH’s prices exceed the prices charged by each of the other four hospitals in the geographic market. The evidence, therefore, strongly suggests that prices did rise to a supra competitive level without a reduction of output, although the evidence on that issue is not conclusive. However, as noted earlier, Complaint Counsel need not make such a definitive showing in order to find Respondent in violation of Section 7.

A review of the evidence demonstrates that: (1) ENH achieved substantial price increases as a result of the merger; (2) empirical analysis establishes that ENH’s prices rose relative to other

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comparison hospitals; and (3) explanations of price increases other than market power are ruled out. F. 326-755. The evidence therefore demonstrates that the relative price increases were the result of ENH's enhanced market power, achieved through elimination of a competitor as a consequence of the merger. Complaint Counsel's post-acquisition evidence of relative price increases, which confirms the structural evidence of concentration, concentration, clearly establishes the probable anticompetitive effects of the merger necessary to find a violation of Section 7 of the the Clayton Act.

**(2) Respondent Achieved Substantial Price
Increases as a Result of the Merger**

Contemporaneous evidence demonstrates that ENH sought and achieved substantial price increases as a result of the merger. It is clear that the primary motivation for the merger was economic, although the parties to the merger were well aware of the importance of quality and brand image, especially for stage two competition for patients. E.g., F. 45, 343, 368. As noted, such evidence is entitled to significant weight. Managed care testimony in this case is confirmed by the contemporaneous actions of the managed care organizations and therefore such testimony is considered credible, despite the fact that the managed care organizations have an interest in the outcome of this litigation.

**(a) Evanston and Highland Park Sought
Market Power from the Merger**

As early as 1994, the CEOs of the merging parties shared the view that hospitals should "stand united" in order to get "better pricing" and "leverage" from the managed care organizations. F. 29. In 1998, as merger discussions began, the CEOs wrote: "[p]ricing pressures will escalate on healthcare providers from both both government and managed care." F. 331. Their recommendations included: "[s]trengthen negotiating positions with with managed care through merged entities and one voice" and

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“[m]aintain and enhance local community ties for long-term success success – make indispensable to marketplace.” F. 331. Evanston’s CEO told managers and the Evanston board that the merger would “[i]ncrease our leverage, limited as it might be, with the managed care players, and help our negotiating posture.” F. 353. Evanston’s CEO candidly admitted at trial that one of the goals of the merger was to obtain better prices and better terms from managed care. F. 330.

The evidence further establishes that Evanston wanted to merge with Highland Park in no small part to eliminate a competitor within the geographic market. Evanston’s management reminded its board of the risk of “not undertaking [the] merger.” F. 334. Skokie Valley Community Hospital, located three miles to Evanston’s south, had been a “sleeping dog” competitor until it affiliated with the Rush system of hospitals, at which point Rush renamed it Rush North Shore, invested heavily in the hospital, and the former “sleeping dog” awoke to become a stronger, more competitive hospital. F. 334. The point of the story was clear: if Evanston did not act first, the same problem could occur to Evanston’s north, and another hospital system would come in to further strengthen the competitive position of Highland Park. F. 334. Thus, one of Evanston’s goals was to stop Highland Park from competing with it. The merger was seen by Evanston as an “opportunity to join forces and grow together rather than compete with each other.” F. 333.

Highland Park similarly sought to eliminate a competitor within the geographic market. Highland Park’s board chairman recognized that the merger would allow the two health care providers to “[s]top competing with each other.” F. 341. Highland Park management hoped that a merger with Evanston would build “negotiating strength with payers.” F. 340. Evanston, Glenbrook, and Highland Park would form a triangle and “together would have have a significant market penetration in these very affluent, attractive communities.” F. 339 (emphasis added). Highland Park

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saw Evanston, Lake Forest, Northwest Community, and Condell as merger candidates, the attractiveness of each turning on “how concentrated could this market be for us.” F. 340. Highland Park believed that merging with Evanston would build the greatest pricing strength with managed care organizations. F. 340.

In 1999, Highland Park’s CEO and board convened to frankly discuss the merger. F. 342. The CEO described the problem:

the reality in my view is that we are not looking at a rosie future economically on this site. Neither are they. We are not looking at the opportunity to control this market individually. The largest . . . payors in this arena have consolidated and are big enough, strong enough, and probably bent on assuring that the physicians who practice here and at Evanston and the institutions don’t make a hell of a lot of money. That is the reality and I am not even laying that on the insurers I am laying that on the employers. The same speech I have made over and over.

F. 342.

The solution was the merger with Evanston:

I think the ultimate benefit to these communities is pretty positive. There are cost economies, there are quality issues, there are ways to at least I think to push back on the managed care phenomenon and get the rates back where they ought to be if you are a big enough concerted enough entity which is important enough to the employers in this community. I think it would be real tough for any of of the Fortune 40 companies in this area whose CEOs either use this place or that place to walk from

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from Evanston, Highland Park, Glenbrook and 1700
1700 of their doctors.

F. 343. At that same meeting, there was a comment on “the economic benefit of not being out there doing battle with one another in what will be a common battle ground if you want to call it that.” F. 345. The above evidence clearly shows the primary motivation for the merger was to attain enhanced market power which could be utilized by the merged entity in negotiations with the managed care organizations. Such market power, however, could only be obtained through the elimination of a competitor in the geographic market.

The antitrust laws afford neither solace nor escape from the rigors of competition induced by managed care. In *Hospital Corporation of America*, the Seventh Circuit upheld an FTC challenge to mergers that would have reduced the number of owners/managers of Chattanooga hospitals. The Court recognized that hospitals were under “great pressure” from managed care organizations (and the federal government) to “cut costs.” 807 F.2d at 1389. However, efforts by hospitals to resist this pressure through mergers that confer market power may violate the Clayton Act. The “fewer the independent competitors in a hospital market, the easier they will find it ... to frustrate efforts to control hospital costs.” *Id.* The Court opined that the Commission was entitled to make such efforts by hospitals “less effective by preserving a substantial number of competitors.” *Id.* As noted by the Seventh Circuit, hospitals thus risk violating the Clayton Act by acquiring market power to shield them from the pricing pressures of managed care.

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(b) ENH Sought to Increase Prices Through Contract Negotiations and Chargemaster Chargemaster Increases

Even before the merger was fully consummated, Respondent made extensive efforts to exercise its enhanced market power by increasing its charges to managed care organizations. In December 1999, ENH negotiators sent consent to assignment agreements to managed care organizations to assign the higher of the Evanston or Highland Park rates. F. 349. In January 2000, while the status of many contracts was still in limbo, Chan, who was responsible for managed care contracting for Highland Park, instructed ENH's billing department to "continue to use the current Highland Park Hospital rates" – in some instances in which Highland Park had higher rates – until all of the hospital contracts had been renegotiated. F. 350.

ENH decided that all three hospitals would operate under one contract, with one price, and one chargemaster, even though other multi-hospital systems in the Chicago area charged different rates for different hospitals. F. 355-66. ENH demanded the same rate regardless of the level or complexity of services provided at each hospital. F. 359. ENH successfully moved all three hospitals to the same contract and equalized the charges for all three facilities post-merger. F. 364. Indeed, under ENH's billing system, managed care organizations can not "distinguish between services at the three hospitals" to determine which services are rendered at a particular hospital in the system. F. 362. Though Evanston had previously included Glenbrook in its contracts and chargemaster prior to the merger, Glenbrook was developed and built by Evanston (F. 2) and had never been an independent competitor like Highland Park. This consolidation into one contract enabled ENH to charge higher prices at all three hospitals.

The record reveals further strategies by the newly-merged ENH to maximize its pricing. One such method utilized by ENH in negotiations with managed care organizations was to seek the

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higher of Evanston's or Highland Park's existing contract rates and add a "premium" on top of that. F. 367. The "premium" represented one of ENH's self described "benefits" of the merger and was depicted by Highland Park's vice president of business development as resulting from the "additional negotiating power and leverage with the payors." F. 367. Bain & Company ("Bain"), an economic consulting firm, advised ENH that it could "sell" these higher rates to managed care by emphasizing "the value ENH brings to a payor's network" such as brand, patient access, cost management, and quality, in order to "[j]ustify premium pricing (i.e., above the competitive average)." F. 368.

According to ENH, one of the "accomplishments" of the merger was the renegotiation of managed care contracts, which collectively resulted in an increased annualized economic value of at least \$18 million for ENH. F. 370. Evanston "had never achieved" a price increase as high as \$18 million prior to the merger. F. 371. Although ENH argues that pricing "above the competitive average" does not mean supra competitive pricing, it is clear from the context of all of the contemporaneous documents that one of ENH's primary motives for the merger was to obtain supra competitive prices.

The record further demonstrates that, as a result of its enhanced market power, ENH succeeded with numerous managed care organizations in negotiating discount off charges arrangements, which were "more favorable" for ENH. F. 373. Fixed rates tend to result in greater discounts – "up to 50%" – than discount off charges. F. 373. As the Unicare representative explained, in discount off charges arrangements, the "hospital sets their own prices," and managed care organizations "have no control over . . . what the services are going to cost in any given admission or service." F. 374. Moving managed care organizations to discount off charges contracts permitted ENH to institute additional price increases by allowing it to unilaterally increase its chargemaster. F. 384-91. These subsequent price

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increases did not necessitate additional negotiation, and in many cases did not even require notification to managed care organizations. F. 386-87. Respondent notes that some managed care organizations negotiated some relief from subsequent chargemaster increases, but, as Haas-Wilson's empirical analysis shows, those limits, where they existed, were not effective. F. 469-469-692.

As part of the merger integration process, ENH consolidated the Highland Park and Evanston chargemasters in 2000. F. 378. In a "fairly simplistic analysis," ENH examined the chargemasters at the two hospitals and adopted the higher of the Highland Park or Evanston chargemaster rates for each line item. F. 380. As of September 30, 2000, only nine months after the merger, Neaman, ENH's CEO, reported to ENH's board of directors that ENH's "Unified Pricing Structure" for the chargemaster had already resulted in \$5 million of annualized economic value. F. 383. This increase is larger than the estimated increase in net revenues from the renegotiated contracts with any single managed care organization. F. 370, 383. Without the merger, chargemaster increases would most likely have been restrained by the possibility of losing managed care customers through selective contracting, steering, and competition. F. 158-69. As a result of the merger, and its newly-enhanced market power, ENH was able to impose anticompetitive chargemaster increases.

In addition to the price increases obtained in the 2000 renegotiations and through the 2000 chargemaster consolidation, ENH subsequently increased its chargemaster rates four times between 2002 and 2003. F. 384. Together, ENH's four chargemaster chargemaster increases in 2002 and 2003 represented a { } price increase. F. 391. ENH instituted a price increase of { } on April 15, 2002; { } on October 1, 2002; { } on June 1, 2003; and { } on October 1, 2003. F. 385, 388-90. The April 15, 2002 increase, alone, was projected to have an annual net impact impact { } F. 385. The evidence does not provide a comparable estimate of the net impact on annual net revenue of the last three

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increases, but it clearly would be substantial. The evidence does not compare these increases to increases at other hospitals, and they are included to demonstrate that ENH possessed the market power to impose substantial, unilateral, and repeated price increases.

The fact that ENH realized these substantial increased revenues was not widely advertised. In March 2002, Hillebrand advised that for chargemaster increases, “the only notification we make is to Blue Cross” and that “[w]e should not notify anyone beyond those we have a contractual obligation to do so.” F. 387. After ENH raised its chargemaster prices in April 2002, ENH’s executive vice-president for finance wrote to ENH managers that “[f]or a number of reasons we want to be as quiet as possible and there are relatively few people who have seen the scope of the changes.” F. 386. It is clear that these chargemaster changes added significant increased revenue to the merged ENH. The evidence thus establishes that as a result of the merger, ENH was able to use its enhanced market power to implement a continuous and ongoing mechanism to impose significant price increases through a discount off charges fee arrangement. These increases negatively impact self insured patients, as well. Contrary to Respondent’s assertion, these chargemaster revisions were certainly more than a one time, catch up occurrence and appear to be aimed almost exclusively at revenue enhancement.

**(c) Managed Care Representatives’ Testimony
Confirms Price Increases**

As the following evidence demonstrates, managed care representatives’ testimony confirms that ENH significantly increased its prices post-merger by negotiating contracts with increased discount off charges terms. As previously noted, by increasing the number of discount off charges terms in managed care contracts, ENH was able to obtain significant additional

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revenue from managed care organizations through subsequent unilateral chargemaster increases.

(i) United

Before the merger in 2000, Highland Park and Evanston hospital representatives formulated a strategy for the renegotiation of a contract with United. F. 394. Bain identified the United contract as a “1st Priority” contract with “upside revenue potential” for which the merged entity had “enough leverage to improve terms.” F. 395. Bain advised ENH that United had reimbursed Evanston 45 to 50% less than it paid Highland Park. F. 395. Moreover, Bain informed Evanston that its outdated contract with United had cost the hospital \$30 million over the preceding five years. F. 395.

The negotiations resulted in { } F. 396. In 2002, United stated that the merger had enabled ENH to “dominat[e] Chicago’s north shore, providing the only hospital locations . . . ranging between Evanston and Highland Park, as well as a significant stretch of territory moving inland” and noting “the strategic importance of ENH’s geographic exclusivity.” F. 398. In August 2002, United requested a renegotiation of United’s contract with ENH because, since the 2000 contract, ENH had been an “outlier” hospital with “much higher than the average reimbursement.” F. 399. United was concerned in part because the 2000 contract relied primarily on a discount off charges payment methodology, resulting in higher and higher reimbursements from United, which witnessed “alarmin[g] escalating costs in [ENH’s] billed charges” that were “outside of the norms for the market.” F. 400. United was also concerned that in 2002, “from quarter to quarter, the [chargemaster] increases were still occurring. It was not a one-time event.” F. 402. { } F. 403.

Having had no success in lowering ENH’s prices, United pursued the more modest goal of asking ENH to stop increasing prices so much. F. 404. { } F. 404. The new contract between ENH

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ENH and United was signed on April 14, 2004, with an effective date of June 1, 2004. F. 405. { } F. 406. { } F. 407. Even today, today, with Lake Forest, Rush North Shore, St. Francis, and other neighboring hospitals in its network, United believes it cannot satisfy its customers without ENH. F. 408.

(ii) PHCS

Prior to the merger, PHCS obtained competitive pricing from Evanston and Highland Park because PHCS “could choose between the two and work them against each other.” F. 409. On December 1, 1999, ENH notified PHCS of the impending merger and sought to assign Highland Park’s rates. F. 410. In response to that letter, PHCS sought to renegotiate the rates. F. 410.

Bain advised ENH that it had “significant leverage in negotiations with PHCS as they have strong North Shore presence and need us in their network.” F. 411. Bain indicated that Highland Park’s pre-merger contract terms with PHCS were significantly more favorable than Evanston’s contract terms. F. 411. ENH justified the request for an increase by indicating that it was one system which “controlled the marketplace,” according to one managed care representative. F. 412. The “best scenario” for PHCS customers, strictly looking at dollars, was to eliminate ENH and redirect enrollees to the surrounding hospitals, such as Lake Forest, Advocate Lutheran General, and St. Francis. F. 413. PHCS believed, however, that customers did not want to “buy the [PHCS] network if they did not have [ENH in] it.” F. 414. Thus, PHCS agreed to the { } F. 418.

(iii) One Health (Great West)

In December 1999, ENH contacted One Health (formerly Great Great West) to request the renegotiation of its hospital contract. F. 420-21. Bain noted the “substantial difference” between One Health’s Highland Park and Evanston contract terms. F. 422. Bain

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advised ENH to “[a]chieve [Highland Park] terms or better” in its negotiations with One Health. F. 422.

Having last renegotiated the Highland Park and Evanston contracts in 1996 and in 1995, respectively, One Health “agreed that it had been several years since the contracts had been renegotiated and that it was appropriate to [] increase some of the rates.” F. 423. One Health was willing to give a price increase { } F. 423.

In the first half of 2000, ENH and One Health did not reach an agreement on the renegotiation of the PPO and HMO contracts. F. 424. One Health accepted ENH’s notice of termination. F. 424. One Health’s contract with ENH subsequently terminated on August 31, 2000. F. 425. One Health made provisions for women who were in the third trimester of pregnancy at the time of the contract termination. F. 426. While One Health was able to negotiate a continuation of benefits for those expecting mothers, ENH charged One Health rates that were higher than contract rates that had been in place under the 1996 premerger One Health contract. F. 426.

One Health customers complained about not having access to ENH, although One Health pointed to Lake Forest, Northwest Community, Advocate Lutheran General, Rush North Shore, and St. Francis as substitutes. F. 427. In the months following the termination of the ENH contract, One Health’s monthly membership reports began to reflect a “loss of membership within [the] network.” F. 428. In addition, before discussions between ENH and One Health resumed in early October 2000, One Health received a written notice of termination, effective December 31, 2000, from Lake Forest and its medical group. F. 429. Since Lake Forest was the primary alternative to Highland Park, it would have been “very problematic” for One Health to have lost Lake Forest Hospital from the network at the same time that One Health had no contract with ENH. F. 429.

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One Health returned to ENH prepared to accede “essentially regardless of what the ultimate price was.” F. 430. One Health accepted a new agreement with an effective date of January 1, 2001, four months after the prior contract lapsed. F. 431. { } F. 432. { } F. 433.

(iv) Aetna

Aetna “would have walked away” from Evanston if faced with a significant price increase before the merger. F. 434. “[T]here probably would have been a walk-away point with the two independently. But with the two together, that was a different conversation.” F. 434. With the merger of “three extremely important hospitals negotiating together in a very important geography,” Aetna was “extremely concerned.” F. 435. Bain identified Highland Park’s rates for Aetna’s PPO and POS products as higher than Evanston’s rates for those products. F. 436. Evanston’s contract with Aetna was nearly four years old in November 1999, so Bain recommended renegotiation of the Aetna contract as a priority. F. 436.

Aetna had not renegotiated its contract with Evanston since 1996 and expected ENH to make a proposal to renegotiate. F. 437. Based on the 3% increase per year in medical CPI between 1996 and 1999, Aetna calculated an appropriate increase compounded over three years to be { } F. 437. During the 2000 negotiations, ENH originally sought a discount off charges arrangement for PPO and POS plans. F. 438. Aetna, however, did not agree to that payment methodology. F. 438. ENH and Aetna agreed { } F. 439. { } F. 441. { } F. 443. { } F. 442. { } F. 444. { } F. 445. Aetna believed it “couldn’t walk away” from post-merger ENH because it would have “devastated us,” and “shut down” Aetna’s marketing to local employers. F. 446.

(v) Unicare

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In 2000, Unicare acquired Rush Prudential, another managed care organization. F. 447. Prior to the merger, Rush Prudential had contracted with both Evanston and Highland Park, and Unicare had contracted with just Evanston. F. 447. { } F. 448. With the merger, ENH proposed an unusual “all-or-nothing deal” in which there would be one rate for all three hospitals, regardless of the level of services at each facility.” F. 449. { } F. 450. { } F. 450.

Even if Unicare representatives had expected an increase in ENH contract rates after the merger, the rates proposed by ENH in 2000 were above what Unicare considered to be a “reasonable” increase, { } F. 451. { } F. 451.

The result for Unicare { } F. 452. { } F. 453. { } F. 453. According to Unicare, ENH had indicated that it could obtain higher prices because it had “a lot more leverage now that they have three hospitals in their service area” and that ENH had a “stronger presence” in the area, meaning ENH had “basically sewn up the North Shore geography.” F. 455. Unicare would be in a bind without ENH, now a “key provider” in the North Shore. F. 456. ENH’s “contiguous service area” made it “hard, painful, for customers to see [ENH] leave the network.” F. 456.

(vi) Summary

The evidence of ENH’s negotiations with managed care organizations clearly demonstrates that the combined ENH had enhanced its market power from the premerger period when Evanston and Highland Park had been negotiating as independent competitors. This increase in market power occurred immediately after and solely due to the merger and not to any other changes in market forces. Moreover, at the time, the price increases were never ascribed by the parties as being related to improvements in quality of care or any changes in the level of services provided by the ENH hospitals. Rather, ENH’s ability to increase prices stemmed from its geographic exclusivity in an important region.

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ENH was fully aware of its enhanced market power as a result of the merger and utilized its newly-formed competitive position to obtain much more favorable contracts with managed care organizations than either Evanston or Highland Park could have negotiated as independent hospitals.

**(d) Respondent Highlighted the Managed
Care Price Increases as a Merger
Accomplishment**

Internal memoranda indicate that ENH highlighted, even celebrated, the managed care price increases as an achievement directly related to the merger. The contemporaneous documents demonstrate that ENH's primary merger accomplishment was increased revenues, the majority of which came from managed care organizations. On March 14, 2000, ENH's COO drafted ENH's 2001-2003 Strategic Plan. In the draft of the Strategic Plan, ENH's COO stated:

Through our growth initiatives, we will expand our presence in our marketplace in order to provide leverage to our market position as we negotiate relationships with the purchasers of care. Our goal will be to receive superior pricing for our services and to become indispensable to the purchaser of care as they sell their product in our marketplace.

F. 459. This aptly summarizes ENH's accomplishments.

Additional contemporaneous documents highlight the significant significant price increases achieved as a result of the merger. In June 2000, it was reported that Neaman, ENH's CEO, "reviewed the the list of merger accomplishments. Important successes have been been accomplished in managed care contracting. There has been a \$12 million improvement on the Hospital side and \$8 million to physicians' practices to date." F. 460. By October 2, 2000, Neaman

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Neaman reported: “[s]ome \$24 million of revenue enhancements have been achieved – mostly via managed care renegotiations. (This figure does not include some \$13 million of additional managed care revenues to participating physicians.)” F. 464. In addition, “[s]ome \$12 million of cost improvements have been achieved – mostly from corporate overhead areas.” F. 464. The hospitals’ revenue enhancements from the managed care renegotiations were thus double the revenue enhancements from cost cost improvements. None of these savings were passed on to managed care organizations, or therefore consumers, in the form of lower prices. *See* F. 326-755; *see also* Closing argument, Tr. 6582-83. Nor were any of the initial post-merger price increases obtained by ENH from managed care organizations reduced in subsequent years, with the exception of a { } F. 466.

Evanston’s CEO acknowledged that the price increases to managed care organizations were the direct result of the merger. Neaman’s July 3, 2000 “Interdependence” memorandum stated:

our success in the merger integration effort is not a product of our “independence,” but of our “interdependence.” Neither Evanston nor Highland Park alone could achieve these results. Our three Hospitals, together with our 1500 physicians as a “fighting unit” appear to have helped provide at least a small advantage for an interim period.

F. 462. At a September 27, 2000 meeting, Neaman stated that “the larger market share created by adding Highland Park Hospital has translated to better managed care contracts.” F. 463. Neaman’s October 2, 2000 report reiterated: “[a]s stated previously, none of this could have been achieved by either Evanston or Highland Park alone. The ‘fighting unit’ of our three hospitals and 1600 physicians was instrumental in achieving these ends.” F. 465. Respondent’s argument that these statements should not be taken at face value or are taken out of context is unpersuasive.

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ENH thus achieved its goal of “superior pricing” due to its enhanced post-merger market power and competitive position. F. 326-755. ENH, who was in the best position to evaluate the effect of the merger, repeatedly attributed the increased prices to post-merger renegotiations with the managed care organizations. F. 457-68. In addition to the ENH documents, Highland Park representatives testified that all the rates Highland Park Hospital had in place in July 1, 1999, were the best that Highland Park could accomplish at that time without threatening termination. F. 467. Highland Park’s CEO testified that, at the time of the merger, Highland Park would not have been successful in raising its rates because the hospital could not sustain a strategy where it kept losing contracts. F. 468. He did not *see* an opportunity to raise the rates before the merger. F. 468. The fact that Highland Park executives were concerned about contract terminations premerger is illustrative of the competitive environment that existed before 2000 and stands in contrast to the actions of ENH officials who, given their competitive situation, were not constrained by such prospects in their renegotiations with managed care representatives post-merger.

Thus, ENH continued to tout the principal accomplishment of the merger as revenue enhancement, which the evidence indicates resulted from its post-merger market power in managed care negotiations. This market power allowed ENH to maintain significant price increases over a number of years and was achieved as a direct result of the merger. The totality of the evidence thus demonstrates that Evanston and Highland Park merged to eliminate competition from each other, enhance their competitive position in the market, and obtain substantial price increases from managed care organizations. The evidence further demonstrates that as soon as the merger was consummated, Respondent began using its enhanced market power to impose significant price increases on managed care organizations, and ultimately consumers.

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(3) Empirical Analysis Establishes That Respondent's Prices Rose Relative to Other Hospitals

In addition to the contemporaneous evidence and managed care testimony, the economic evidence establishes that ENH's post-merger price increases were attributable to market power. Complaint Counsel's expert, Haas-Wilson, utilized data from four different sources – managed care organizations; the State of Illinois Department of Public Health ("IDPH"); a Civil Investigative Demand ("CID") to ENH; and National Economic Research Associates ("NERA"), ENH's consultant. F. 469. Data from all four sources shows that "for most [managed care plans], there were large post-merger price increases at ENH." F. 498. The data from the managed care organizations and the State of Illinois contained pricing data for hospitals other than ENH, so only those two sources provide specific data for a comparative analysis of relative price increases. *See* F. 573-74. The CID and NERA data is compared to the Chicago medical CPI. F. 614, 644. Respondent objects to the use of the Chicago CPI as opposed to a national hospital CPI and objects to the use of this data in a comparative fashion. RRFF ¶ 404. Although not as precise as the relative comparison obtained by Haas-Wilson for the managed care and DPH databases, the CID and NERA data, in combination with the other data, confirms the conclusion that ENH significantly increased prices relative to other hospitals' price increases. The NERA and CID data is particularly useful because it encompasses many more payors than the managed care and IDPH data. F. 612, 642.

Complaint Counsel acknowledges that "large price increases alone do not mean that the merger gave ENH market power." CCB CCB at 45; *see also Blue Cross & Blue Shield United of Wisconsin v. Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1411-12 (7th Cir. 1995). Therefore, Haas-Wilson examined whether ENH's price increases were attributable to changes in the marketplace that would affect all hospitals equally. F. 477-80. This required

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comparing ENH's price increases against three control groups of hospitals. F. 481.

The role of the hospital control groups is to control for market-wide factors that might provide alternative (completely benign) explanations for the observed relative price increases, such as changes in cost, regulation, or demand that might be impacting comparison hospitals and the merging hospitals the same way. F. 694-96, 702. Haas-Wilson's three control groups were: (1) all general acute care hospitals in the Chicago Primary Metropolitan Statistical Area ("PMSA") (the "Chicago PMSA Hospitals" control group); (2) all general acute care hospitals in the Chicago PMSA, that were not involved with a merger with another hospital between 1996 and 2002 (the "Non-Merging Chicago PMSA Hospitals" control group); and (3) all general acute care hospitals in the Chicago PMSA that were involved in some teaching activity during the study period (the "Chicago PMSA Teaching Hospitals" control group). F. 481. Applying a "difference in differences" technique, Haas-Wilson first calculated the difference in premerger and post-merger prices for ENH and for the control groups, expressed as a percentage, and then compared ENH's numbers to the control groups' numbers. F. 477-80.

Respondent argues that Complaint Counsel's control groups are overbroad and do not control for idiosyncratic but competitively competitively benign changes to ENH's prices. RB at 39. Indeed, the the Chicago PMSA Hospitals control group includes one hundred hospitals and the Chicago PMSA Teaching Hospitals control group group includes fifty hospitals. F. 486. However, Haas-Wilson rejected the concept of picking only hospitals that "looked like" Evanston to use as her control group because this would have required making arbitrary decisions on which neither theory nor previous empirical work provided guidance. F. 487. Any attempt to to match hospitals with ENH to form a control group that "looked like" ENH would have to account for the fact that Evanston and

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Highland Park had different characteristics pre-merger. F. 488. Upon review, Haas-Wilson's methodology in selecting her control groups is considered more reliable and appropriate than that of ENH's expert, Noether. *See also infra* Section III.C.2.a.3.

Haas-Wilson found that, with the exception of Blue Cross Blue Shield, ENH's price increases across all managed care organizations were higher than the price increases at the control group hospitals. F. 473. This means that changes in costs, regulations, or demand – market conditions that would be expected to cause similar price increases across all hospitals – could *not* explain the higher prices at ENH. F. 698-713.

ENH's argument that its Blue Cross Blue Shield rates are inconsistent with market power (RB at 52-53) is unpersuasive. Blue Cross Blue Shield is the largest managed care organization in Chicago, and accounts for approximately twenty percent of ENH's business. F. 561. Thus, Blue Cross Blue Shield has the power to limit ENH's price increases. That ENH has not, to date, imposed price increases on Blue Cross Blue Shield does not undermine the conclusion that ENH gained market power through the merger. As Bain acknowledged, ENH's bargaining position with each managed care organization was different and ENH's "leverage" in contract negotiations with Blue Cross Blue Shield was "less than with most payors." F. 562. There is no dispute that Blue Cross Blue Shield had a very strong bargaining position against ENH. Thus, Blue Cross Blue Shield has the power to limit ENH's price increases. That ENH has not, to date, imposed price increases on Blue Cross Blue Shield does not undermine the conclusion that ENH gained market power through the merger.

Haas-Wilson observed that changes in ENH's patient mix, customer mix, and teaching intensity varied from the control group hospitals. In order to assess the impact of these changes, Haas-Wilson conducted a multiple regression analysis that compared ENH's percentage price changes against the control groups' price increases while at the same time accounting for the

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three variables. F. 727. The regression analysis showed that ENH's ENH's percentage price increases were higher than the control groups' price increases even after accounting for changes in patient patient mix, customer mix, and teaching intensity. F. 583. The only only exception to Haas-Wilson's pricing analysis results was Blue Cross Blue Shield – ENH increased its prices, but the percentage increase was similar or the same as the increases at the control group group hospitals. F. 571-72. This means that changes in customer mix, patient mix, and teaching intensity also do not explain ENH's ENH's price increases. F. 583.

The pricing analyses conducted by both Complaint Counsel's expert and Respondent's expert show significantly higher percentage price increases by ENH than by other hospitals. Haas-Wilson found that ENH's price increases to the following managed care organizations exceeded the price increases of the control groups by the amounts shown: { } F. 520-22, 535-37, 558-60. Haas-Wilson's results are presented as ranges because the specific price increase results depend on the measurement and control group against which prices are compared. F. 481. Haas-Wilson's results are statistically significant at the 1% level, the "highest level of significance." F. 489, 502, 524, 540, 584, 591-93, 599-601, 608-10.

The IDPH data includes all managed care plans in Illinois, thereby allowing Haas-Wilson to compute ENH's price increases across all managed care organizations. F. 573. Across all managed care plans, ENH's price increases exceeded the control groups by 11 to 18%, i.e., if other hospitals raised prices by 10%, ENH raised prices by 21 to 28%. F. 591-93, 599-601, 607-10. ENH's price increase would be even higher if Blue Cross Blue Shield was excluded because Blue Cross Blue Shield was the only managed care organization that did not incur a price increase from ENH that was higher than the control group hospitals' price increases. F. 571-72.

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Respondent's economic expert, Dr. Jonathan B. Baker, agreed that ENH's post-merger price increases were higher than other hospitals. F. 688-89. Even Baker calculated ENH's post-merger price increase as 9 to 10% higher than his control group hospitals. F. 689-90. Moreover, Baker's figure represents data from only four managed care organizations: United, Aetna, Humana, and Blue Cross Blue Shield. F. 675-79. Including Blue Cross Blue Shield, the largest managed care organization and with whom ENH has little leverage, weighs down ENH's number. F. 561-62. Not included in Baker's calculations are data from One Health or any of the other health plans included in the Illinois Department of Public Health data. *See* F. 675-79, 685. Only Haas-Wilson presented aggregated pricing analysis results that covered all managed care plans.

**(4) Explanations of Price Increases Other than
Market Power Are Ruled Out**

Haas-Wilson examined ten possible explanations for ENH's higher prices, including the two principal explanations advanced by Respondent, learning about demand and improved quality of care. *See infra* III.C.2.a and III.C.2.b. Haas-Wilson did not test every conceivable reason for the price increase, just those that were reasonable and supported by sound economic theory. F. 693-95, 702. Utilizing multiple regression analyses, Haas-Wilson ruled out six alternative explanations by the pricing analysis: increases in cost, changes in regulation, increases in demand, changes in patient mix, changes in customer mix, and changes in teaching intensity. F. 698-755. Also excluded was the possibility that ENH offset the higher inpatient prices with lower outpatient prices because the data showed that ENH's outpatient prices did not decrease relative to the control groups. F. 703, 717-26.

Two other possible explanations, learning about demand and quality of care improvements, are also ruled out. F. 714-16, 756-837, 756-837, 853-868. As discussed in Section III.C.2.a, the learning about demand theory is flawed; is inconsistent with Respondent's

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contemporaneous actions; and Respondent's empirical analysis supporting the theory is unreliable. The evidence also does not demonstrate that overall quality of care at Highland Park improved improved relative to other hospitals, as discussed at length in Section III.C.2.b. ENH's expert conceded that there is no need to adjust the higher prices to account for quality of care if the quality at at ENH did not increase relative to control group hospitals. F. 838. 838. Thus, the evidence demonstrates that learning about demand and quality of care improvements do not justify ENH's price increases to managed care organizations.

An analysis of the empirical data establishes that enhanced market power is the only plausible, economically sound, and factually well-founded explanation for ENH's post-merger relative price increases. F. 469-755. This conclusion is corroborated by the business documents and testimony of managed care organizations and ENH employees. F. 327-468. There is also no dispute that ENH's price increases were higher than other comparison hospitals' price increases. F. 473-74, 690. Respondent's expert, Noether, acknowledged that a hospital merger could lead to market power at the same time the hospital learns more about demand for its services. F. 757. Respondent's expert, Baker, similarly conceded that the pattern of price increases at United, Aetna, and Humana was consistent with ENH obtaining market power through the merger. F. 684. Thus, through the elimination of Highland Park as a competitor, which enhanced ENH's market power, the merger is likely to result in the restraints condemned under Section 7 and poses an appreciable danger of anticompetitive consequences.

2. Procompetitive Justifications

The analysis of market concentration establishes a "highly concentrated" market and constitutes presumptive evidence of the probable anticompetitive effects of the merger. In addition, Complaint Counsel established, through direct evidence, that ENH

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ENH exercised its enhanced market power to raise prices significantly to managed care organizations. As such, Complaint Counsel has established a *prima facie* case of Clayton 7 liability. The burden thus shifts to Respondent to rebut the presumption arising from the market concentration statistics and evidence of direct anticompetitive effects. *See Baker Hughes*, 908 F.2d at 982. “The more compelling the *prima facie* case, the more evidence the the defendant must present to rebut it successfully.” *Baker Hughes*, *Hughes*, 908 F.2d at 991.

A respondent may present evidence of a number of factors that are relevant in determining whether a transaction is likely to substantially lessen competition. In this case, Respondent offers two main arguments to rebut Complaint Counsel’s *prima facie* showing. First, it contends that the post-merger price increases are not due to market power, but rather were the result of ENH, coincident with the merger, “learning about demand” for its services. RB at 40-54. Second, ENH argues that the price increases can be accounted for by post-merger “quality of care improvements” to Highland Park. RB at 67-99. In addition, Respondent offers further arguments regarding the merging hospitals’ nonprofit status, the lack of barriers to entry, and the weakness of the acquired hospital. RB at 58-67. As set forth below, Respondent’s arguments are unpersuasive. Respondent fails, therefore, to rebut Complaint Counsel’s *prima facie* case.

a. Learning About Demand

Respondent asserts that as a result of its premerger due diligence diligence and review of information about Highland Park’s contract contract rates with managed care organizations, Evanston learned that some of its contracts were outdated and that its rates were below below market. RB at 40. Respondent further contends that it used this new information to negotiate post-merger price increases that brought its prices “in-line with those charged by other comparison hospitals.” RB at 40. Complaint Counsel contends that Evanston did did not underprice itself before the merger; that Evanston had higher

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higher ultimate prices; and that the price level comparison conducted by Respondent's expert, including the choice of control groups, is flawed. CCB at 60-65.

A review of the record refutes Respondent's assertions and demonstrates that the price increases ENH was able to command after the merger were not a consequence of obtaining new information, but instead were the result of newly created market conditions which affected the *demand* for ENH's services -- the elimination of Highland Park as a price constraining competitor. *See supra* Section III.C.1.b. As discussed below, the evidence demonstrates that there are flaws in the learning about demand theory as applied in this case; that Respondent's contemporaneous actions are not consistent with the learning about demand theory; and that the empirical analysis conducted by Respondent's expert in support of the theory is unreliable.

(1) Unsupported Foundations for the Theory

Experts from both sides agree that Respondent's prices rose after the merger. *See* F. 473-74, 690. Respondent contends, however, that prior to the merger, Evanston was priced below a competitive level and that, during due diligence work connected with the merger, Evanston learned that, for some contracts, it had the same or lower contract rates than Highland Park. RB at 40. From this new information regarding Highland Park's rates, Evanston asserts that it learned that it was underpricing itself. RB at 40. Therefore, Respondent argues, the increase in post-merger prices merely reflects ENH's attempt to "catch up" with competitive pricing levels and obtain fair market value for its services. RB at 40. As the evidence demonstrates, however, there are a significant number of problems with this theory.

First, Respondent does not contend that it merely raised Evanston's prices so that they were comparable to Highland Park's Park's rates. Rather, Respondent asserts that, as a teaching or

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“academic” hospital, Evanston was entitled to even higher rates than Highland Park. RB at 48. In this regard, Haas-Wilson testified that the “empirical literature . . . suggests that costs and therefore prices ‘might’ be different at hospitals that are engaged in in ‘teaching activity’ versus those that are not.” F. 758. In fact, Noether’s empirical analysis shows that her control group of “academic hospitals” are priced higher than her control group of “community hospitals.” F. 818-19.

Though the evidence indicates that managed care organizations pay more for “advanced teaching hospitals” or “academic teaching hospitals” (presumably, those that offer *inter alia*, quaternary care), the evidence does not show that Evanston qualified for such treatment. Representatives from One Health, PHCS, and United testified that they do not view any of the ENH hospitals as “advanced teaching hospitals” or as “academic teaching hospitals.” F. 772-83. Evanston, for example, does not offer quaternary services such as major organ transplants or a severe burn unit. F. 203. Although Evanston is a “teaching hospital” (Evanston Hospital/ENH has been named by one publication as a top 15 teaching hospital and a top 100 hospital in the country, F. 786), it is not considered a top-tier, major academic center like the University of Chicago or Rush-Presbyterian-St. Luke’s, against whom its rates were compared by ENH’s expert. F. 775, 779, 782.

Therefore, the empirical evidence does not support Respondent’s Respondent’s assumption that Evanston’s fair market value at the time of the merger was either higher than Highland Park’s, or comparable to those hospitals in Noether’s academic control group. Learning about Highland Park’s non-teaching hospital rates at the time of the merger told Evanston nothing about other hospitals’ rates or prices, and most certainly did not provide any information about rates or charges at teaching hospitals or advanced advanced teaching hospitals. Respondent’s argument implies that certain teaching hospitals, due to their enhanced level of services, form their own product market because the demand for their services

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services is higher, an argument that was rejected in *Long Island Jewish Medical Center*. 983 F. Supp. at 138-40 (finding government's characterization of an anchor hospital as a relevant product market unnecessarily restrictive).

Next, even if Evanston deserved higher prices based on its teaching status, Highland Park would not. After the merger, only one department at Highland Park had residents, and that department only had 6 residents at the time of trial, below the Medicare Payment Advisory Commission ("MedPAC") definition of .25 residents per bed. F. 809. Being owned by a teaching hospital did not transform Highland Park into a teaching hospital. F. 992. However, managed care organizations who wanted any of the three ENH hospitals in their hospital networks had to contract with all three for the same higher rates. F. 355-66. Therefore, even if the evidence demonstrates that Evanston deserved higher prices because of its teaching status, this does not provide any justification for charging the same higher rates for Highland Park, a non-teaching community hospital. Thus, the learning about demand theory does not explain or justify price increases that ENH instituted at Highland Park.

Finally, in an effort to explain its post-merger price increases, Respondent merges its learning about demand argument with its contention that some of its contracts were outdated. RB at 43-44. Indeed, a number of managed care representatives testified that their contracts with Evanston were, in fact, outdated and that Evanston was due for an increase consistent with medical CPI. F. 437. However, those managed care organizations also testified that the price increases obtained by ENH well exceeded their expectations of a reasonable increase. F. 392-456. Evanston presumably was, or should have been, fully aware that some of its contracts were outdated and did not need the Highland Park merger to learn of this fact. Thus, any argument regarding ENH's outdated contracts does not support Respondent's learning about demand theory and is irrelevant to the analysis of the issue.

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(2) Contemporaneous Actions

In addition to the practical problems attendant with the learning about demand justification, the theory is inconsistent with Respondent's contemporaneous actions. Respondent appears to lay much of the blame for its allegedly under-market contract prices on its lead negotiator, Jack Sirabian, who claimed at trial that his objective in negotiating managed care contracts was to be in every managed care network and that he sought to nurture relationships with managed care organizations, rather than to get the best possible deal for Evanston. RB at 41. However, after learning about Highland Park's allegedly higher rates with the merger, ENH nevertheless retained and rewarded Sirabian and his supervisor Hillebrand, who had general oversight for managed care contracting, with substantial post-merger bonuses. F. 761-70. It seems counter-intuitive that a firm would retain, let alone reward, an individual who was thought to be principally responsible for below market contracts, one of which Bain described as having cost ENH approximately \$30 million over the past five years. F. 395; RB at 42.

Such conduct is particularly peculiar in light of ENH's decision, post-merger, not to retain Theresa Chan, who had negotiated what Respondent now claims were superior contracts with managed care organizations on behalf of Highland Park. F. 771. It also contradicts the trial testimony of ENH's COO, who testified that ENH's negotiating stance was equally "aggressive" before and after the merger. F. 767. Although Bain advised ENH that it "should recognize its position and not be afraid to ask to be paid fair market value" for its services, F. 764, Respondent was not able to point to any contemporaneous documents which reflect that ENH's learning about Highland Park's rates taught ENH about other hospitals' pricing or that its "fair market value" would be comparable to advanced teaching hospitals rather than community hospitals.

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(3) Empirical Analysis**(a) Highland Park's Prices Compared to Evanston's Prices**

Respondent has not demonstrated that it did, in fact, learn that it was underpricing itself as compared to Highland Park. F. 784-97. Sirabian testified that in approximately one third of the thirty-five or forty managed care contracts, Highland Park had higher contract rates than Evanston. F. 787. However, rates are just one factor that goes into determining ultimate prices. There are multiple factors in hospital contracts that determine the actual price or the reimbursement per case. F. 789. In addition to per diem rates, contracts also include stop loss provisions, which specify at what point the per diem no longer applies and instead the hospital gets reimbursed on a different basis specified in the contract. F. 790. The contract itself also shows nothing about the hospital's chargemaster. F. 791. Thus, if two hospitals have contracts that specify a ten percent discount off charges, without knowing the respective chargemasters, knowing the discount off charges rates does not show which hospital had higher ultimate prices. F. 791.

As Chan identified at the time, the evidence demonstrates that Evanston's chargemaster was higher than Highland Park's chargemaster, premerger. F. 793. Based on Noether's calculations of actual price levels in the premerger period, the prices at Evanston were higher than the prices at Highland Park. F. 794. An analysis by Baker also showed that Evanston's premerger prices were higher than Highland Park's prices for three out of the four managed care organizations examined. F. 797. Therefore, although although Highland Park had higher *rates* on some contracts, factoring in the different chargemasters and services offered, Highland Park's premerger *prices* to the four managed care organizations examined by Noether were actually below Evanston's Evanston's prices. F. 787-97. Thus, because Evanston's ultimate

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prices were actually higher than Highland Park's ultimate *prices*, ENH could not have learned about demand from this comparison.

(b) Noether's Control Groups Were Flawed

Finally, the empirical studies performed by Noether are not economically sound and do not confirm Respondent's proposition that ENH's price increases reflect its learning about demand. To evaluate Respondent's learning about demand theory, Noether compared ENH's premerger and post-merger prices to those of two control groups of hospitals. Noether testified that she developed her list of eighteen hospitals for her control groups after she "reviewed the evidence from a variety of sources in the record and developed a list based on [her] analysis of the information," including hospitals which Noether testified were "in some way competitors to Evanston and/or Highland Park." F. 802.

Noether then divided these eighteen hospitals into two control groups – "academic hospitals" and "community hospitals" – based on breadth of services, teaching intensity, and size. F. 808. Noether decided that ENH should be compared to the "academic hospitals" group, which she defined as including: Northwestern Memorial, Rush-Presbyterian-St. Luke's, Advocate Lutheran General, Advocate Northside, University of Chicago and Loyola. F. 805. The remaining twelve hospitals became Noether's community hospital control group. F. 806.

Noether's "academic" control group, however, is not reliably defined as it primarily utilizes subjective rating factors. Specifically, there is no official government designation defining what criteria are used to establish hospitals as "community hospitals" or "academic hospitals." F. 807. Without sufficient explanation, Noether established her academic control group as only hospitals with 370 or more Diagnosis Related Groups ("DRGs"), more than .25 residents per bed, and more than 300 staffed beds. F. 808.

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Noether's teaching intensity classification is consistent with the MedPAC definition which defines a "major teaching hospital" as a hospital with at least .25 residents per bed. F. 809. However, MedPAC does not evaluate diagnosis related groups. For example, the number of DRGs can vary depending on the time period used, and can even vary depending on whether a fiscal or calendar year is used. F. 812. There is no basis in the health care literature to require a hospital to be above a certain number of DRGs in order to be considered an "academic hospital." F. 814. Similarly, the MedPAC criteria defining a major teaching hospital do not rely on size as an evaluation factor. F. 817. The evidence does not justify the arbitrary cutoff number chosen by Noether for size. F. 817, 829. The record thus casts doubt as to whether Noether utilized objective standards to construct her "academic hospital" control group and whether the standards she utilized are consistent with established industry criteria.

The six "academic" hospitals selected by Noether for her "academic" comparison group are larger than ENH, some of them with significantly more beds. F. 817, 829. In addition, the four quaternary hospitals in her academic control group – Loyola, Northwestern Memorial, University of Chicago, and Rush-Presbyterian-St. Luke's – handle significantly more complex cases than ENH and perform sophisticated quaternary services, such as severe burn cases or liver and kidney transplants, which are not treated at Evanston. F. 824-25. Notably, four of the six hospitals included in Noether's "academic" control group are among the most expensive hospitals in Chicago. F. 818. As previously noted, the evidence does not support Respondent's contention that the ENH should be priced at the level of these top-tier major teaching hospitals. Noether's academic control group excluded less expensive hospitals even though many of those excluded hospitals can handle most of the patients Evanston treated and treat more complex cases than ENH. F. 819.

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Given the above contradictions, it is difficult to evaluate Noether's conclusions against either objective research standards or the facts of the case. This is especially true when one considers that, of the six hospitals placed in the academic control group to which Noether compared ENH's prices, only one such hospital was included in her proposed geographic market. F. 805; RB at 23. Moreover, as discussed earlier, Noether only analyzed one data source which included usable data from only four managed care organizations. *See supra* Section III.C.1.b. Even if Respondent's learning about demand theory was valid and countered the direct evidence of anticompetitive effects (price increases), the theory is not relevant to the structural evidence of market concentration. Accordingly, the flaws noted in Noether's methodology and data, along with managed care organizations' testimony and contemporaneous evidence, demonstrate that Respondent's learning about demand theory cannot explain the post-merger price increases at ENH.

b. Quality of Care

Respondent's second main argument in rebuttal to Complaint Counsel's *prima facie* case is that the quality improvements at Highland Park justify ENH's increased prices and outweigh any anticompetitive effects of the merger. RB at 69-71. This argument raises the issue of whether quality of care is relevant to the competitive effects analysis, and if so, whether it should be considered a procompetitive justification.

Respondent contends that quality of care improved at Highland Highland Park as a result of the merger; that Respondent's expert as well as independent assessments affirm improvements in quality of care at both Evanston and Highland Park post-merger; and, that no fact witness called by Complaint Counsel countered any showing of quality improvement at Highland Park. RB at 67-67-107. Respondent's argument is not cast as an "efficiency" defense, but rather as an assertion that quality of care improvements are procompetitive justifications that should be

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considered in conjunction with the competitive effects analysis. RB RB at 68; Closing argument, Tr. 6478-79.

Complaint Counsel contends that Respondent failed to demonstrate that: quality of care improved patient outcomes and satisfaction; that the quality changes were merger specific; and that any such benefits outweigh the anticompetitive harm. CCB at 11-17. Given the evidence of market power, Complaint Counsel asserts that any doubts must be resolved against the validity of the quality of care defense. CCB at 17-18. Complaint Counsel further states that any merger specific efficiencies that have been verified should be given due weight, but asserts that Respondent's claimed improvements cannot be sufficiently proved or quantified. CCB at 12.

(1) Legal Framework

The precise role of quality of care in the antitrust context has yet to be determined. "[B]ecause contemporary antitrust law does not create many obvious placeholders for nonprice concerns, quality may be litigated under alternative guises." Peter Hammer & William Sage, *Antitrust, Health Care Quality, and the Courts*, 102 Colum. L. Rev. 545, 563 (April 2002). The economic testimony in this case appears to view quality as part of the cost/price continuum. F. 838-39. The Eighth-Circuit has suggested that quality of care may be relevant to the competitive effects analysis. *Tenet Health Care*, 186 F.3d at 1054.

The district court in *Rockford Memorial* rejected a quality of care argument as irrelevant to the competitive effects analysis, stating:

Undoubtedly, the improvement in services would have a positive effect for consumers of healthcare in the relevant market and economic benefits for the area as a whole. Unfortunately, the creation of a

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a tertiary referral center, while a laudatory goal, is not relevant for our purposes today. The court's exclusive role is to evaluate the merger's effect on competition for the relevant market and no more.

United States v. Rockford Memorial Corp., 717 F. Supp. 1251, 1288 (N.D. Ill. 1989), *aff'd*, 898 F.2d 1278 (7th Cir. 1990).

In *Rockford Memorial*, the district court found “the defendants’ intention to create a state-of-the-art tertiary referral center and all its corresponding benefits in quality and community development as irrelevant for the present § 7 inquiry.” *Id.* at 1289. On appeal, the Seventh Circuit was unpersuaded by the merging parties’ defenses, stating: “[t]he government showed large market shares in a plausibly defined market in an industry more prone than many to collusion. The defendants responded with conjectures about the motives of nonprofits, and other will o’ the wisps, that the district judge was free to reject, and did.” *Rockford Memorial*, 898 F.2d at 1286.

Respondent, *sub judice*, argues that the district court’s holding in *Rockford Memorial* is inapposite because it was limited to the “present § 7 inquiry” and because the Seventh Circuit did not rely on the district court’s remarks on quality of care. RB at 71 n.49 n.49 (quoting *Rockford Memorial*, 898 F.2d at 1289). Respondent contends that enforcement officials at the FTC and DOJ have publicly agreed that quality, innovation, and similar factors are an important part of analyzing the competitive effects of a transaction; that in bringing recent enforcement actions, governmental antitrust agencies have asserted that quality and innovation are relevant in merger analysis; and that in more recent joint venture and non-merger cases, the Commission and courts have found that improvements in quality and innovation are also relevant. RB at 68-71. Moreover, as Respondent correctly observes, economists on both sides agree that quality improvements should be taken into account in evaluating whether the merger, on balance, had a positive or negative impact on

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competition. RB at 71, 838-39. Complaint Counsel acknowledges quality as a legitimate defense, citing the *Merger Guidelines*. CCB at 12; CCRB at 38.

The *Merger Guidelines* recognize that “mergers have the potential to generate significant efficiencies by permitting a better utilization of existing assets, enabling the combined firm to achieve lower costs in producing a given quantity and quality than either firm could have achieved without the proposed transaction” and that efficiencies “can enhance the merged firm’s ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products.” *Merger Guidelines* § 4; *H.J. Heinz*, 246 F.3d at 720. The *Merger Guidelines* indicate that the “[a]gency considers whether cognizable efficiencies likely would be sufficient to reverse the merger’s potential to harm consumers in the relevant market.” *Merger Guidelines* § 4. Thus, the *Merger Guidelines* recognize quality, at least in the guise of an efficiency, as a relevant antitrust consideration.

The D.C. Circuit has acknowledged that “although the Supreme Court has not sanctioned the use of the efficiencies defense in a section 7 case, the trend among lower courts is to recognize the defense.” *H.J. Heinz*, 246 F.3d at 720. As noted, Respondent does not argue that economic efficiencies in the form of cost savings were passed on to consumers. Closing argument, Tr. 6584-85. In fact, the record is clear that any cost savings realized by the merger were *not* passed on to consumers in the form of lower prices. F. 326-755.

As with many components of this case, the law with respect to quality of care is not well-settled. Given the difficulty of proof inherent in the analysis of quality of care arguments and the confusion which can result from the attempt to quantify quality of care improvements, the courts in non-merger contexts treat the issue with skepticism. *See, e.g., FTC v. Indiana Federation of Dentists*, 476 U.S. 447, 464 (1986) (“even if concern for the quality

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quality of patient care could under some circumstances serve as a justification for a restraint” of trade, the evidence did not support a finding under the facts).

If quality of care is relevant to a hospital merger action under Section 7, it is not clear whether it should be considered a procompetitive justification, an affirmative defense, or an efficiency. Antitrust, to date, has not recognized a single approach to a quality of care defense. Respondent, however, argues that quality of care should be analyzed as a procompetitive justification under the competitive effects analysis, RB 71-72, and the Court will treat it as such. Assuming *arguendo*, that quality of care is relevant to the analysis of the competitive effects of a merger, the facts nevertheless do not support Respondent’s theory. As discussed *supra*, the merger increased concentration in the market for healthcare services in the relevant market (F. 309-25); enhanced ENH’s market power (F. 309-755); and resulted in relative price increases to managed care organizations (F. 392-692) and ultimately consumers (F. 187-90). Considering the substantial evidence of anticompetitive effects, Respondent’s few merger specific improvements to Highland Park do not constitute a sufficiently procompetitive justification that outweighs the harm to competition as a result of the merger.

(2) Factual Analysis

Respondent compares post-merger Highland Park in 2005 with premerger Highland Park in 1999 to argue that Highland Park’s quality of care has substantially improved as a result of the merger. Respondent is correct that significant improvements have been made to Highland Park and that those improvements can be verified. However, there are a number of problems with Respondent’s efforts to demonstrate a procompetitive justification. First, there is no quantifiable evidence that the improvements at Highland Park enhanced competition and thus benefitted consumer welfare. Indeed, the evidence does not demonstrate that the post-merger price increases to managed care

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organizations were related to the improvements at Highland Park. F. 838-52. Second, there is insufficient evidence of overall improvement in quality of care relative to other hospitals. That is, improvements were made at Highland Park, but it is not clear that those improvements affected quality, or, if they did, that they improved quality in relation to hospitals generally. Therefore, there is no way to determine whether the improvements at Highland Park were due specifically to the merger or to nationwide efforts to improve patient care. The improvements only occurred, for the most part, at one of the three ENH hospitals, although the price increases were obtained for all three hospitals. Third, although there were many improvements in Highland Park's physical plant and equipment, processes, and hospital organization, only two of these improvements are found to be merger specific – the EPIC integrated medical electronic record system and the academic affiliation and clinical integration. Although Highland Park, in 2005, has improved since 1999, the evidence does not show that it has improved more than it would have but for the merger. As explained below, as a factual matter, these merger specific improvements are not sufficient to overcome the significant anticompetitive effects associated with the merger and did not justify the post-merger price increases to managed care organizations.

(a) Improvements Can Be Verified

Respondent cannot rely on “mere speculation and promises,” and its proof should be subject to “rigorous” analysis, given the high HHI numbers associated with the merger. *H.J. Heinz*, 246 F.3d at 721. ENH must “substantiate” the purported improvements and verify their magnitude. *Merger Guidelines* § 4; *Staples*, 970 F. Supp. at 1089 (efficiency claims fail if “unreliable” “unreliable” and “unverified”). However, because this is a consummated merger case, Respondent has provided significant evidence of actual improvements to Highland Park. Respondent's arguments cannot therefore be dismissed as “mere speculation and

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promises.” Indeed, the evidence demonstrates that ENH has, in fact, fact, invested \$120 million into Highland Park and has made many many improvements to Highland Park that can be verified. *See* F. 876-993. The mere fact of financial investments and physical improvements to one of the merging entities, however, does not, of of itself, provide a legally sufficient procompetitive justification for for the merger.

**(b) Price Increases to Managed Care Were
Not Related to Improvements at
Highland Park**

The record establishes that at the time it increased its prices, ENH did not justify its price increases to managed care based on improvements being made at Highland Park. F. 840. Managed care representatives testified that during contract negotiations, the topic of quality improvements simply never came up. F. 844-47. ENH’s COO admitted that he did not tell managed care representatives that the higher prices were justified by quality changes to Highland Park. F. 842. Similarly, ENH’s CEO conceded that he never saw any documents correlating the higher prices with the quality changes at Highland Park. F. 843.

Even after implementing these changes, ENH never advertised them to managed care organizations. F. 841-47. If quality improvements justified the price increases to managed care, logic would dictate that ENH would have gone out of its way to advertise, advertise, or at least inform, managed care organizations of such improvements. Respondent argues that a press release which mentioned planned clinical service improvements put managed care, care, and the public, on notice of the improvements. RRB at 77-78. 77-78. However, the solitary general press release does not alter the the Court’s analysis. *See* F. 848. The lack of contemporaneous documentation or managed care testimony supporting Respondent’s Respondent’s quality of care argument thus undermines its litigation litigation position. Rather, the totality of the evidence strongly suggests that Respondent’s quality of care argument is a *post hoc*

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attempt to justify its post-merger price increases found to exist even even by its own expert.

A review of the record shows that there is no substantial evidence that managed care's demand for ENH's services changed as a result of its quality improvements. That is, the improvements at Highland Park did not translate into an increase in demand. Highland Park was already a highly desirable hospital in terms of quality, and remained so after the merger. Highland Park management and outside observers believed that the quality of care at Highland Park was "very good, if not excellent" at the time of the merger. F. 850. Highland Park was also described as an "excellent community hospital" that "delivers basic services at a very high level." F. 851. Evanston and Highland Park "were both very good hospitals." F. 852. Nevertheless, the managed care representatives testified that the value of ENH to their networks was principally due to the hospitals' geography, not quality. F. 226-42. This is not a case where the merger created a hospital that provided better medical care than the hospitals could have provided separately. *See Tenet Health Care*, 186 F.3d at 1054.

The record reveals that it would have been hard for ENH to justify the price increases to managed care because of quality improvements due, simply, to the timing of the improvements. ENH negotiated its price increases before any quality improvements were ever implemented. Indeed, many of the price increases were instituted in 2000, long before many of the improvements occurred. F. 909, 916, 981. For example, only six days after the merger was finalized, ENH reported that it had renegotiated a managed care contract, which was effective January 1, 2000. F. 457. Few quality improvements had occurred that quickly, and several, such as the ambulatory care center, did not become operational until as late as 2005. F. 911.

The evidence discussed below demonstrates that the post-merger post-merger price increases to managed care and, ultimately,

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consumers, were not justified by ENH's improvements at Highland Highland Park. These improvements, therefore, cannot overcome Complaint Counsel's strong showing of anticompetitive effects.

**(c) No Evidence of Improvement in Overall
Quality of Care Relative to Other
Hospitals**

Quality of medical care is not easily defined or measured. In fact, Respondent did not present an explanation of how to value the "improvements" or how to compare them to the price increases to managed care organizations. There was significant debate in this case regarding whether several changes made by ENH to Highland Park were, in fact, improvements, and, if improvements, whether they affected quality of care. Quality of care is continually evolving and changing with additional medical developments. In addition, there is no definitive measurement of quality, with one exception, discussed below. Accordingly, the ultimate determination that quality of care improvements do not outweigh the anticompetitive effects of the merger does not rest on the extent to which quality improved, but rather on the fact that most of the improvements to Highland Park were not merger specific and cannot, therefore, be considered in the competitive effects analysis.

Just as price increases must be compared to other hospitals' price increases to rule out industry-wide changes, the same can be said for quality of care improvements. Complaint Counsel's healthcare quality expert, Dr. Patrick S. Romano, testified that since the late 1990's, there has been a nationwide trend of improved improved quality, with one major study finding an average per state state inpatient improvement rate of 12% through 2001. F. 859. Respondent did not provide sufficient evidence to determine whether Highland Park improved its overall quality relative to hospitals generally. As a result, Respondent has not demonstrated whether the improvements are unique to Highland Park and the merger, or simply part of an overall trend unrelated to Highland

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Park's merger with Evanston. Assertions of quality of care improvements to Highland Park without reference to relative improvements at other hospitals cannot overcome Complaint Counsel's *prima facie* case.

Respondent argues that the improvements at Highland Park outweigh any purported anticompetitive effects of the merger. RB at 69-71. Complaint Counsel argues that such improvements did not inure to the benefit of patients who did not use Highland Park, but who were affected by the price increase, because the combined ENH was priced as a single unit. CCB at 14-15. Respondent replies that if quality improved at one part of the integrated ENH system, without a decrease in quality at any other part of the system, then the quality for the whole system would have improved. RRB at 8.

Evanston is a larger hospital than Highland Park. F. 5, 22. Significantly more managed care dollars go to treat patients at Evanston than for patients treated at Highland Park. In *H.J. Heinz*, the D.C. Circuit found that cost reductions must be measured across the new entities' combined production, not just the premerger output of one of the merging parties. *H.J. Heinz*, 246 F.3d at 721. Here, ENH did not present evidence establishing that quality improved as a whole over the combined ENH system relative to other hospitals. F. 853-68. As in *H.J. Heinz*, Respondent failed to present evidence from which the improvements could be measured across the combined entity and therefore any evidence of improvements cannot overcome the showing of anticompetitive effects.

The parties argue extensively about whether quality improved in sixteen areas identified by Respondent. The Court has carefully considered the parties' arguments and evidence on quality of care, including the extensive data on outcomes, structure, process measures, and patient satisfaction. This quality of care evidence, however, is inconclusive in many instances. For example, Complaint

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Complaint Counsel's expert, Romano, using U.S. Agency for Healthcare Research and Quality ("AHRQ") measures found { } at } at Highland Park relative to a control group. F. 861. However, using the Joint Commission on Accreditation of Healthcare Organizations measure ("JCAHO"), Romano found { } at Highland Highland Park, although that evidence was not statistically significant. F. 862. In obstetrics, using the AHRQ measures, Romano Romano found { } using the JCAHO measures. F. 863. This conflict in the evidence may stem, in part, from the different methodologies utilized by AHRQ and JCAHO to risk adjust the data. data. F. 864. These conflicting findings, however, cannot be reconciled on the record provided. In particular, unlike individuals who may consider quality as it relates to a particular service area, managed care organizations consider actual and perceived overall quality of care. Whether quality increased or decreased in a particular service area is not the critical issue in the antitrust analysis. Rather, the focus should be on whether there was an overall overall improvement in quality relative to other hospitals and whether the public perceived Highland Park as providing high quality medical treatment.

The record does not provide definitive evidence on patient satisfaction. Complaint Counsel's expert relies, in part, on patient satisfaction data from Press Ganey for certain hospital procedures. The reliability of this data, however, is unclear. F. 865-68. Respondent's healthcare quality expert, Dr. Mark R. Chassin, made a made a rough estimate that the response rate of this data was only about twenty percent, which Complaint Counsel's healthcare quality quality expert admitted would be suboptimal. F. 867. In addition, the the experts were not aware of the survey methodology used by Press Press Ganey, so that the survey's trustworthiness could not be determined. F. 868. Again, however, the proper focus should be on on overall quality improvement relative to other hospitals rather than than limited patient satisfaction data. As discussed above, managed managed care organizations were not aware of a significant increase increase in overall quality at Highland Park and believed that it was was an excellent hospital both before and after the merger. F. 846-

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846-47, 851. Although other evidence of patient satisfaction was presented, none of it presents scientifically valid, comprehensive, and reliable data. In addition, the only industry-wide and nationally nationally recognized measure of overall quality did not demonstrate an improvement at Highland Park, as described below. below.

JCAHO regularly evaluates overall hospital quality nationally, including at Highland Park and Evanston. JCAHO accreditation is necessary to qualify for Medicare, as well as most managed care plans. F. 853, 858. In 1999, in its last year before the merger, Highland Park received a preliminary score of 95 and a final score of 96. F. 853. In 1999, Evanston received a preliminary score of 94 and a final score of 95 in 2000 under the same standard. F. 854. These scores are based on approximately 1200 elements of hospital performance. F. 856. In 2002, Highland Park received a JCAHO score of 94. F. 853. Accordingly, based on the JCAHO standard, there is no evidence that the overall quality of care at post-merger Highland Park improved relative to other hospitals. In fact, Highland Park's JCAHO score declined slightly. Thus, the JCAHO evidence, at least from 1999 to 2002, does not support Respondent's argument that overall quality of care improved at Highland Park. Rather, Highland Park's overall quality of service before the merger was excellent and was not declining, as Respondent depicts. After the merger with Evanston, Highland Park continued to maintain its reputation for quality.

**(d) Majority of Improvements Were Not
Merger Specific**

To be relevant to the Section 7 analysis, the asserted quality of care improvements, in addition to being verifiable, must be merger merger specific. *H.J. Heinz*, 246 F.3d at 721-22; *Cardinal Health*, 12 12 F. Supp. 2d at 62-63; *Mercy Health Serv.*, 902 F. Supp. at 987; *Merger Guidelines* § 4. In other words, efficiencies (or in this case, case, procompetitive justifications), will be considered only where

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comparable savings or effects cannot “reasonably be achieved by the the parties through other means.” *Merger Guidelines* at § 3.5. Efficiencies are not merger specific if they could be produced by practical alternatives less restrictive of competition, i.e., generated independent of the merger. *University Health*, 938 F.2d at 1222 n.30; n.30; *Cardinal Health*, 12 F. Supp. 2d at 62-63; *Long Island Jewish Jewish Med. Ctr.*, 983 F. Supp. at 147.

For example, in *H.J. Heinz*, the D.C. Court of Appeals rejected the claim that Heinz could produce better baby food by acquiring Beech-Nut and its recipes. *H.J. Heinz*, 246 F.3d at 722. The Court of Appeals reasoned that Heinz, on its own and without the need of a merger, could simply invest more money to make a better tasting product. *H.J. Heinz*, 246 F.3d at 722. Thus, to be cognizable, the benefits of quality of care improvements must be merger specific because otherwise, the benefits could be achieved without the concomitant loss of competition. *See H.J. Heinz*, 246 F.3d at 722. As explained below, the evidence conclusively demonstrates that the majority of improvements made by ENH were not merger specific.

The record establishes that Highland Park would likely have improved quality even without the merger. In 1999, Highland Park Park outlined a premerger strategic plan which included plans to invest more than \$100 million to improve its quality of care. F. 871-871-72. The long range capital budget identified \$43 million for investment in strategic initiatives and master plan items such as cardiology services, ambulatory services, oncology, assisted living, living, and facility expansion and \$65 million for hospital construction, routine capital, and information technology. F. 873. The investments were to be directed at, among other things: enhancing its core clinical competencies (cardiac surgery, oncology, oncology, and specialty surgery) by itself or with other hospitals, strengthening its medical staff with new doctors and nurses as well well as enhancing leadership and morale, upgrading technology, equipment, and facilities, and increasing patient satisfaction and outcomes so that they would exceed those of competitors and

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national standards. F. 870. Absent the merger, with the need to keep keep itself attractive relative to Evanston and other competing hospitals for managed care and patients, Highland Park would have have had every incentive to continue improving its quality of care. This proposed expenditure of over \$100 million compares favorably favorably to the \$120 million spent on Highland Park by ENH.

Highland Park's finance committee concluded that based on growth through new clinical services and existing cash and investments and cash flow, the hospital could "generate sufficient cash" to "restore the profitability" of Highland Park and fund the proposed improvements. F. 874. The evidence thus demonstrates that Highland Park had sufficient funds to make the planned improvements to the hospital. *See also infra* Section III.C.2.e.

The evidence thus supports Complaint Counsel's arguments that Highland Park intended to make improvements, had a history of making improvements, had the economic ability to make improvements, and would have made the improvements because to do so was in Highland Park's economic self interest. Certainly, the improvements made by Highland Park, without a merger, may have differed from the improvements actually made by ENH. But, the antitrust inquiry is not whether Highland Park would be identical today, absent the merger, but only whether the improvements made by ENH are merger specific. Except for two quality improvements discussed below, the answer is no. Therefore, the expenditures by ENH for improvements to Highland Park cannot overcome Complaint Counsel's evidence of anticompetitive effects because Highland Park could have made all but the two improvements without merging with Evanston.

Respondent's claimed quality improvements generally fall into into three categories: (1) new or improved facilities or equipment; (2) increased staffing, improved training, and culture of teamwork; teamwork; and (3) new or improved procedures. None of these changes are merger specific. With sufficient funds, new or improved

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improved facilities or equipment could have been purchased. With proper funding Highland Park could have increased staff and in many areas; Highland Park had already begun improvements to training and teamwork. Contrary to ENH's assertion, a change in culture does not emanate only from a merger – it can occur as the result of different management or in response to recommendations from outside organizations. Similarly, it does not take a merger for a hospital to implement new procedures. The only two benefits that would not have been achieved absent the merger are the acquisition of the state of the art EPIC computerized records management system and the academic affiliation and clinical integration. These two merger specific improvements are discussed below in section III.C.2.b.3.e. The other fourteen of Respondent's improvements were not merger specific, as explained immediately below.

(i) Obstetrics and Gynecological Services

At the time of the merger, the Obstetrics and Gynecological (“Ob/Gyn”) department was the largest patient care area at Highland Park. F. 876. After the merger, ENH instituted nighttime and weekend coverage by obstetricians; installed a full-time chair of the Ob/Gyn department; improved nurse training models of care; instituted an Ob/Gyn preoperative surgery review program; and initiated physician discipline proceedings against a few of Highland Park's Ob/Gyn physicians. F. 877-82. Respondent argues that Highland Park had major quality deficiencies, including inadequate coverage, lack of effective leadership, inadequate nursing, inappropriate practice patterns, and a weak quality assurance program in its delivery of obstetrics and gynecological services. RB at 75-77. According to Respondent, these problems were identified in 1998, but corrections were not instituted until ENH intervened after the merger. RB at 75-76.

Prior to the merger, Highland Park had invited the { } review of review of the hospital as part of its ongoing effort to improve quality quality of care. F. 883. { } made a number of recommendations to

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to improve the { } F. 884. Many changes were made in response to response to the { } report. F. 885. In fact, Highland Park's efforts to efforts to implement { } recommendations were subsequently recognized by the Chicago Hospital Risk Pooling Program after a site visit and report issued in November of 1999. F. 886. The Chicago Hospital Risk Pooling Program made additional recommendations for improvement. F. 887.

The evidence demonstrates that Highland Park was aware of the need to improve and was, in fact, making the necessary improvements. There is no evidence that Highland Park was incapable of changing its Ob/Gyn nursing culture, rather, the evidence shows that Highland Park was aware of and actively taking steps to change the culture, but that such changes take time. F. 885-86, 903-10. The improvements made by ENH to obstetrics and gynecological services could have been implemented by Highland Park without merging with Evanston.

(ii) Quality Assurance Program

ENH changed the structure within the clinical departments of how oversight of physicians was conducted by replacing part-time and private practice chairs with full-time ENH clinician chairs; took disciplinary action against a number of Highland Park physicians; and reviewed physician practices during periodic recredentialing. F. 888-90. Respondent criticizes Highland Park's premerger quality assurance program as being ineffective. RB at 77-82.

Highland Park, premerger, regularly had initiated disciplinary actions against its physicians, including the suspension, reduction, or or removal of staff privileges. F. 892. There are a number of examples of Highland Park's review of adverse events prior to the merger and it is not clear whether the culture actually improved under ENH. F. 893. Indeed, { } was requested by Highland Park, Park, premerger, because of a disciplinary action in the { } F. 894.

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894. The quality assurance changes made by ENH at Highland Park Park after the merger merely reflect the emerging consensus in the field of quality assurance. F. 895. Highland Park had an active quality assurance program and the Court is persuaded that it, like many hospitals, likely would have kept up with the emerging consensus in the field of quality assurance. In addition, Highland Park could have utilized clinical department heads, if it had chosen to organize its departments in that manner, without merging. Thus, improvements to the quality assurance program could have been implemented by Highland Park through means other than the merger with ENH.

(iii) Quality Improvement Program

Critical pathways and care maps are protocols identifying best practices for treatment of patients. F. 897. After the merger, the critical pathways at ENH were aligned with the care maps being used at Highland Park, improving both. F. 896. Respondent criticizes Highland Park's premerger quality improvement program as being inadequate. RB at 77-82.

Highland Park's strategic plan for 1999-2003, included among its goals to: provide documented and measurable outcomes of quality which exceed those of the competition and establish national standards and provide a continuum of care for the patient across the delivery system including providing the highest quality clinical and non-clinical services. F. 870. Prior to the merger, Highland Park conducted an internal review of quality programs which highlighted areas for improvement. F. 898. Nothing in the record suggests that ENH's critical pathways were better than the care maps used by Highland Park before the merger or that Highland Park would not have continued to develop other care maps after 1999 on its own. F. 899. Indeed, the evidence does not clearly show whether the critical pathways are always being followed. F. 900. The evidence demonstrates that critical pathways are constantly being revised and improved and Highland Park likely would have continued to make similar

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improvements to its care maps. F. 901. The quality improvement changes made by ENH at Highland Park after the merger merely reflect the emerging consensus in the field of quality improvements. F. 902. Thus, improvements to the quality improvement program could have been implemented by Highland Park without merging with Evanston.

(iv) Nursing Staff

ENH improved communication and teamwork between nurses and physicians; improved nurse training; and eventually improved recruiting, vacancy, and turnover rates. F. 903-05, Respondent claims that Highland Park lacked several key elements of an effective nursing program and that without the cultural change that ENH brought to Highland Park, nursing services would not have improved. RB at 83-84.

Highland Park had a “high quality nursing staff” in the 1990’s. F. 907. Nonetheless, in 1999, Highland Park adopted a comprehensive initiative to train, retain, and reward its nurses. F. 908. The nursing culture at Highland Park underwent a transition from a punitive and dysfunctional culture to a much more effective culture over a period of years beginning before the merger and continuing until 2004. F. 909. The change in the nursing culture was an evolutionary process that took many years. F. 910. Indeed, it seems highly unlikely that Highland Park is unusual in having nurse staffing problems. The evidence is clear, however, that Highland Park was aware of and committed to improving these problems. Improvements in the nursing staff could thus have been implemented by Highland Park without merging with Evanston.

(v) Physical Plant

ENH built a new ambulatory care center which opened in February 2005, which houses radiation medicine, nuclear medicine,

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medicine, the Kellogg Cancer Care Center, and a new breast imaging center. F. 911. ENH built a new cardiac cath lab to support support the interventional cardiology program; renovated and expanded the emergency department and psychiatry units; and added added modern equipment in a variety of areas. F. 912. ENH replaced replaced the Highland Park patient care building's electrical distribution and ventilation systems, plumbing, and waste pipes and and built a new central plant at Highland Park, including a new power plant that houses utilities such as electric generators, backup backup generators, boilers, and air ventilation equipment. F. 913-14. 913-14. ENH added an additional boiler, new air handlers for the ventilation system, replaced the electrical generator, and added a second emergency electrical generator. F. 915. ENH began remodeling all of its patient rooms in December 2003. F. 916. The process of remodeling patient rooms is continuing and scheduled at at least through 2006. F. 916. ENH added a new parking garage and and made improvements to the lobby corridor and entrance to Highland Park. F. 917. Respondent asserts that it invested millions of dollars into expansions and renovations of Highland Park's facilities. RB at 85-86.

On April 15, 1999, the Illinois Department of Public Health and Healthcare Financing Administration performed a facility survey of Highland Park which identified 144 physical plant deficiencies that needed to be corrected to continue to participate in Medicare. F. 918. On August 26, 1999, 26 items were removed from the list and 3 were added, for a total of 121 deficiencies. F. 919. On December 9, 1999, a reinspection was conducted and 88 additional items were removed from the list, leaving a total of 33 items. F. 920. The plan for correction of these remaining items was submitted by Highland Park on December 28, 1999 and these remaining items were corrected by ENH by August 1, 2000. F. 920. Highland Park was aware of and had addressed or planned to address all of the issues identified during these inspections.

The evidence does not demonstrate that ENH's expenditures were merger specific because, as previously noted, premerger,

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Highland Park had budgeted a total of \$108 million in capital expenditures through 2003, for, among other things, upgrading technology, equipment, and facilities. F. 872-73. The financial condition of Highland Park would have allowed it to make these improvements to its physical plant. F. 1028-69. Thus, improvements to the physical plant could have been implemented by Highland Park without merging with Evanston.

(vi) Oncology Services

Through the Kellogg Cancer Center at Highland Park, ENH implemented a multidisciplinary approach that brought together an oncology team consisting of the physician oncologist, nurse, pharmacist, psychologist, social workers, and nutritionists who were available to patients in one location. F. 920. ENH brought subspecialty oncologists to Highland Park so that patients would not have to travel for their consultations. F. 922. The Kellogg Cancer Center moved into a new section of the ambulatory care center in March 2005. F. 923. Respondent points to the benefits of improvements in the delivery of oncology services at Highland Park through the expansion of the Kellogg Cancer Center as a merger specific improvement. RB at 86-88.

Before the merger, Highland Park had already undertaken numerous initiatives in oncology services and had a variety of options other than the merger to achieve these same ends. F. 924. Highland Park also had detailed plans to expand multi-disciplinary multi-disciplinary oncology services alone or with other hospitals. F. 925. Highland Park had considered joint comprehensive oncology oncology programs with organizations other than ENH. F. 925. In the 1990's, Highland Park had created centers of excellence for oncology and breast cancer that it was continually improving until the time of the merger. F. 926. These centers of excellence already had access to the necessary technology, physicians, and research protocols in place to develop a comprehensive oncology program, and Highland Park merely needed to develop the community

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perception of excellence in these areas. F. 927. To this end, Highland Highland Park could have expanded its oncology services and research activities through an affiliation agreement with a hospital other than ENH and, in fact, it had been exploring this option at the the time of the merger. F. 928. Thus, improvements to oncology services could have been implemented by Highland Park without merging with Evanston.

**(vii) Radiology, Radiation Medicine, and
Nuclear Medicine**

ENH purchased a linear accelerator for Highland Park; added two new CT scanners in Highland Park's radiology department; upgraded radiation therapy equipment; and purchased additional equipment. F. 929-30. ENH purchased a CT pet, a diagnostic tool, for the nuclear medicine department. F. 931. ENH extended RADNET, its radiology imaging system and PACS, its filmless radiology imaging system, to Highland Park. F. 932. ENH added additional radiology staff to improve turnaround times for reading radiology reports. F. 933. Respondent claims that these changes, including the significant investment in new equipment, improved the radiology services at Highland Park. RB at 91.

Highland Park had a premerger budget of \$9.5 million to improve radiology services. F. 934. Highland Park had the resources and the commitment to improve radiology, radiation medicine, and nuclear medicine. Thus, improvements to radiology services could have been implemented by Highland Park without merging with Evanston.

(viii) Emergency Care

ENH improved both the physical layout and service components components of Highland Park's emergency department. F. 935. ENH ENH expanded physician coverage; renovated and expanded facilities; improved physician and nurse staffing; and improved the the fast track procedure in the emergency department. F. 936.

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Respondent claims that it has significantly improved the emergency emergency care rendered at Highland Park. RB at 89-90.

Prior to the merger, the emergency department at Highland Park was “very good,” and was “on par, if not better” than Highland Park’s peers. F. 937. Throughout the 1990’s, Highland Park had continually made improvements to its emergency care: it had implemented a fast-track program to improve turnaround times; it had added physician assistants to the emergency room; it had streamlined the radiology process; and it had reduced the time that it took for a patient to receive an EKG. F. 938. Further, Highland Park planned to “expand the Emergency Department from a facilities standpoint.” F. 939. In fact, Highland Park could have made the changes to the emergency department absent the merger. For example, most emergency departments at hospitals like Highland Park are staffed through contracts with physician groups, and Highland Park simply could have “demanded” higher staffing of the emergency room as a condition of its contract. F. 940. Thus, improvements in emergency care could have been implemented by Highland Park without merging with Evanston.

(ix) Laboratory Medicine

Prior to the merger, Highland Park operated Consolidated Medical Labs (“CML”), a joint venture with Lake Forest that consisted of a main laboratory located between the two hospitals with satellite laboratories at Highland Park and Lake Forest. F. 941. After the merger, ENH decided to close CML and expand the on-site laboratory at Highland Park. F. 942. Certain tests are sent to the lab at Evanston. F. 942. ENH constructed new histology and cytology laboratories at Highland Park, installed over \$1 million in state of the art lab equipment, and introduced more stringent quality controls. F. 943. Respondent asserts that it made significant changes in the laboratory services that were furnished at Highland Park. RB at 90-91.

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Prior to the merger, Highland Park's joint venture for laboratory services with Lake Forest operated "actually exceptionally well." F. 944. CML afforded Highland Park's lab "greater volume," "access to greater human pathology," and the "opportunity to provide a greater benchmark in terms of [the lab's] performance." F. 944. Highland Park could have implemented further changes in its laboratory in the absence of the merger. F. 945. Many of the changes that ENH made after the merger were simply consistent with updates that all hospital laboratories made during that period in order to meet licensing and accreditation standards. F. 946. Thus, improvements in the laboratory services could have been implemented by Highland Park without merging with Evanston.

(x) Pharmacy Services

ENH installed twenty Pyxis automated drug distribution machines at Highland Park in 2000. F. 947. In the summer of 2003, ENH added an additional pharmacist to dispense medications at night. F. 949. ENH decentralized the pharmacists. F. 948. Respondent highlights changes to pharmacy services at Highland Park, including the installation of Pyxis, as a quality of care improvement. RB at 91-92.

Highland Park's strategy prior to the merger was to implement "the latest technology to support patient care across the continuum." F. 870. The Pyxis system did not become available to hospitals until the late 1990's, when there was a "trend" in which pharmaceuticals and medications were decentralized in order to be located within the individual units. F. 950. Pyxis costs about \$20,000 per machine, and Highland Park could have installed the machines on its own. F. 951. Thus, improvements in the pharmacy services, including the installation of Pyxis or a similar system, could have been implemented by Highland Park without merging with Evanston.

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(xi) Cardiac Surgery

ENH opened a cardiac surgery program at Highland Park in June 2000. F. 952. Cardiac surgery is a necessary component of a full-service cardiology program. F. 953. Cardiac surgery procedures include coronary artery bypass grafting, valve procedures, and surgery on the aorta. F. 954. Respondent touts the benefits of introducing cardiac surgery and interventional cardiology programs at Highland Park. RB at 94-96.

Before the merger, Highland Park already had plans to open a cardiac surgery program with Evanston or another hospital. F. 955. Highland Park also considered a joint cardiac surgery program with Northwestern Memorial or Advocate Lutheran General. F. 956. ENH runs successful joint cardiac surgery programs with Swedish Covenant and Louis A. Weiss. F. 957. Highland Park and Evanston executed a contract for a joint cardiac surgery program before the merger. F. 958. The Certificate of Need Application for the Highland Park cardiac surgery program suggests that the collaboration necessary to implement the program did not depend on the merger. F. 959. Thus, improvements in cardiac surgery and interventional cardiology could have been implemented by Highland Park without merging with Evanston.

(xii) Interventional Cardiology

Interventional cardiology refers to the treatment of obstructions in coronary arteries (coronary disease) by dilating the plaques obstructing the arteries and inserting little wire tubes called stents to keep the arteries open. F. 960. After the merger, ENH established an interventional cardiology program at Highland Park. F. 961. ENH built a new cardiac catheterization lab at Highland Park that performs both diagnostic and interventional procedures such as angioplasties. F. 962.

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Highland Park's premerger medical staff included physicians with the expertise to perform interventional cardiac procedures. F. 963. Highland Park planned to expand the diagnostic capabilities of its existing cardiac catheterization lab and to provide emergent angioplasty in conjunction with the planned cardiac surgery program or even "without open heart on-site." F. 964. Thus, improvements to interventional cardiology could have been implemented by Highland Park without merging with Evanston.

(xiii) Psychiatry

Before the merger and through the spring of 2001, Highland Park and Evanston each had separate inpatient psychiatric units that treated both adult and adolescent patients. F. 965. In the spring of 2001, ENH consolidated the adolescent inpatient services at Highland Park and the adult inpatient services at Evanston. F. 966. ENH hired several, adolescent psychiatrists to staff the Highland Park adolescent unit. F. 967. ENH remodeled the psychiatric unit in December 2003 to include private patient rooms with a keyless entry system and secure furniture. F. 968.

Highland Park could have chosen to refer its adult patients to Evanston or another hospital and expand its adolescent services without the merger. In addition, Highland Park could have chosen to expand its adolescent services, without the merger and without closing the adult services.

(xiv) Intensivist Program

ENH added an intensivist program to Highland Park after the merger. F. 970. An intensivist is a physician who specializes in the care of intensive care patients and who has more experience dealing with the complications of these critically ill people. F. 971. Intensivists also have an administrative role in overseeing and coordinating the medical and nursing staff that provide care to critically ill patients. F. 972. Respondent claims credit for the intensivist program at Highland Park. RB at 96-97.

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Intensivist programs in hospitals like Highland Park became popular only after the merger. F. 973. Pulmonary Physicians of the North Shore, which provides the intensivist coverage at Highland Park, does so through a contractual arrangement. F. 974. Highland Park did not need to merge with Evanston in order to provide the intensivist services currently provided by Pulmonary Physicians of the North Shore. Highland Park could independently contract to have an intensivist program. F. 975. Thus, the intensivist program could have been implemented by Highland Park without merging with Evanston.

(e) Merger Specific Improvements

The Court next addresses the two previously mentioned improvements made by ENH which the Court does find to be merger specific. Upon integration with ENH, medical care providers at Highland Park had access to comprehensive medical records through a state of the art computerized information system known as EPIC. In addition, the merger provided academic affiliation and clinical integration. These benefits could only reasonably have been achieved through the merger with Evanston. Especially in the latter case, these were not benefits that a stand alone Highland Park could have obtained.

(i) Electronic Medical Records System

In 2001, ENH decided that its current medical records system was not sufficient to meet the needs of its three hospitals and ENH began its search for a better system. F. 976. In June 2001, the EPIC system was selected from a group of competing technologies. F. 977. EPIC is a nationally recognized software system for managing patient records for both hospitals and physicians and was selected, in part, for its ability to work with physician offices. F. 978. The EPIC system was implemented in order to integrate records from health care providers who practiced at all three ENH hospitals, at the faculty practice medical

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medical group, and at all the affiliated physician practices that were willing to participate. F. 980.

The use of EPIC allows physicians to review records of other care givers that have seen a patient. EPIC became functional at Highland Park in December 2003. F. 981. Because EPIC currently integrates information from three hospitals and seventy physician offices, care givers who currently use EPIC at Highland Park have access to a wealth of information. F. 980. EPIC includes a computerized physician order entry system and clinical decision support systems. F. 979. Respondent rightfully contends that it improved quality at ENH by installing the EPIC system. RB at 97-99. EPIC is thus a merger specific improvement in that Highland Park, as an independent hospital, was unlikely to license such a state of the art, comprehensive system.

The evidence, however, does not establish that a stand alone Highland Park would have needed to change its medical records system to EPIC. Meditech, the medical records system used by Highland Park before the merger, was and is an “excellent” system that other hospitals continue to use today. F. 986. The Meditech system, however, was not state of the art. For example, Meditech, as deployed at Highland Park, was not paperless, could not be accessed remotely, and lacked ambulatory capability. F. 985. Even if an independent Highland Park licensed EPIC, the benefits would be limited by the fewer number of health care providers linked into the system.

The federal government has established a national initiative to develop a universally accessible electronic healthcare record for all all citizens and in 2004, the Office of National Healthcare Information Technology was created to achieve this end. F. 987. Therefore, medical records systems and technology are likely to continue to evolve, and EPIC may not remain the state of the art system that it is today. Even if EPIC is maintained by Highland Park, much of the integrated benefit will be lost because the other ENH hospitals and physician providers would not, presumably, be

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connected to the same licensed system. A stand alone Highland Park, Park, however, would not require the same level of integration that that currently exists with ENH.

(ii) Academic Affiliation and Clinical Integration

As previously noted, the merger did not transform Highland Park into an academic hospital. Indeed, family medicine is the only department at Highland Park that utilizes residents and at the time of trial the department maintained only 6 residents. F. 988. There is no evidence that Highland Park benefitted simply by being owned by a teaching hospital. F. 993.

However, since the merger, physicians in pathology, radiology, emergency medicine, cardiology, cardiac surgery, and some parts of anesthesiology rotate through all three ENH campuses. F. 989. Following the merger, about sixty Highland Park physicians obtained appointments at Northwestern Medical School. F. 990. This interaction with Northwestern Medical School is clearly a merger specific benefit. The evidence does not establish, however, that the relationship with Northwestern Medical School had a noticeable impact on quality of care of patients, patient satisfaction, or improved structure, process, or outcomes. *See* F. 853-68. Nonetheless, it has been a benefit to the physicians who were able to obtain faculty appointments and this relationship may have encouraged some top physicians to join the staff at Highland Park. This affiliation with the medical school will be lost upon divestiture.

(3) Merger Specific Quality of Care Improvements Do Not Outweigh Probable Anticompetitive Effects

As discussed, the vast majority of improvements at Highland Park were not merger specific. The Court is aware of the significant

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significant improvements at Highland Park, including the substantial substantial time and resources taken to fund and make such improvements a reality. The Court is also cognizant that Highland Park, under ENH, continues to be an excellent hospital. The finding finding that the majority of the alleged procompetitive justifications justifications are not merger specific in an antitrust context is in no no way intended to undermine their importance to care givers or patients at ENH. However, their ultimate impact on overall relative relative quality of patient care, patient satisfaction, and outcomes is is limited. F. 853-68. Considering the persuasive evidence of the merger's anticompetitive effects, Respondent's two merger specific specific improvements to Highland Park, if legally cognizable and relevant to the analysis, do not sufficiently outweigh the merger's harm to competition and ultimately to consumers. Even if Respondent's quality of care theory was valid and countered the direct evidence of anticompetitive effects (price increases), the quality improvements are not relevant to the structural evidence of of market concentration. Nor do Respondent's remaining defenses, defenses, including nonprofit status, ease of entry, and failing firm, firm, save the merger.

c. Nonprofit Status

Respondent has argued that ENH's nonprofit mission reduces the potential for competitive harm. Specifically, Respondent asserts that ENH has a deep commitment to the community; that the ENH Board consists largely of members of the community; that ENH provides benefits to the community, including charity care and new services; and that ENH created an independent foundation which provides grants to local organizations. RB at 65-67. Respondent further asserts that courts have recognized that the nonprofit status of hospitals may be taken into account in evaluating a merger case. RB at 65-66.

Complaint Counsel asserts that ENH's nonprofit status did not prevent ENH from exercising market power and that ENH's management structure, just like for profit entities, created incentives

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incentives for ENH to raise prices, including awarding significant bonuses and salary increases for achieving revenue and income growth. CCRB at 36-37. Complaint Counsel further asserts that courts have explicitly rejected the argument that a hospital's nonprofit status renders a merger not anticompetitive. CCRB at 36-36-37.

In both *Rockford Memorial* and *Hospital Corporation of America*, the Court of Appeals for the Seventh Circuit rejected hospitals' arguments that their nonprofit status removed ground for concern that hospitals might seek to maximize profits through avoidance of price or service competition. *Rockford Memorial*, 898 F.2d at 1285; *Hospital Corp. of Am.*, 807 F.2d at 1390. As explained in *Rockford Memorial*:

We are aware of no evidence – and the [appellees] present none, only argument – that nonprofit suppliers of goods or services are more likely to compete vigorously than profit-making suppliers. . . . If the managers of nonprofit enterprises are less likely to strain after that last penny of profit, they may be less prone to engage in profit-maximizing collusion but by the same token less prone to engage in profit-maximizing competition.

Rockford Memorial, 898 F.2d at 1285.

Moreover, the Seventh Circuit has stated that “[t]he adoption of the nonprofit form does not change human nature . . . , as the courts have recognized in rejecting an implicit antitrust exemption for nonprofit enterprises.” *Hospital Corp. of Am.*, 807 F.2d at 1390 (citing *Nat’l Collegiate Athletic Ass’n v. Bd. of Regents*, 468 U.S. 85, 100 n.22 (1984)). “‘Nonprofit hospitals, in fact, make rather sizable profits and these profits have been growing over time.’” *Hospital Corp. of Am.*, 807 F.2d at 1390 (citation omitted).

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Respondent points to district court cases that recognized that the nonprofit status of hospitals may be taken into account in evaluating the potential anticompetitive effects. RB at 65-67 (citing *Long Island Jewish Med. Ctr.*, 983 F. Supp. at 146; *Butterworth Health Corp.*, 946 F. Supp. at 1296-97; *United States v. Carilion Health Sys.*, 707 F. Supp. 840, 849 (W.D. Va. 1989) (unpublished opinion)). In these cases, the district courts were asked to speculate about the potential effects of a proposed merger and each held that the nonprofit status might serve as a check on anticompetitive behavior. *E.g.*, *Butterworth Health Corp.*, 946 F. Supp. at 1297 (nonprofit status was material where economist's findings suggested that the proposed merger was not likely to result in price increases). But in this case, there is substantial evidence of actual price increases post-merger. F. 326-755. Thus, an inquiry into whether the nonprofit status of the hospitals might serve as a check on price increases is not a relevant inquiry. *See Hospital Corp. of Am.*, 807 F.2d at 1390 (While "different ownership structures might reduce the likelihood of collusion, . . . this possibility is conjectural.").

Further, the court in *Long Island Jewish Medical Center* held only that "nonprofit status may be considered if supported by other evidence that such status would inhibit anticompetitive effects." 983 F. Supp. at 146. In this case, Respondent has presented evidence that the Healthcare Foundation of Highland Park provides funds to support indigent or uncompensated care at Highland Park, dispenses grants to charities in the Highland Park area, and has improved access to healthcare for underserved populations in southeast Lake County. F. 1012. This evidence, however, does not overcome the convincing evidence presented by Complaint Counsel that ENH's nonprofit status has not inhibited the anticompetitive effects of the merger. *See* F. 326-755.

Although ENH's Board of Directors contains community representatives, the ENH board did not actively monitor the pricing pricing decisions of hospital management. F. 1003. Further, the

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senior executives of ENH received enhanced compensation agreements and substantially higher awards at the end of 2000 compared to the awards in 1998 and 1999. F. 998-1000. Thus, ENH's compensation contracts did not align management's interests with consumers on the issue of price. F. 1001. And, most importantly, when ENH set prices for the 2000 contract renegotiations with managed care organizations, the fact that it was a nonprofit entity did not restrain its efforts to obtain higher prices. *See* F. 326-755. Thus, the evidence in this case is consistent with cases holding that "if there is the potential for anticompetitive behavior, there is nothing inherent in the structure of of the corporate board or the nonprofit status of the hospitals which which would operate to stop any anticompetitive behavior." *Mercy Mercy Health Serv.*, 902 F. Supp. at 989.

The entirety of the evidence, including ENH's contemporaneous documents, testimony, and the post-merger pricing data, shows that ENH exercised market power and that its nonprofit status was irrelevant to that end. Accordingly, Respondent's nonprofit status does not rebut Complaint Counsel's *prima facie* case.

d. Entry or Expansion

Concentration in the relevant market may not inherently lead to to collusive or anticompetitive behavior when existing competitors competitors could easily enter the market and provide enough capacity to defeat an exercise of market power. *See Hospital Corp. Corp. of Am.*, 807 F.2d at 1387; *Long Island Jewish Med. Ctr.*, 983 983 F. Supp. at 149 ("A merger is not likely to cause an anti-anti-competitive effect if other participants can enter the relevant markets and reduce the likelihood of a price increase above competitive levels."). If customers could turn to new entries in the market in sufficient numbers to make the exercise of market power power unprofitable for merging hospitals, then any present concentration in the relevant market would be irrelevant. *Rockford*

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Rockford Memorial, 717 F. Supp. at 1281. Therefore, among factors factors which courts have previously considered to be relevant is ease of entry into the market. *Id.* “Most hospital cases have stated the inability to build new hospitals as a strong barrier to entry.” *Mercy Health Serv.*, 902 F. Supp. at 986. It is against this standard that the record is reviewed to determine the relative ease or difficulty of entering the relevant market.

Respondent asserts that, in order for a merger to harm competition, repositioning by the non-merging firms must be unlikely. RB at 58. Respondent argues that Complaint Counsel has not demonstrated significant barriers to expansion such that rival hospitals would be unable to reposition themselves to compete with ENH. RB at 58. Respondent further asserts that competitor hospitals are able to and have expanded their capacity and service offerings. RB at 59. Complaint Counsel counters that evidence of hospitals’ actions to expand capacity or enter in the area is not sufficient to constrain and has not constrained ENH’s prices. CCRB at 33 n.34.

A new entrant must overcome significant regulatory barriers to enter the relevant market. The Illinois Certificate of Need (“CON”) law presents a barrier to persons wishing to provide new acute hospital inpatient care in the relevant geographic market. *See* F. 1014. The Illinois Health Facilities Planning Board, when reviewing a CON application for additional beds, considers whether the proposed beds are actually needed at the facility. F. 1016. Other hospitals can intervene to oppose a hospital’s CON application. F. 1020. Based on the Planning Board’s current addendum to its inventory, there is no need for additional beds in the Evanston, Glenview, and Highland Park areas for services in medical/surgical, pediatrics, or intensive care units. F. 1018.

Moreover, there have been no CON applications for the construction of new hospitals in the area around Highland Park, Evanston, or Glenbrook over the past five years. F. 1021. No new entry by a hospital has occurred in the North Shore area since the

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merger. F. 1027. And, while the regulatory environment for entry and expansion may ease if the Illinois CON law is repealed, as scheduled for July 1, 2006 (F. 1023), any effect this may have on entry or repositioning by incumbent providers is speculative. Further, irrespective of the CON law, it takes about two and a half to three years to build a new hospital. F. 1024.

The critical question is whether expansion from existing hospitals or entry by new hospitals is sufficient to constrain ENH's prices. *Cardinal Health*, 12 F. Supp. 2d at 55-58 (entry or expansion "must be proven to 'be timely, likely, and sufficient in its magnitude, character and scope to deter or counteract the competitive effects of concern'" (quoting *Merger Guidelines*, § 3.0); *Chicago Bridge & Iron*, Dkt. No. 9300, at 31. *See also Staples*, 970 F. Supp. at 1088 (finding that expansion by Wal-Mart would not constrain the merging parties' prices). The evidence in this case clearly shows that other hospitals do not significantly constrain ENH's prices. *See* F. 326-755.

The substantial evidence in this case is that expansion from existing hospitals has not counteracted the ENH price increases implemented subsequent to the merger. There is insufficient evidence that new entry or repositioning by rival hospitals will be timely, likely, and sufficient in its magnitude, character, and scope to constrain ENH. Therefore, the evidence does not demonstrate that entry or expansion is likely to replace the competition lost through the acquisition or to sufficiently constrain ENH from future anticompetitive actions.

e. Failing Firm

Respondent also asserts that, at the time of the merger, Highland Highland Park was in a deteriorating financial condition, which, it argues, is an additional factor contributing to a finding that the merger did not substantially lessen competition. RB at 61-65. Complaint Counsel asserts that Highland Park's premerger financial

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financial condition was sound and that Highland Park could have pursued an arrangement – a sale, merger, or alliance – with another entity that would have resolved any financial issues without without the attendant antitrust problems of this merger. CCRB at 33-33-36.

The acquired firm's weakness is a factor that a defendant may introduce to rebut the government's *prima facie* case. *University Health*, 938 F.2d at 1221; *Kaiser Aluminum*, 652 F.2d at 1339; *United States v. Int'l Harvester Co.*, 564 F.2d 769, 774 (7th Cir. 1977). "A weak financial condition may mean that a company will be a far less significant competitor than current market share, or production statistics, appear to indicate." *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 153 (D.D.C. 2004). However, such a defense is credited "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." *University Health*, 938 F.2d at 1221. "Since weak firms are not in grave danger of failure . . . 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.'" *Id.* (citation omitted).

A merger is not likely to create or enhance market power or facilitate its exercise if the following circumstances are met: (1) the allegedly failing firm would be unable to meet its financial obligations in the near future; (2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; (3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers of acquisition of the assets of the failing firm that would both keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger; and (4) absent the acquisition, the assets of the failing firm would exit the relevant market. *Merger Guidelines* § 5.1; *Arch Coal*, 329 F. Supp. 2d at 154.

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In this case, Respondent failed to make such a showing. The evidence demonstrates that Highland Park's premerger financial condition was essentially sound. It had more than sufficient cash and assets to cover debts (\$235 million in cash and assets, compared to \$120 million in long-term debt), continue operations, expand services, and invest in new facilities and equipment. F. 1044-45. In developing Highland Park's 1999-2003 financial plan, the Lakeland finance and planning committee noted, "[c]ash and investments are forecasted to grow from \$238 million in 1998 to \$323 million in 2003," forecasted that its investments would generate a return of \$28 million in incremental net revenues in 2003, emphasized that "[e]xisting cash and investments are available to fund strategic initiatives and generate new programs," and concluded that Highland Park "can remain financially strong over the foreseeable future." F. 1029, 1031-33. Highland Park's 1999-2004 Financial Plan projected that cash and investments would increase by \$48 million from 1999-2004, and that long-term debt would be reduced by \$24.3 million, excluding amortization, and projected that it had sufficient cash flow for both planned capital expenditures (\$79 million) and planned strategic initiatives (\$24 million). F. 1037-38. The Highland Park board and management was advised that "the financial condition of Highland Park was such that it did not require a financial reason to go forward with the merger." F. 1040.

In the fall of 1998, Highland Park contemplated both a merger strategy, as well as an independent, stand alone growth strategy. F. 1056. Highland Park was prepared to proceed with the status quo, unaffiliated option if the ENH merger talks failed. F. 1057. If the merger with ENH had not closed, Highland Park had "the financial wherewithal to sustain [itself]." F. 1059. Highland Park management and board believed that "[t]here was no urgency to have an alternative immediately available." F. 1059. Stearns, Highland Park's Chairman of the Board, testified that he believed that Highland Park was not in danger of exiting the market for at least ten years. F. 1059. Highland Park never considered filing for

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bankruptcy. F. 1064. This stands in marked contrast to the facts in *FTC v. Freeman Hospital*, where the hospital to be acquired had a limited future of only two to three years. 911 F. Supp. 1213, 1225 (W.D. Mo. 1995), *aff'd*, 69 F.3d 260 (8th Cir. 1995).

In the fall of 1998, Highland Park contemplated a number of potential merger partners besides Evanston, including Northwest Community, Lake Forest, and Condell. F. 1065. If the ENH merger had not closed, Highland Park was prepared to continue to explore other partnership options. F. 1067. Highland Park had “an attractive service area,” and therefore, Highland Park’s chairman of the board believed it “would be attractive to other partnership candidates.” F. 1069.

The evidence in this case thus demonstrates that Highland Park was able to meet its financial obligations in the near future; was not in danger of bankruptcy; was exploring other options, including remaining a stand alone entity; and was not in danger of exiting the market in the foreseeable future. Therefore, Respondent has failed to show that, because of Highland Park’s financial prospects, Complaint Counsel’s *prima facie* case does not accurately reflect the acquisition’s likely effect on future competition.

D. Affirmative Defense**1. Evanston and Highland Park Are Separate Persons Subject to Section 7 of the Clayton Act**

Respondent asserts as an affirmative defense that prior to the merger, Evanston and Highland Park were not separate persons as required for the application of Section 7 of the Clayton Act, and that that the merger is exempt from antitrust liability under the Copperweld doctrine (*Copperweld Corp. v. Independence Tube Co.*, Co., 467 U.S. 752 (1984)). Answer, p. 20. In *Copperweld*, the Supreme Court held that a parent company and its wholly-owned subsidiary, as a single entity, were not capable of conspiring in

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violation of the Sherman Act. 467 U.S. at 771. Section 7 of the Clayton Act provides in pertinent part: “[n]o person . . . shall acquire, directly or indirectly, the whole or any part of the stock or or other share capital . . . [or] the whole or any part of the assets of of another person” when “the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly.” 15 U.S.C. § 18 (2005).

Respondent asserts that the merger of Evanston and Highland Park did not involve two “persons” because at the time of the merger they were sister corporations owned by the same parent. RB at 110-13. Complaint Counsel asserts that Evanston and Highland Park were “separate economic actors pursuing separate economic interests” and thus do not qualify for the *Copperweld* defense. CCB at 84.

In the early 1990's, Evanston and Lakeland (Highland Park's parent), along with Children's Memorial Hospital Center and Northwestern Memorial Hospital, formed the Northwestern Healthcare Network (“Network”). F. 35-39. Among the goals of the Network was to allow hospitals to come together to respond to anticipated marketplace behavior with respect to managed care contracting and exclusive contracting with certain managed care organizations. F. 40. The four hospital members entered into a Network Affiliation Agreement that provided for the creation of a council of governors that had control over the Network, including, *inter alia*, the authority to appoint and to remove members of the board of directors of the Network. F. 46. The Network negotiated contracts for the provision of hospital services by its member hospitals with the International Brotherhood of Teamsters, Health Network, Great West, and MultiPlan. F. 42.

Respondent asserts that, because, under the Network Affiliation Agreement, the Network became the “sole member” of the member hospitals, in accordance with the Illinois General Not For Profit Corporation Act of 1986, as amended, Evanston and

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Highland Park were no longer two separate “persons,” as that term is defined by the Clayton Act. RB at 111. A review of the evidence, however, demonstrates that under the Network Affiliation Agreement, Evanston and Highland Park remained separate economic entities.

Under the Network Affiliation Agreement, the governing boards of each of the hospitals retained “local autonomy and control,” of their own hospitals. F. 48. Each institution developed its own budget and operated independently. F. 49. Members of the Network only shared the cost of running the Network. F. 68. There was no combined profit and loss or profit-sharing. F. 68.

Each hospital retained autonomy and control over the decisions related to the delivery of health care services at its hospital. F. 60. Each hospital maintained its own medical staff and retained the exclusive authority over granting medical staff privileges at its hospital. F. 55, 57. The Network could not terminate the employment of the administrators of the individual member hospitals, except for limited, specifically defined reasons. F. 52. Each hospital developed its own hospital program expansion plans. F. 61.

Each hospital also retained the authority to enter into a contract or to refuse to enter into a contract with each individual managed care organization. F. 65. The Network did not have the authority to enter into a contract binding on the individual member hospitals. F. 65. The hospitals that were members of the Network continued to compete with each other, unilaterally negotiating contracts with managed care companies, “‘slicing’ each other up in the market,” and “undercutting each other.” F. 66.

The evidence in this case, thus, demonstrates that Evanston and Highland Park remained “separate economic actors pursuing separate economic interests,” and that their merger “suddenly [brought] together economic power that was previously pursuing divergent goals.” *Copperweld*, 467 U.S. at 769. Factors the Supreme

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Supreme Court considered in *Copperweld* in making its determination were whether a parent and its wholly owned subsidiary had “a complete unity of interests”; and whether “their general corporate actions [were] guided or determined not by two separate corporate consciousnesses, but one.” *Id.*

The key to determining if two separate organizations actually constitute a “single entity” for assessing whether they are incapable of conspiring with each other in violation of Section 1 of the Sherman Act is assessment of “economic unity.” *Freeman v. San Diego Assoc.*, 322 F.2d 1133, 1147-48 (9th Cir. 2002). “Where there is substantial common ownership, a fiduciary obligation to act for another’s economic benefit or an agreement to divide profits and losses, individual firms function as an economic unit and are generally treated as a single entity.” *Id.* at 1148. “[I]n the absence of economic unity, the fact that joint venturers pursue the common interests of the whole is generally not enough, by itself, to render them a single entity.” *Id.*

As summarized above, the hospitals in the Network did not have a fiduciary obligation to act for each other’s economic benefit or to divide profits and losses; they did not function as an economic unit, but rather, retained autonomy with respect to hospital administration, staff, delivery of health care services, budget, and expansion plans. F. 46-71. Further, unlike the *Copperweld* parent company, the NH Network could not “keep a tight rein” over the individual member hospitals because the NH Network could not “assert full control at any moment if the [member hospitals] fail[ed] to act in the [NH Network’s] best interests.” *Copperweld*, 467 U.S. at 771-72. In fact, managed care organizations testified that premerger, the competition between Highland Park and Evanston had allowed them to negotiate lower rates. F. 229-32.

Respondent also asserts that Evanston and Highland Park were not separate persons, as required by Section 7 because the

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parties were not required to file a Report and Notification Form (“HSR Form”) pursuant to the Hart-Scott-Rodino Antitrust Improvement Act of 1976, as amended (“HSR Act”). RB at 111-12. 111-12. Respondent asserts that, prior to the merger, the parties to the merger asked the staff of the FTC’s Premerger Notification Office whether they would be required to file an HSR Form, given the fact that the Network served as the sole corporate member member of a number of hospitals and hospital holding companies, and that the parties to the proposed merger were nonprofit, tax exempt corporations. RB at 111-12 (citing FTC Premerger Notification Office Informal Staff Opinion No. 9908002 (August 10, 10, 1999), *available* at <http://www.ftc.gov/bc/hsr/informal/opinions/9908002.htm>).

That the parties to the merger may not have been required to file a Report and Notification Form pursuant to the HSR Act does not change the conclusion that Evanston and Highland Park were separate “persons.” The Clayton Act makes clear that the administration of the HSR Act has no bearing on an FTC action brought under Section 7: “[a]ny action taken by the [FTC] . . . or any failure of the [FTC] . . . to take any action under [the HSR Act] shall not bar any proceeding or any action with respect to such acquisition at any time under any other section of this Act.” 15 U.S.C. § 18a(i). Further, Section 7 permits a merger challenge at “any time the acquisition threatens to ripen into a prohibited effect.” *E.I. du Pont*, 353 U.S. at 597. Thus, Complaint Counsel’s action is not barred.

The mechanics of this merger and the dissolution of the NH Network further confirm that Evanston and Highland Park were not a single entity controlled by the NH Network. The NH Network did not direct the hospitals to merge; instead, Evanston and Highland Park independently agreed to merge and notified the NH Network afterward of their plans. NH Network members confirmed their independence when, in 1999, the member hospitals voted to dissolve the NH Network rather than submit themselves to the “full control” of the NH Network. F. 76.

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The evidence conclusively shows that, under the *Copperweld* doctrine, Evanston and Highland Park were not already “one person” at the time of their merger. Therefore, Evanston’s merger with Highland Park is subject to Section 7 of the Clayton Act.

E. Summary of Liability**1. Count I is Sustained**

Count I of the Complaint alleges that the merger of ENH and Highland Park has substantially lessened competition in the relevant market, in violation of Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18. Complaint ¶ 27. Specifically, the Complaint alleges that as a result of the merger, ENH has been able “to exercise market power in the relevant market.” Complaint ¶ 18. The Complaint asserts that “ENH negotiated uniform prices for the three hospitals as a single system and raised prices at all three locations” and that the “price increases that resulted from the merger are large and far beyond those achieved by comparable hospitals during this time period.” Complaint ¶¶ 1, 24. Count I further alleges that the market created by the merger is “highly concentrated” as measured by the Herfindahl-Hirschman Index. Complaint ¶ 18.

As explained above, the evidence demonstrates that the relevant relevant product market is general acute care inpatient services sold to managed care organizations, including primary, secondary, and tertiary inpatient services. The evidence further demonstrates that the following seven hospitals are properly included in the relevant geographic market: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. The concentration level under the post-merger Herfindahl-Hirschman Index for the relevant market is 2739 with an increase of 384, which corresponds to a “highly concentrated” market and the presumption that the merger is likely to “create or

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enhance market power.” *Merger Guidelines* § 1.51. This prediction prediction is confirmed by direct evidence that ENH exercised its enhanced post-merger market power through elimination of a competitor and obtained post-merger price increases significantly above its premerger prices and substantially larger than price increases obtained by other comparison hospitals. Neither Respondent’s learning about demand theory nor quality of care improvements justify the substantial price increases to managed care care organizations and consumers. Respondent’s other defenses are are similarly unpersuasive. The only viable explanation for Respondent’s higher prices is that the merger gave ENH enhanced market power.

Complaint Counsel has thus demonstrated a reasonable probability that the structure of the merger will create an appreciable danger of anticompetitive consequences and will substantially lessen competition and harm consumer welfare in the future. Accordingly, as Complaint Counsel has established a violation of Section 7 of the Clayton Act, Count I is **SUSTAINED**.

2. Count II is Dismissed as Moot

Count II also charges that the merger of ENH and Highland Park has substantially lessened competition, in violation of Section 7 of the Clayton Act, but does not allege a relevant product or geographic market. *See* Complaint ¶¶ 28-32 (the paragraphs alleging the relevant product and geographic markets in Count I, paragraphs 16-18, are not incorporated by reference into Count II). Complaint Counsel argues that Counts I and II are alternative approaches to establishing a violation of Section 7 of the Clayton Act. CCB at 51; Closing argument, Tr. 6546-47.

In light of the Court’s finding of Respondent’s liability under Count I, it is unnecessary to reach the government’s Count II claim. *See Brown v. McCormick*, 87 F. Supp. 2d 467, 481 (D. Md. 2000); *Mitchell v. Penton/Industrial Publishing Co., Inc.*, 486 F.

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Supp. 22, 26 (N.D. Oh. 1979). As Count II is not dispositive of the the issues presented, it is moot.

Assuming *arguendo*, that the merits of Count II were still in issue, Complaint Counsel’s direct effects theory of liability does not, in any event, allow it to forgo its burden of proving the relevant market under a Clayton 7 claim. As the Seventh Circuit noted in *Republic Tobacco*, neither *Toys “R” Us, Inc. v. FTC*, 221 F.3d 928 (7th Cir. 2000) nor *Indiana Federation of Dentists*, 476 U.S. at 447 (cited by Complaint Counsel), allows an antitrust plaintiff to dispense entirely with market definition. 381 F.3d at 737. The antitrust plaintiff must show at least the *rough contours* of a relevant market. *Id.* Only upon such a showing and additional proof that the defendant commands a substantial share of the market can “direct evidence of anticompetitive effects . . . establish the defendant’s market power – in lieu of the usual showing of a precisely defined relevant market and a monopoly market share.” *Id.*

Complaint Counsel’s reading of *Rockford Memorial*, 898 F.2d at 1282-83, regarding the “convergence” of the Sherman and Clayton Act enforcement schemes is unpersuasive and does not overcome the Seventh Circuit’s subsequent holding in *Republic Tobacco*. Thus, while *Indiana Federation of Dentists*, 476 U.S. at 460-61, concluded that if there is direct evidence of anticompetitive effects, “elaborate market analysis” is not required, it does not stand for the proposition urged by the government that “it is unnecessary to define a product or geographic market for the purposes of a claim under section 7 of the Clayton Act.” Complaint Counsel Interrog. Answers at 33.

In Count II, by not alleging a relevant product or geographic market, Complaint Counsel asks the Court to adopt a novel theory of of Clayton 7 liability. To do so would undermine decades of established merger jurisprudence – a departure that this Court is unwilling to undertake. The Court’s previous Order denying

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Respondent's Motion to Dismiss Count II is entirely consistent with with the language of Section 7, the case law discussed herein, and the *Merger Guidelines* – all of which require Complaint Counsel to to carry its burden of defining the relevant market. Complaint Counsel's interpretation of Section 7 thus fails as a matter of law.

Accordingly, for the above-stated reasons, Count II is **DISMISSED**.

F. Remedy**1. Applicable Standards**

The effect of the acquisition of Highland Park by ENH has been to substantially lessen competition in violation of Section 7 of the Clayton Act, as amended. Once a violation is found, the Commission has an obligation to order effective relief to protect the public from further violations. The antitrust laws traditionally have favored divestiture to remedy an illegal merger's competitive concerns. Much of the case law has followed this rationale and found divestiture "the most appropriate means for restoring competition lost as a consequence of a merger or acquisition." *Chicago Bridge & Iron*, Dkt No. 9300, at 94.

Section 11(b) of the Clayton Act states that the Commission "shall" order a divestiture of "the stock, or other share capital, or assets held" in violation of Section 7. 15 U.S.C. § 21(b). Through Section 11 of the Clayton Act, Congress expressly directed the Commission to issue orders requiring the violator of Section 7 to divest itself of the assets held in violation of the Clayton Act. *California v. American Stores, Co.*, 495 U.S. 271, 284-85 and n.11 (1990); *FTC v. Western Meat Co.*, 272 U.S. 554, 559 (1926).

Supreme Court precedent holds that divestiture is the usual and and proper remedy where a violation of Section 7 has been found. *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 329, 329, 331 (1961) (ruling that an undoing of the acquisition is "a

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natural remedy,” and “should always be in the forefront of a court’s court’s mind when a violation of § 7 has been found.”). It is “well settled that once the Government has successfully borne the considerable burden of establishing a violation of law, all doubts as as to the remedy are to be resolved in its favor.” *Id.* at 334. In *E.I. du du Pont*, the Supreme Court acknowledged the drastic nature of the the divestiture remedy, but held that it is the “most effective” means means to restore premerger levels of competition. *Id.* at 326; *In re RSR Corp.*, 88 F.T.C. 800, 894 (Dec. 2, 1976), *aff’d*, 602 F.2d 1317 1317 (9th Cir. 1979).

In *Ford Motor Co. v. United States*, the Supreme Court held that Section 7 relief must be directed to that which is “necessary and appropriate in the public interest to eliminate the effects of the acquisition offensive to the statute’ . . . or which will ‘cure the ill effects of the illegal conduct, and assure the public freedom from its continuance.’” 405 U.S. 562, 573 n.8 (1972) (citations omitted); *see also American Stores*, 495 U.S. at 285 n.11 (A person who is allowed to continue holding ownership over stock or assets that created a Section 7 violation would be engaging in a perpetual violation, thus divestiture is the only effective remedy.). As such, the relief must not be punitive but must be designed to “redress the violations” and “to restore competition.” *Id.* at 573. Cases cite the well-established standard that the Commission’s remedy is proper as long as there is a “reasonable relationship between the remedy and the unlawful conduct at issue.” *Atlantic Refining Co. v. FTC*, 381 U.S. 357, 377 (1965); *FTC v. Ruberoid Co.*, 343 U.S. 470, 473 (1952); *FTC v. National Lead Co.*, 352 U.S. 419, 428 (1957).

Respondent asserts that any consideration of the proposed divestiture order must begin with the premise that “[d]ivestiture is itself an equitable remedy designed to protect the public interest.” *E.I. du Pont*, 366 U.S. at 326. As such, “in the case of a judicial determination that an acquisition was in violation of Section 7, a claim of hardship attendant upon complete divestiture can be

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considered in determining the appropriate remedy for the redress of of antitrust violations where something short of divestiture will effectively redress the violation.” *United States v. Int’l Tel. & Tel. Corp.*, 349 F. Supp 22, 31 (D. Conn. 1972).

Thus, “while divestiture is normally the appropriate remedy in a Section 7 proceeding, on occasion, it may possibly be impracticable or inadequate . . . which underscores the importance of the Commission’s having a range of alternatives in its arsenal of remedies.” *In re Ekco Prod. Co.*, 65 F.T.C. 1163, 1217 (June 30, 1964), *aff’d*, 347 F.2d 745 (7th Cir. 1965). As noted in *In re Retail Credit Co.*, 92 F.T.C. 1, 123 (July 7, 1978) (“[t]his is not to say that divestiture is an automatic sanction, mechanically invoked in merger cases.”). Similarly, in *In re National Tea Co.*, 69 F.T.C. 226 (Mar. 4, 1966), the Commission stated, “[a]t least we think it appropriate, in the circumstances of this case, to give those natural forces of competition a chance to correct the imbalances in those markets before turning to the more stringent remedy of divestiture.” *Id.* at 278.

2. Divestiture is the Appropriate Remedy

In addressing the issue of appropriate relief in this case, the Court is guided by the basic principle set forth by the Commission in *In re Fruehauf Corp.*, 90 F.T.C. 891, 892 n.1 (Dec. 21, 1977), that “the burden rests with respondent to demonstrate that a remedy other than full divestiture would adequately redress any violation which is found.” Such an exception to the general rule favoring divestiture can be invoked, however, “only when the proof of their probable efficacy is clear and convincing. In the absence of proof to the contrary the assumption of this Commission must be that ‘only divestiture can reasonably be expected to restore competition and make the affected markets whole again.’” *Diamond Alkali*, 72 F.T.C. at 742 (quoting *National Tea Co.* 69 F.T.C. at 277).

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Upon review of the record, Respondent has failed to meet its burden by identifying any hardship which would entitle it to an exception to the divestiture rule. Nor has Respondent persuaded the Court that any alternative remedies to divestiture would effectively “redress the violation” found herein. The Commission has noted that the purpose of Section 7 relief is to “undo the probable anti-competitive effects of the unlawful merger, to restore competition to the state in which it existed at the time of the merger, or to the state in which it would be existing at the time the relief is ordered.” *Retail Credit Co.*, 92 F.T.C. at 161. It is against this standard that Respondent’s proposed alternative remedies must be considered and assessed.

First, Respondent proposes imposition of a “prior notice” order which would obligate ENH to notify the Commission over a period of five years, before it made any future acquisitions of providers of general acute care inpatient hospital services in the relevant geographic market. *See* Respondent’s Proposed Order A. Such a remedy, Respondent argues, would be reasonably related to the transaction by insuring that any non-reportable acquisition of inpatient services in the relevant market that ENH may pursue in the future would be reviewed by Commission staff prior to consummation. Such a remedy, Respondent asserts, while acknowledging a past violation of Section 7, would not, given what Respondent argues to be an absence of evidence of any present or future anticompetitive effects, interfere with “present competitive market conditions,” nor require any action that would destroy the quality improvements that are currently benefitting consumers. RB at 125.

Such relief, however, fails to speak to the *present competitive market conditions* that have given rise to the Section 7 violation in this case. Respondent cannot demonstrate how such behavioral relief will “undo the . . . [present] anti-competitive effects of the unlawful merger to restore competition” to the levels prior to the acquisition. *Retail Credit*, 92 F.T.C. at 161. The proposed relief

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further ignores the significant post-merger price increases and the evidence that any post-merger quality improvements are outweighed by the anticompetitive effects generated by the illegal acquisition of Highland Park. Respondent's alternative remedy therefore fails to redress the violation found and fails to "make the affected markets whole again." See *Diamond Alkali*, 72 F.T.C. at 742.

Respondent's second alternative, that the Court enter a "narrowly crafted conduct remedy" requiring Evanston and Highland Park to negotiate and maintain separate managed care contracts, is similarly unpersuasive. RB at 125-26. In the absence of structural relief, given the geographic dynamics of the relevant market, the Court is not persuaded that the "natural forces of competition" will be able to adequately redress the anticompetitive imbalances that currently exist as a result of the ENH merger with Highland Park. Thus, Respondent's alternative remedy, of allowing the managed care organizations to select specific pricing methodologies in bidding ENH's inpatient service contracts, would not effectively restore competition to the premerger landscape.

Respondent's proposed remedy fails to demonstrate how such practices would restore competition in the relevant market. The ill effects emanating from the ENH merger are not amenable to short term, transitory cures. The Commission must therefore have leeway to devise effective relief to restore the relevant market's pre-transaction competitive balance.

It has not been shown that non-structural relief could effectively redress the violations at issue in this case. Nevertheless, Respondent asserts several specific reasons why divestiture would not be the most appropriate remedy to protect the public interest. Respondent argues that divestiture would threaten a number of quality improvements and services achieved as a result of the merger. RB at 116-23. The argument that the

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Highland Park community would ultimately be harmed as a result of of divestiture, however, is without merit, both legally and in fact.

As a matter of law, the Court's evaluation of the competitive effects of this merger has determined that, on balance, anticompetitive harm has occurred as a consequence of this transaction, despite procompetitive benefits that resulted. Upon such a finding, divestiture, on balance, could not be deemed to harm consumers as it would eliminate the anticompetitive harm that has been found to exceed any quality benefits. As noted earlier, the evidence demonstrates that most quality of care improvements at Highland Park were not merger specific and will not be lost upon divestiture. F. 869-975. In addition, as discussed below, the evidence does not demonstrate that any quality benefits will be significantly diminished as a result of divestiture.

Respondent asserts that divestiture will harm the community by slowing the rate of improvements in Highland Park's quality of care in the future and by eliminating: improvements already achieved; the benefits of the academic affiliation and clinical integration ENH brings to Highland Park; the leadership structure and collaborative culture; and several important services such as cardiac surgery, interventional cardiology, and EPIC. RB at 116-20. It is true, as discussed below, that some benefits of the merger will be lost, including the current electronic medical records system, EPIC; academic affiliation and clinical integration; and cardiac surgery. The evidence demonstrates, however, that these benefits are insubstantial in relation to the anticompetitive harm resulting from the merger.

Upon divestiture, Highland Park will need to determine how it wishes to maintain its medical records. Highland Park will need to invest in a records management system, through EPIC or another vendor. Highland Park may pursue a license from EPIC, although even if Highland Park created its own EPIC system, the benefits of of having records from multiple hospitals and some physician

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offices would be lost. F. 976-87. There is no evidence, however, from which to quantify the loss of value that would result from Highland Park's choice of medical records systems. This is merely one of many decisions that will need to be made by Highland Park as it transitions into either a stand alone hospital or joins another hospital system.

To the extent that Highland Park physicians participated in teaching residents and benefitted from the affiliation with Evanston, those benefits will also be lost. F. 988-93. However, Highland Park physicians will continue to be able to improve their abilities through professional development activities at Evanston or other venues. Most Highland Park physicians were excellent before the merger and the Court is confident they will remain so after the merger.

In addition, Highland Park would not be able to continue the cardiac surgery program on its own. However, Highland Park could continue cardiac surgery as a joint venture with Evanston, similar to the joint cardiac surgery programs that Evanston has with Swedish Covenant and Louis A. Weiss. F. 957. Or, Highland Park could seek a different partner for its cardiac surgery program. F. 955-56. Even if Highland Park closes the cardiac surgery program, it could still continue to provide interventional cardiac procedures. F. 964.

The record thus establishes that Highland Park, upon divestiture, has the ability to maintain or establish acceptable levels of quality care in most service areas, including the collaborative and multi-disciplinary culture. As to intensivist coverage, Highland Park simply needs to maintain the contract that it has already in place to provide those services. F. 974-75. There is no non-financial reason not to do that on a stand alone basis. The same is true for changes in the emergency department, heart attack care, cancer care, and critical pathways. F. 888-959. Similarly, most of the changes in obstetrics and gynecology, nursing, quality assurance, quality improvements, physical plant,

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laboratory medicine and pathology services, pharmacy services, and and radiology and radiation medicine could be maintained in the event of divestiture. F. 876-975. The changes relating to physical plant, lab, and Pyxis, have already been made at Highland Park and and would remain upon divestiture. F. 911-20, 941-947. The quality quality improvement system could also remain in place at Highland Highland Park because physicians and nurses are familiar with it. F. F. 896-902. Adult psychiatric services could be added to Highland Park or referred to another hospital. F. 965-69. Thus, Highland Park Park would likely continue post-merger organizational, clinical, and and cultural changes and implement nearly any quality improvements it deems beneficial.

“In section 7 cases, the principal purpose of relief is to restore competition to the state in which it existed prior to, *and would have continued to exist, but for the illegal merger.*” *In re B.F. Goodrich Co.*, 110 F.T.C. 207, 345 (March 15, 1988) (emphasis supplied). The evidence demonstrates that only full divestiture of Highland Park can be expected to effectively restore competition in the market. Various managed care organization witnesses affirm this conclusion, having testified that Highland Park, as an independent, stand alone, premerger entity, gave them a valuable alternative with which to restrain Evanston’s prices. F. 229-32. Restoration of the competitive landscape that existed before the merger would thus likely prevent Evanston from predating any anticompetitive pricing based on its post-merger knowledge of demand and pricing for its services. The record does not therefore indicate that divestiture would significantly harm consumers by eliminating the enumerated post-merger improvements at Highland Park.

The Commission has ordered divestiture of integrated assets in in consummated merger cases numerous times where violations of the Clayton Act have been found. *E.g.*, *Chicago Bridge & Iron*, Dkt. Dkt. 9300, at 92; *In re Olin Corp.*, 113 F.T.C. 400, 618-19 (June 13, 13, 1990); *In re Crown Zellerbach Corp.*, 54 F.T.C. 769, 808 (Dec.

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(Dec. 26, 1957), *aff'd*, 296 F. 2d 800 (9th Cir. 1961); *Ekco Products, Products*, 65 F.T.C. at 1228-30. In the instant case, Respondent has not presented sufficient evidence to depart from the usual and customary remedy of divestiture. As such, upon consideration of the the entire record in this case, divestiture is the most effective and appropriate remedy to restore competition and is hereby ordered. The attached Order is designed to unwind the merger and remedy the anticompetitive effects arising from the unlawful transaction.

3. Relief

Courts have given significant deference to the Commission's expertise fashioning such relief because, as the Supreme Court noted in *Ruberoide*, "Congress expected the Commission to exercise a special competence in formulating remedies to deal with problems in the general sphere of competitive practices." 343 U.S. at 473. Similarly, in *Hospital Corporation of America*, the Seventh Circuit noted the Commission's "broad discretion, akin to that of a court of equity, in deciding what relief is necessary to cure a violation of law and ensure against its repetition." 807 F.2d at 1393.

The Commission has wide discretion in determining what type of order is necessary to remedy the unfair practices found. *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611 (1946); *National Lead Co.*, 352 U.S. at 428. "The relief which can be afforded" from an illegal illegal acquisition "is not limited to the restoration of the status quo quo ante" but may include that "which is necessary and appropriate appropriate in the public interest." *Ford Motor Co.*, 405 U.S. at 573 573 n.8. Thus, in addition to fashioning an appropriate divestiture remedy, the Commission also has authority to order ancillary relief. Ancillary relief is ordered here, in order to: (1) correct any informational and bargaining imbalance that may exist between Respondent and the prospective acquirer of the divested assets; (2) enhance and expand the competitive viability of the buyer; and and (3) reduce any adverse incentives of Respondent, which may put put the divested business at risk. *See Federal Trade Comm'n, A*

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Study of the Commission's Divestiture Process (1999) (available at www.ftc.gov/os/1999/08/divestiture.pdf).

A few of the provisions sought by Complaint Counsel are not “necessary and appropriate in the public interest,” as required by *Ford Motor Company*. 405 U.S. at 573 n.8. Deferring to the Commission’s expertise in fashioning effective relief, the Proposed Order submitted by Complaint Counsel is herein adopted, except as noted below. Provisions found to be beyond the relief necessary to cure the violation or unnecessary are:

- The proposed requirement that Respondent take actions necessary to assist the Acquirer in ensuring the provision or continuation of a cardiac surgery program at Highland Park Hospital that is capable of providing an equivalent standard of care in substantially the same manner as the cardiac surgery program established at Highland Park after the merger. Proposed Order, II.E.
- The proposed language relating to the purpose of the divestiture and the factors the Commission will consider. Proposed Order, II.L.
- The proposed requirement that Respondent vest pension benefits and provide any ENH Employee to whom the Acquirer has made a written offer of employment with reasonable financial incentives to accept a position with the Acquirer. Proposed Order, II.H.3.
- The proposed indemnification clauses, for holding harmless both the Monitor and the

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Divestiture Trustee. Proposed Order, V.B.6,
VI.C.7.

Accordingly, such provisions are not adopted and shall not be ordered. In addition, slight modifications from the language proposed by Complaint Counsel are made within the following paragraphs of the Proposed Order: I.H, I.K, I.X, I.Z, I.AA, II.A, II.D, and VI.C.5.

IV. SUMMARY OF CONCLUSIONS OF LAW

1. Respondent Evanston Northwestern Healthcare (“ENH”) is a nonprofit corporation organized, existing, and doing business under the laws of the state of Illinois.

2. In the challenged merger, consummated on January 1, 2000, ENH acquired the assets of Highland Park Hospital (“Highland Park”).

3. Section 7 of the Clayton Act applies to asset acquisitions by nonprofit hospitals.

4. The Federal Trade Commission (“FTC”) has jurisdiction over Respondent and the subject matter of this proceeding pursuant to Sections 7 and 11 of the Clayton Act, 15 U.S.C. §§ 18, 21(b).

5. Complaint Counsel bears the burden of proof of establishing each element of the violations alleged in the Complaint by a preponderance of the evidence.

6. Section 7 of the Clayton Act prohibits any acquisition of stock or assets “where in any line of 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.

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7. The appropriate line of commerce (relevant product market) within which to evaluate the probable anticompetitive effects of the merger is general acute care inpatient services sold to managed care organizations, which includes primary, secondary, and tertiary inpatient services.

8. The appropriate section of the country (relevant geographic market) within which to evaluate the probable anticompetitive effects of the merger is the area encompassing the following seven hospitals: Evanston, Glenbrook, Highland Park, Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis.

9. Section 7 of the Clayton Act is designed to arrest in its incipency the substantial lessening of competition from the acquisition by one corporation of the assets of a competing corporation. Complaint Counsel must show a reasonable probability that the transaction would substantially lessen competition in the future.

10. Complaint Counsel must establish a *prima facie* case that the acquisition is unlawful. A *prima facie* case may be made by showing that the transaction will significantly increase market concentration and by introducing other types of evidence relating to market conditions.

11. Market concentration under the *Merger Guidelines* is measured by the Herfindahl-Hirschman Index (“HHI”). Under the *Merger Guidelines*, a market in which the post-merger HHI is above 1800 is considered “highly concentrated,” and a merger in a highly concentrated market that increases the market’s HHI by over 100 is presumed to be “likely to create or enhance market power or facilitate its exercise.”

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12. In the relevant geographic market determined by the Court, the merger results in an HHI of 2739, with an increase of 384 from premerger levels.

13. The post-merger HHI of 2739 is substantially above the *Merger Guidelines*' threshold of 1800 to consider a market "highly concentrated," and the increase of over 384 far exceeds the *Merger Guidelines*' threshold of 100 to presume that the merger is "likely to create or enhance market power or facilitate its exercise."

14. In the relevant geographic market, in 1999, Evanston and Highland Park had a combined market share of approximately 35%. ENH's post-merger market share increased to approximately 40% by 2002, with the other four hospitals in the geographic market all losing market shares from 1999 to 2002.

15. The post-merger market share presents the threat of undue concentration.

16. Complaint Counsel established a *prima facie* case by demonstrating sufficient market concentration to predict probable anticompetitive effects.

17. These predictions of probable anticompetitive effects are confirmed by Complaint Counsel's demonstration that ENH exercised its enhanced post-merger market power and obtained post-merger price increases substantially above its premerger prices and significantly larger than price increases obtained by other comparison hospitals.

18. Complaint Counsel established that the price increases were achieved as a result of market power and not because of learning about demand or improvements in quality of care.

19. Respondent's learning about demand theory cannot explain the post-merger price increases at ENH.

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20. The vast majority of the quality of care improvements made by ENH to Highland Park were not merger specific. Two quality of care improvements to Highland Park were merger specific, but they do not justify ENH's increased post-merger prices or outweigh the probable anticompetitive effects of the merger.

21. The evidence demonstrates that entry or expansion from existing hospitals is not likely to replace competition lost through the acquisition or to sufficiently constrain ENH from future anticompetitive actions.

22. The evidence demonstrates that the nonprofit status of ENH has not operated to constrain ENH's exercise of market power.

23. The evidence demonstrates that Highland Park was able to meet its financial obligations in the near future; was not in danger of bankruptcy; had other options besides merging with ENH; and was not in danger of exiting the market in the foreseeable future.

24. Respondent did not rebut the presumption of a violation of Section 7 of the Clayton Act.

25. The merger is subject to Section 7 of the Clayton Act because Evanston and Highland Park were not already "one person" at the time of the merger.

26. The merger violates Section 7 of the Clayton Act because "the effect of such acquisition may be substantially to lessen competition or to tend to create a monopoly." 15 U.S.C. § 18.

27. Complaint Counsel met its burden of proof in support of Count I of the Complaint because, in a line of commerce, in an activity affecting commerce in a section of the country, the effect of

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of the merger may be substantially to lessen competition. Count I is is therefore **SUSTAINED**.

28. In light of the Court's finding of liability under Count I, it is unnecessary to reach Count II, as it is not dispositive of the issues presented and is thus moot. Count II is therefore **DISMISSED**.

29. Divestiture is the most effective and appropriate remedy to address the violation in this case.

30. Complete divestiture of all Highland Park assets acquired in the merger is required to restore competition as it existed prior to the merger.

31. Relief designed to restore competition as it existed prior to the merger is appropriate.

32. The Order entered hereinafter is necessary and appropriate to remedy the violation of law found to exist.

ORDER

I.

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

- A. "Acquirer" means any Person approved by the Commission to acquire the Highland Park Hospital Assets pursuant to this Order.
- B. "Acquirer Hospital Business" means all activities relating to general acute care inpatient hospital services and other related health care services to be conducted by the Acquirer in connection with the Highland Park Hospital Assets.

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- C. “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 provision of General Acute Care Inpatient Hospital Services.
- D. “Commission” means the Federal Trade Commission.
- E. “Direct Cost” means the cost of direct material and direct labor used to provide the relevant assistance or service.
- F. “Divestiture Agreement” means any agreement between Respondent (or between a Divestiture Trustee appointed pursuant to Paragraph VI of this Order) and an Acquirer approved by the Commission, and all amendments, exhibits, attachments, agreements, and schedules thereto that have been approved by the Commission, to accomplish the purpose and requirements of this Order.
- G. “Divestiture Trustee” means the Person appointed pursuant to Paragraph VI of this Order.
- H. “ENH” means Evanston Northwestern Healthcare Corporation, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; its subsidiaries, divisions, joint ventures, groups, and affiliates controlled by ENH (including, but not limited to, ENH Faculty Practice Associates and ENH Medical Group, Group, Inc.), and the respective directors, officers, employees, agents, attorneys, representatives, successors, and assigns of each. ENH Faculty Practice Associates is an an Illinois non-profit corporation that, inter alia, employs physicians who primarily serve the patients of ENH, and is

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is the sole shareholder of ENH Medical Group, Inc., an Illinois for-profit corporation.

- I. “ENH Contractor” means any Person that provides physician or other health care services pursuant to a contract with ENH (including, but not limited to, the provision of emergency room, anesthesiology, pathology, or radiology services) in connection with the operation of the Post-Merger Hospital Business at Highland Park Hospital.
- J. “ENH Employee” means any Person employed by ENH in the operation of the Post- Merger Hospital Business, including, but not limited to, any physician employed by ENH Faculty Practice Associates.
- K. “ENH License” means: (i) a worldwide, royalty-free, paid-up, perpetual, irrevocable, transferable, sublicensable, non-exclusive license to all Intellectual Property owned by or licensed to ENH relating to operation of the Post-Merger Hospital Business other than the HPH Name and Marks, which shall be divested, assigned and conveyed to the Acquirer on a permanent and exclusive basis, to the extent allowable under the existing ENH License, 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.
- L. “ENH Medical Staff Member” means any physician or other health care professional who: (1) is not an ENH Employee, and (2) is a member of the ENH medical staff, including, but not limited to, any ENH Contractor.
- M. “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

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and care of physically injured or sick persons with short term term or episodic health problems or infirmities, that include include an overnight stay in the hospital by the patient. General Acute Care Inpatient Hospital Services include what what are commonly classified in the industry as primary, secondary, and tertiary services, but exclude: (i) services at at hospitals that serve solely military and veterans, (ii) services at outpatient facilities that provide same-day service service only, (iii) those specialized services known in the industry as quaternary services, and (iv) psychiatric, substance abuse, and rehabilitation services.

- N. “Highland Park Hospital” means the Acute Care Hospital located at 718 Glenview Avenue, Highland Park, Illinois 60035.
- O. “Highland Park Hospital Assets” means all of ENH’s right, title, and interest in and to Highland Park Hospital and all related healthcare and other assets, tangible or intangible, business, and properties, including any improvements or additions thereto made subsequent to the Merger, relating to the operation of the Post-Merger Hospital Business in Highland Park, Illinois, including, but not limited to:
 - 1. All real property interests (including fee simple interests and real property leasehold interests), whether or not located on the Highland Park Hospital campus;
 - 2. All personal property, including equipment and machinery;
 - 3. All inventories, stores, and supplies;

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4. All rights under any contracts and agreements (*e.g.*, leases, service agreements such as dietary and housekeeping services, supply agreements, procurement contracts), including, but not limited to, all rights to contributions, funds and other provisions for the benefit of Highland Park Hospital pursuant to the Foundation Agreement dated December 16, 1999, between ENH and Highland Park Hospital Foundation (“Foundation Agreement”);
5. All rights and title in and to use of the HPH Name and Marks on a permanent and exclusive basis (even as to ENH), and an ENH License to all other Intellectual Property (“Licensed Intellectual Property”); *provided, however*, that ENH may retain a worldwide, royalty-free, paid-up, perpetual, irrevocable, transferable, sublicensable, non-exclusive license to the Licensed Intellectual Property; *provided further, however*, that ENH shall retain no rights to use the HPH Name and Marks;
6. All governmental approvals, consents, licenses, permits, waivers, or other authorizations;
7. All rights under warranties and guarantees, express or implied;
8. All items of prepaid expense; and
9. All books, records, and files (electronic and hard copy).

Provided, however, that the Highland Park Hospital Assets shall not include assets not located exclusively in Highland Park, Illinois, whose use is shared with or among other ENH Acute Care Hospitals.

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- P. “Hospital Provider Contract” means a contract between a Payor and any hospital to provide General Acute Care Inpatient Hospital Services and related healthcare services to enrollees of health plans.
- Q. “HPH Name and Marks” means the name “Highland Park Hospital” and “HPH,” and any variation of these names, in connection with the Highland Park 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 unpublished works, relating to the Highland Park Hospital Assets.
- R. “Intellectual Property” means, without limitation: (i) the HPH Name and Marks; (ii) all copyrights, copyright registrations and applications, in both published works and unpublished works, other than those associated with the HPH Name and Marks; (iii) all patents, patent applications, applications, and inventions and discoveries that may be patentable; (iv) all know-how, trade secrets, software, technical information, data, registrations, applications for governmental approvals, inventions, processes, best practices (including clinical pathways), formulae, protocols, protocols, standards, methods, techniques, designs, quality control practices and information, research and test procedures and information, and safety, environmental and health practices and information; (v) all confidential or proprietary information, commercial information, management systems, business processes and practices, customer lists, customer information, customer records and and files, customer communications, procurement practices practices and information, supplier qualification and approval practices and information, training materials, sales sales and marketing materials, customer support materials,

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advertising and promotional materials; and (vi) all rights in in any jurisdiction to limit the use or disclosure of any of the 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.

- S. “Merger” means the merger of Highland Park Hospital into ENH pursuant to the Agreement and Plan of Merger among Evanston Northwestern Healthcare Corporation, Lakeland Health Services, Inc., and Highland Park Hospital, dated as of October 29, 1999, which was consummated on or about January 1, 2000.
- T. “Monitor” means the Person appointed pursuant to Paragraph V of this Order.
- U. “Payor” means any Person that pays, or arranges for payment, for all or part of any General Acute Care Inpatient Hospital Services for itself or for any other Person. Payor includes any Person that develops, leases, or sells access to networks of Acute Care Hospitals.
- V. “Person” means any individual, partnership, firm, corporation, association, trust, unincorporated organization or other entity or governmental body.
- W. “Post-Merger Hospital Business” means all activities relating to the provision of General Acute Care Inpatient Hospital Services and other related health care services conducted by ENH after the Merger, including, but not limited to, all health care services, including outpatient services, offered at Highland Park Hospital.
- X. “Pre-Merger Highland Park Hospital Business” means all activities relating to the provision of General Acute Care Inpatient Hospital Services and other related healthcare

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services that Highland Park Hospital was offering prior to the Merger.

Y. “Respondent” means ENH.

Z. “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.

AA. “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.

BB. “Transitional Services” means Transitional Administrative Services and Transitional Clinical Services.

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

A. No later than one hundred eighty (180) days from the date the divestiture requirements of this Order become final, Respondent shall divest and convey the Highland Park Hospital Assets at no minimum price, absolutely and in good faith, to an Acquirer that receives the prior approval of the Commission and in a manner (including an executed divestiture agreement) that receives the prior approval of the Commission. To the extent that:

1. The Highland Park Hospital Assets as of the date the divestiture requirements of this Order become final do

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not include (i) assets that Respondent acquired on the date of the Merger, or (ii) assets that replaced those acquired on the date of the Merger, (iii) any other assets assets that Respondent acquired and has used in or that are related to the Post-Merger Hospital Business in Highland Park, Illinois, *then* Respondent shall add to the the Highland Park Hospital Assets additional assets (of a a quality that meets generally acceptable standards of performance) to replace the assets that no longer exist, are no longer controlled by Respondent, or are no longer longer located in Highland Park, Illinois;

2. After the Merger and prior to the date the divestiture requirements of this Order become final, Respondent terminated any clinical service, clinical program, support function, or management function (i) performed by the Pre-Merger Highland Park Hospital Business, or (ii) performed by the Post-Merger Hospital Business in Highland Park, Illinois, *then* Respondent shall restore such service, program, or function (of a quality that meets generally acceptable standards of care or performance), no later than the date the Highland Park Hospital Assets are divested, or any other date that receives the prior approval of the Commission.

Provided, however, that Respondent shall not be required to to replace any asset or to restore any service, program or function contemplated by Paragraphs II.A.1 or II.A.2 of this this Order if, in each instance, Respondent can demonstrate demonstrate to the Commission that termination of such asset, service, program or function was for good cause or that the Acquirer does not need such asset, service, program program or function to effectively operate the Acquirer Hospital Business in a manner consistent with the purpose of of this Order, and the Commission approves the divestiture

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without the replacement or restoration of such asset, service, service, program or function.

- B. Respondent shall comply with all terms of the Divestiture Agreement approved by the Commission pursuant to this Order, and any breach by Respondent of any term of the Divestiture Agreement shall constitute a violation of this Order.
- C. Respondent shall cooperate with the Acquirer to ensure that the Highland Park Hospital Assets are transferred to the Acquirer as a financially and competitively viable Acute Care Hospital operating as an ongoing business, including but not limited to providing assistance necessary to transfer to the Acquirer all governmental approvals needed to operate the Highland Park Hospital Assets as an Acute Care Hospital.
- D. No later than the date the Highland Park Hospital Assets are divested, to the extent allowable under the existing ENH Licenses, ENH shall grant to the Acquirer an ENH License to all Licensed Intellectual Property for any use in the Acquirer Hospital Business, and shall take all actions necessary to facilitate the unrestricted use of the Licensed Intellectual Property by the Acquirer.
- E. Respondent shall take all actions necessary and shall effect all arrangements in connection with the divestiture of the Highland Park Hospital Assets as will ensure that the Acquirer can conduct the Acquirer Hospital Business in substantially the same manner as Respondent has conducted conducted the Post-Merger Hospital Business at Highland Park Hospital, with an independent full-service medical staff staff capable of providing General Acute Care Inpatient Hospital Services, and an independent full-service hospital staff and management, including, but not limited to,

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providing Transitional Services, the opportunity to recruit and employ ENH Employees, and the opportunity to recruit, recruit, contract with, and extend medical staff privileges to to any ENH Medical Staff Member, including as provided in in Paragraphs II.F, II.G, and II.H of this Order.

- F. At the request of the Acquirer, for a period not to exceed twelve (12) months from the date Respondent divests the Highland Park Hospital Assets, 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. Respondent shall provide Transitional Services to the Acquirer sufficient to enable the Acquirer to conduct the Acquirer Hospital Business in substantially the same manner that Respondent has conducted the Post-Merger Hospital Business at Highland Park Hospital; and
 2. Respondent shall provide the Transitional Services required by this Paragraph II.F at substantially the same level and quality as such services are provided by Respondent in connection with its operation of the Post-Merger Hospital Business.

Provided, however, that Respondent shall not (i) require the 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 Transitional Services because of a material breach by the Acquirer of any agreement to provide such assistance, in the 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 damages (such as indirect, special, and consequential

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damages) that the Acquirer would be entitled to seek in the event of Respondent's breach of such agreement.

- G. Respondent shall allow the Acquirer an opportunity to recruit and employ any ENH Employee in connection with the divestiture of the Highland Park 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 six (6) weeks before execution of a divestiture agreement, Respondent shall (i) identify each ENH Employee, (ii) allow the Acquirer an opportunity to interview any ENH Employee, and (iii) allow the Acquirer to inspect the personnel files and other documentation relating to any ENH Employee, to the extent permissible under applicable laws.
 2. Respondent shall (i) not offer any incentive to any ENH Employee to decline employment with the Acquirer, (ii) remove any contractual impediments with Respondent that may deter any ENH Employee from accepting employment with 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 the ENH Employee to be employed by the Acquirer, and (iii) not otherwise interfere with the recruitment of any ENH Employee by the Acquirer, including, but not limited to, by refusing or threatening to refuse to extend medical staff privileges at any Respondent Acute Care Hospital.
 3. For a period of two (2) years from the date the divestiture of the Highland Park Hospital Assets is completed, Respondent shall not, directly or indirectly,

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hire or enter into any arrangement for the services of any any ENH Employee employed by the Acquirer, unless such ENH Employee's employment has been terminated terminated by the Acquirer; *provided, however*, this Paragraph II.G.3 shall not prohibit Respondent from: (i) (i) advertising for employees in newspapers, trade publications, or other media not targeted specifically at the employees, or (ii) hiring employees who apply for employment with Respondent, as long as such employees were not solicited by Respondent in violation violation of this Paragraph II.G.3.

- H. Respondent shall allow the Acquirer an unimpeded opportunity to recruit, contract with, and otherwise extend medical staff privileges to any ENH Medical Staff Member in connection with the divestiture of the Highland Park 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, Respondent shall (i) identify each ENH Medical Staff Member, (ii) allow the Acquirer an opportunity to interview any ENH Medical Staff Member, and (iii) allow the Acquirer to inspect the files and other documentation relating to any ENH Medical Staff Member, to the extent permissible under applicable laws.
 2. Respondent shall (i) not offer any incentive to any ENH ENH Medical Staff Member to decline to join the Acquirer's medical staff, (ii) remove any contractual impediments with Respondent that may deter any ENH ENH Medical Staff Member from joining the Acquirer's Acquirer's medical staff, including, but not limited to, any non- compete or confidentiality provisions of employment or other contracts with Respondent that

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would affect the ability of the ENH Medical Staff Members to be recruited by the Acquirer, and (iii) not otherwise interfere with the recruitment of any ENH Medical Staff Member by the Acquirer, including, but not limited to, by refusing or threatening to refuse to extend medical staff privileges at any Respondent Acute Care Hospital.

- I. Except in the course of performing its obligations under this Order, Respondent 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 its obligations under this Order and (ii) only to Persons who agree in writing to maintain the confidentiality of such information;
 3. enforce the terms of this Paragraph II.I 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.I, including any actions that Respondent would take to protect its own trade secrets or sensitive or proprietary commercial or financial information.

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- J. No later than ninety (90) days from the date the Highland Park Hospital Assets are divested, Respondent shall terminate any Hospital Provider Contract negotiated or amended after the Merger that is in effect as of the date the divestiture provisions of this Order become final; provided, however, that nothing in this Paragraph II.J. shall preclude Respondent (i) from completing any post-termination obligations relating to any Hospital Provider Contract or (ii) from entering into a new Hospital Provider Contract with any Payor after the current contract has been terminated.

III.

IT IS FURTHER ORDERED that:

- A. From the date this Order becomes final (without regard to the finality of the divestiture requirements herein) until the date the Highland Park Hospital Assets are divested pursuant to this Order, Respondent shall take such actions as are necessary to maintain the viability, marketability, and competitiveness of the Highland Park Hospital Assets and the Post-Merger Hospital Business relating to the Highland Park Hospital Assets. Among other things that may be necessary, Respondent shall:
1. Maintain the operations of the Post-Merger Hospital Business relating to the Highland Park Hospital Assets in the ordinary course of business and in accordance with past practice (including regular repair and maintenance of the Highland Park Hospital Assets).
 2. Use best efforts to maintain and increase sales of the Post-Merger Hospital Business relating to the Highland Highland Park Hospital Assets, and to maintain at budgeted levels for the year 2005 or the current year, whichever are higher, for all administrative, technical,

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and marketing support for the Post-Merger Hospital Business relating to the Highland Park Hospital Assets. Assets.

3. Use best efforts to maintain the current workforce and to retain the services of employees and agents in connection with the Post-Merger Hospital Business relating to the Highland Park Hospital Assets, including payment of bonuses as necessary, and maintain the relations and good will with customers, suppliers, vendors, employees, landlords, creditors, agents, and others having business relationships with the Post-Merger Hospital Business relating to the Highland Park Hospital Assets.
 4. Assure that Respondent's employees with primary responsibility for managing and operating the Post-Merger Hospital Business relating to the Highland Park Hospital Assets are not transferred or reassigned to other areas within Respondent's organization except for transfer bids initiated by employees pursuant to Respondent's regular, established job posting policy.
 5. Provide sufficient working capital to maintain the Post-Merger Hospital Business relating to the Highland Park 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 Highland Park Hospital Assets.
- B. No later than forty five (45) days from the date this Order becomes final, Respondent shall file a verified written report

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report to the Commission that identifies (i) all assets included in the Highland Park Hospital Assets, (ii) all assets originally acquired or that replace assets originally acquired by Respondent as a result of the Merger, (iii) all assets relating to the Post-Merger Hospital Business in Highland Park, Illinois, that are not included in the Highland Park Hospital Assets, and (iv) all clinical services, support functions, and management functions that that ENH discontinued at Highland Park Hospital after the Merger (hereinafter “Accounting”).

IV.

IT IS FURTHER ORDERED that no later than ten (10) days from the date this Order becomes final (without regard to the finality of the divestiture requirements herein), Respondent shall provide a copy of this Order and Complaint to each of Respondent’s officers, employees, or agents having managerial responsibility for any of Respondent’s obligations under Paragraphs II and III of this Order.

V.

IT IS FURTHER ORDERED that:

- A. At any time after this Order becomes final (without regard to the finality of the divestiture requirements herein), the Commission may appoint a Person (“Monitor”) to monitor Respondent’s compliance with its obligations under this Order, consult with Commission staff, and report to the Commission regarding Respondent’s compliance with its obligations under this Order.
- B. If a Monitor is appointed pursuant to Paragraph V.A of this Order, Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Monitor:

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1. The Monitor shall have the power and authority to monitor Respondent'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 the purposes of this Order and in consultation with the Commission or its staff.
2. Within ten (10) days after appointment of the Monitor, Respondent 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 Respondent's compliance with the terms of this Order in a manner consistent with the purposes of this Order. If requested by Respondent, 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 V.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 V shall terminate three business days after the Monitor has completed his or her final report pursuant to Paragraph V.B.7(ii), or at such other time as directed by the Commission.
4. Respondent 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 Respondent's books, records, records, documents, personnel, facilities and technical

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information relating to compliance with this Order, or to any other relevant information, as the Monitor may reasonably request. Respondent shall cooperate with any any reasonable request of the Monitor. Respondent shall take no action to interfere with or impede the Monitor's ability to monitor Respondent's compliance with this Order.

5. The 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 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 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. 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.
 7. The Monitor shall report in writing to the Commission (i) every sixty (60) days from the date this Order becomes final, (ii) no later than thirty (30) days from the date Respondent completes its obligations under this Order, and (iii) at any other time as requested by the staff of the Commission, concerning Respondent's compliance with this Order.
- C. Respondent shall submit the following reports to the Monitor: (i) no later than twenty (20) days after the date the the Monitor is appointed by the Commission pursuant to

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Paragraph V.A, a copy of the Accounting required by Paragraph III.B of this Order; and (ii) copies of all compliance reports filed with the Commission.

- D. 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.

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

- A. If Respondent has not divested, absolutely and in good faith the Highland Park Hospital Assets within the time and manner required by Paragraph II.A of this Order, the Commission may at any time appoint one or more Persons as Divestiture Trustee to divest the Highland Park Hospital Assets, at no minimum price, in a manner that satisfies the requirements of this Order.
- B. In the event that the Commission or the Attorney General brings an action pursuant to § 5(1) of the Federal Trade Commission Act, 15 U.S.C. § 45(1), or any other statute enforced by the Commission, Respondent 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 VI 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(1) 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.

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- C. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Paragraph VI, 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 effect the divestiture for which he or she has been appointed pursuant to the terms 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, Respondent 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 Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the divestiture 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 VI.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. Respondent shall provide the Divestiture Trustee with full and complete access to the personnel, books, records records and facilities related to the assets to be divested,

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divested, or to any other relevant information, as the Divestiture Trustee may request. Respondent shall develop such financial or other information as such Divestiture Trustee may reasonably 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 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 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 Respondent from among those approved by the Commission; *provided, further*, that Respondent 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 Respondent, on such reasonable and customary terms and conditions as the Commission or a court may set. The

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Divestiture Trustee shall have the authority to employ, at at the cost and expense of Respondent, such consultants, consultants, accountants, attorneys, investment bankers, bankers, business brokers, appraisers, and other representatives and assistants as are necessary to carry out the Divestiture Trustee's duties and responsibilities. responsibilities. The Divestiture Trustee shall account for for all monies derived from the divestiture and all expenses incurred. After approval by the Commission or, or, in the case of a court-appointed Divestiture Trustee, by the court, of the account of the Divestiture Trustee, including fees for his or her services, all remaining monies shall be paid at the direction of the Respondent, Respondent, and the Divestiture Trustee's power shall be be terminated. The Divestiture Trustee's compensation shall be based at least in significant part on a commission arrangement contingent on the Divestiture Trustee's divesting the assets.

7. 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 VI for appointment of the initial Divestiture Trustee.
 8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the assets to be divested.
 9. 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 at the request of the Divestiture Trustee, issue such

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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. Respondent 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 (without regard to the finality of the divestiture requirements herein), and every thirty (30) days thereafter (measured from the date the first report is filed) until the divestiture of the Highland Park Hospital Assets is accomplished, and (ii) thereafter, every sixty (60) days (measured from the date of divestiture) until the date Respondent completes its obligations under this Order; *provided, however*, that Respondent shall also file the report required by this Paragraph VII at any other time as the Commission may require.
- B. Respondent 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.

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VIII.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to (1) any proposed dissolution of Respondent, (2) any proposed acquisition, merger or consolidation of Respondent, or (3) any other change in Respondent 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 Respondent.

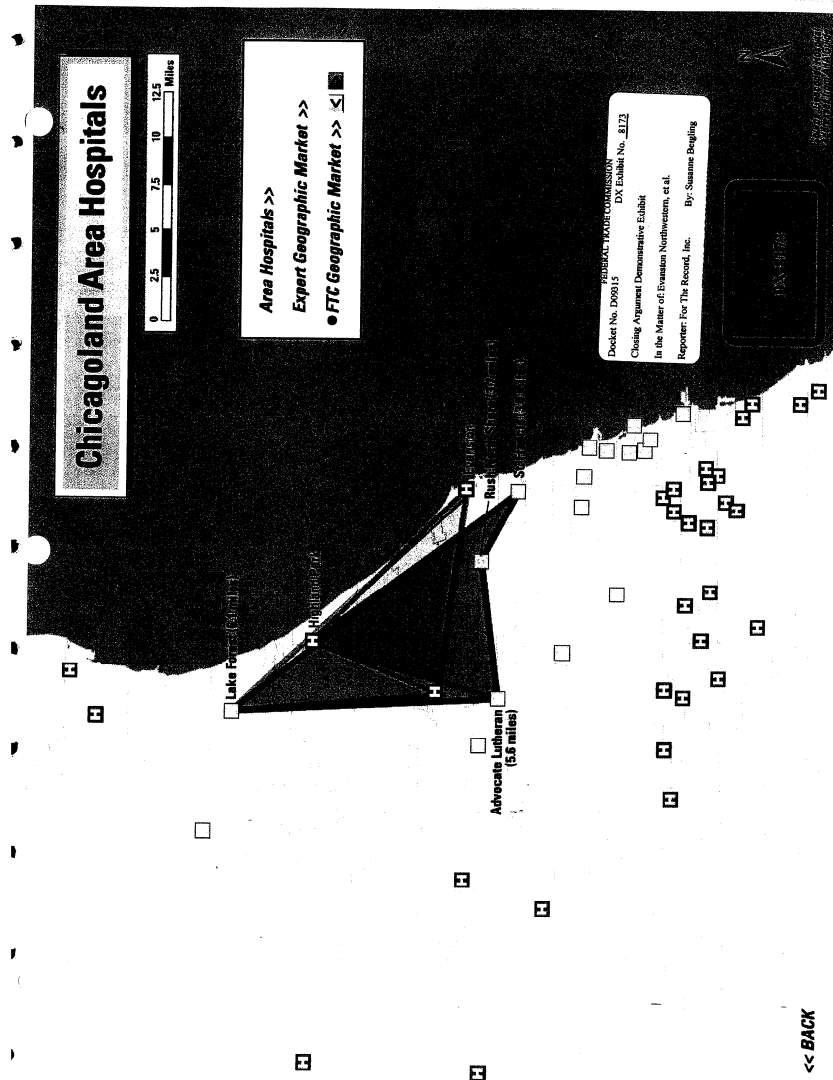
IX.

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, 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 relating to any matter contained in this Order; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from them, to interview their officers, directors, or employees, who may have counsel present, regarding any such matters.

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ATTACHMENT 1



Opinion of the Commission

OPINION OF THE COMMISSION

By Majoras, Chairman

I. INTRODUCTION¹

In 2000, Evanston Northwestern Healthcare Corporation (“Evanston”) merged with Highland Park Hospital (“Highland Park”). Prior to the merger, Evanston owned Evanston Hospital and Glenbrook Hospital.²

The Commission issued an administrative complaint challenging Evanston’s acquisition of Highland Park under Section 7 of the Clayton Act four years after the transaction closed. Given that the merger was consummated well before the Commission commenced this case, we were able to examine not

¹ This opinion uses the following abbreviations:

- CB – Complaint Counsel’s Brief on Appeal and Cross-Appeal
- CFF – Complaint Counsel’s Proposed Findings of Fact
- CX – Complaint Counsel’s Exhibit
- DX – Demonstrative Exhibit
- ID – Initial Decision of the Administrative Law Judge
- IDF – Numbered Findings of Fact in the ALJ’s Initial Opinion
- JX – Joint Exhibits
- RB – Respondent’s Appeal Brief
- RFF – Respondent’s Proposed Findings of Fact
- RFF Reply – Respondent’s Reply Findings of Fact
- RPTB – Respondent’s Post-Trial Brief
- RRB – Respondent’s Brief in Reply and Opposition to Cross-Appeal
- RX – Respondent’s Exhibit
- TR – Transcript of Trial before the ALJ.

² In this opinion, unless otherwise noted, we adopt complaint counsel’s convention of referring to the pre-merger Evanston Northwestern Healthcare Corporation entity (including Glenbrook Hospital) as “Evanston” or “Evanston Hospital.” “Highland Park” refers to the pre- and post-merger Highland Park Hospital facility, as well as Lakeland Health Services, Inc., the parent corporation of Highland Park Hospital prior to the merger. “ENH” refers to the post-merger entity that includes Evanston Hospital, Glenbrook Hospital, and Highland Park Hospital.

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only pre-merger evidence, but also evidence about what happened after the merger.

There is no dispute that ENH substantially raised its prices shortly after the merging parties consummated the transaction. There is disagreement about the cause of those price increases, however. Complaint counsel maintains that the merger eliminated significant competition between Evanston and Highland Park, which allowed ENH to exercise market power against health care insurance companies. Respondent argues that, during the due diligence process for the merger, ENH obtained information about Highland Park's prices that showed that Evanston had been charging rates that were below competitive levels for a number of years. Respondent contends that most of ENH's merger-related price increases simply reflect its efforts to raise Evanston Hospital's prices to competitive rates. Respondent also maintains that some portion of the merger-related price increases reflects increased demand for Highland Park's services due to post-merger improvements at the hospital.

Chief Administrative Law Judge Stephen J. McGuire ("ALJ") found in his Initial Decision that the transaction violated Section 7 of the Clayton Act and ordered ENH to divest Highland Park. We affirm the ALJ's decision that the transaction violated Section 7 of the Clayton Act. Considered as a whole, the evidence demonstrates that the transaction enabled the merged firm to exercise market power and that the resulting anticompetitive effects were not offset by merger-specific efficiencies. The record shows that senior officials at Evanston and Highland Park anticipated that the merger would give them greater leverage to raise prices, that the merged firm did raise its prices immediately and substantially after completion of the transaction, and that the same senior officials attributed the price increases in part to increased bargaining leverage produced by the merger.

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The econometric analyses performed by both complaint counsel's and Respondent's economists also strongly support the conclusion that the merger gave the combined entity the ability to raise prices through the exercise of market power. The economists determined that there were substantial merger-coincident price increases and ran regressions using different data sets and a variety of control groups that ruled out the most likely competitively-benign explanations for substantial portions of these increases. The record does not support Respondent's position that the merger-coincident price increases reflect ENH's attempts to correct a multi-year failure by Evanston's senior officials to charge market rates to many of its customers, or increased demand for Highland Park's services due to post-merger improvements.

We do not agree with the ALJ, however, that a divestiture is warranted. The potentially high costs inherent in the separation of hospitals that have functioned as a merged entity for seven years instead warrant a remedy that restores the lost competition through injunctive relief.

II. PROCEDURAL HISTORY

A. Pleadings

The Commission issued a three-count complaint on February 10, 2004. The first count alleged that the merger violated Section 7 of the Clayton Act in specified relevant product and geographic markets. Compl. ¶¶ 16-17, 27. The complaint alleged that the relevant product market was "general acute care inpatient hospital services" and that the relevant geographic market consisted of the "area directly proximate to the three ENH hospitals and contiguous geographic areas in northeast Cook County and southeast Lake County, Illinois." *Id.* ¶¶ 16-17.

Count II charged that the transaction violated the Clayton Act because it enabled ENH to raise its prices to private payors above

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the prices that the hospitals would have charged absent the merger. merger. *Id.* ¶ 32. Unlike Count I, however, Count II did not allege a particular product or geographic market and did not incorporate the complaint's earlier product market and geographic market allegations by reference. *Id.* ¶¶ 29-32.

Respondent denied the material allegations of Counts I and II. Respondent also asserted a number of defenses, the most pertinent of which is that the merger yielded significant efficiencies and improvements in the quality of patient care that outweigh any alleged anticompetitive effects. Second Am. Answer, ¶¶ 1-15, 20-21.

The complaint's third count alleged that ENH had engaged in price fixing on behalf of physicians whom it employed and other affiliated physicians. Compl. ¶¶ 33-44. This count was resolved by a by a consent agreement, which became final on May 17, 2005.³ Count III is not at issue in this appeal.

B. Initial Decision

The case was assigned to the ALJ, who conducted an eight-week trial. Forty-two witnesses testified, and the ALJ admitted more than 1600 exhibits into evidence.

The ALJ issued his Initial Decision on October 17, 2005. The ALJ first made careful and extensive findings of fact about the merging parties, the health care sector, and the transaction's competitive effects. The ALJ then started his legal analysis by holding that the Clayton Act requires complaint counsel to prove the the relevant product and geographic markets. ID 131. Complaint counsel argued at trial that the relevant product market was general general acute care inpatient services sold by hospitals to private

³ In re Evanston Northwestern Healthcare Corp., Dkt. No. 9315 (FTC May 17, 2005), available at <http://www.ftc.gov/os/adjpro/d9315/050520do.pdf>.

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health insurance companies, which typically are referred to as managed care organizations or “MCOs.” *Id.* ENH maintained that the product market also included hospital-supplied outpatient services. ID 131-32; RPTB 16-17. The ALJ rejected ENH’s position and found that MCOs cannot substitute outpatient for inpatient services, determining that ENH had set its inpatient rates without concern that patients would switch from inpatient to outpatient services. ID 133.⁴

The ALJ then defined the relevant geographic market. ID 135-49. Complaint counsel argued that the geographic market consisted of the geographic triangle immediately surrounding the three merging hospitals, which contained only the ENH hospitals. ID 137. Respondent advocated that the geographic market included the three ENH hospitals and at least six other hospitals (Lake Forest, Advocate Lutheran General, Rush North Shore, St. Francis, Condell, and Resurrection). *Id.* The ALJ held that the geographic market was larger than that proposed by complaint counsel, but smaller than the market advocated by respondent, finding that the geographic market consisted of the area that covered the three ENH hospitals and four other hospitals – Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. ID 143.

The ALJ next assessed the competitive effects of the merger. ID 150-69. Using the seven-hospital geographic market, the ALJ found that the ENH hospitals had a 35% pre-merger market share based on inpatient revenues. IDF ¶ 317. The ALJ then calculated a

⁴ Relying on the U.S. Court of Appeals for the Seventh Circuit’s decision in *United States v. Rockford Memorial Corp.*, 898 F.2d 1278, 1284 (7th Cir. 1990), the ALJ also held that the fact that inpatient and outpatient services have a common provider does not compel a finding that they are in the same relevant product market. ID 133-34.

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pre-merger Herfindahl-Hirschman Index (“HHI”)⁵ of 2355, and a post-merger HHI increase of 384 to 2739. IDF ¶¶ 314-19. The ALJ found that, under § 1.51 of the Department of Justice’s and Federal Trade Commission’s *Merger Guidelines*, the HHI change and post-merger HHI created a presumption that the merger was likely to create or enhance market power. IDF ¶¶ 314-25; ID 150-52. 150-52.

The ALJ also considered direct evidence of the transaction’s effect on competition. The ALJ found that senior officials at Evanston and Highland Park had predicted before the merger that the transaction would put the combined firm in a better bargaining position with the MCOs, that ENH’s revenues increased substantially after the merger, and that ENH management believed that the merger had “translated to better managed care contracts.” ID 155-60, 165. The ALJ also relied heavily on the econometric evidence presented at trial, which he found, viewed in conjunction with other evidence, supported a finding that market power was “the only plausible, economically sound, and factually well-founded explanation for ENH’s post-merger relative price increases.” ID 166-69.

The ALJ also concluded that entry by new hospitals, or expansion by existing hospitals, was not likely to replace the competition lost due to the merger. ID 194-95. Finally, the ALJ concluded that the merger had not produced significant improvements in the quality of care at Highland Park that offset the anticompetitive exercise of market power. ID 175-92.

Based on his findings of fact and conclusions of law, the ALJ ruled that the transaction violated the Clayton Act, as alleged in

⁵ The HHI is calculated by summing the squares of the individual market shares of all the participants. U.S. Dep’t of Justice & Federal Trade Comm’n, Horizontal Merger Guidelines § 1.5 (1992, revised 1997) (“Merger Guidelines”), available at <http://www.ftc.gov/bc/docs/horizmer.htm>.

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Count I of the complaint. ID 200.⁶ The ALJ dismissed Count II as moot, but held that, if it were not moot, he would have dismissed it because complaint counsel had not established as part of Count II that respondent possessed a substantial share of a relevant market. ID 200-01. As stated, the ALJ ordered ENH to divest Highland Park. ENH appealed the ALJ's Initial Decision to the Commission. Complaint counsel cross-appealed the ALJ's decision decision not to make a ruling against respondent under Count II and also requested that the Commission supplement and revise the ALJ's divestiture order.⁷

⁶ The ALJ rejected several other arguments made by ENH. First, he rejected ENH's contention that its nonprofit status reduced the likelihood of competitive harm, finding that there was no evidence in the record that ENH's nonprofit status had restrained its efforts to negotiate higher prices. ID 192-94. Second, the ALJ rejected ENH's argument that the merger was necessary for Highland Park's economic survival, concluding that, at the time of the merger, Highland Park was able to meet its financial obligations for the near future, and was in no danger of entering bankruptcy or exiting the market. ID 197. Finally, the ALJ rejected ENH's position that the merger of Evanston and Highland Park could not violate the Clayton Act because, at the time of the merger, the two hospitals were not separate entities. ID 197-99. He found that the two hospitals were separate entities and that the transaction was subject to the Clayton Act. ID 197-99. Respondent did not identify this last issue as one of the "questions presented" on appeal, RB 23, and only briefly referenced it at the end of its brief in the context of discussing the appropriate remedy. RB 86. Accordingly, the Commission views the issue as not properly before us. In any case, for the reasons set forth by the ALJ, the Commission also finds that the transaction was subject to the Clayton Act.

⁷ Complaint counsel also requested that the Commission vacate the ALJ's order of September 24, 2006, which denied complaint counsel's motion to compel the production of certain documents on respondent's electronic back-up tapes. The Commission denies this request because the issue is now moot.

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III. STANDARD OF REVIEW

Pursuant to 16 C.F.R. § 3.54 (2007), the Commission reviews the the record *de novo* by considering “such parts of the record as are cited or as may be necessary to resolve the issues presented and exercis[ing] all the powers which [the Commission] could have exercised if it had made the initial decision.”⁸

IV. FINDINGS OF FACT**A. Third-Party Payor Insurance System**

In many markets, vendors set or negotiate a price, which is paid paid in full by their customers. The costs and benefits of the product product or service are fully internalized by the vendors and the customers. The market for hospital services is more complex. Hospitals and patients rarely negotiate directly over the price of hospital services, and patients almost never pay directly the full cost cost of the hospital services that they receive. TR 480 (Mendonsa); (Mendonsa); TR 2456-58, 2461, 2464-65 (Haas-Wilson); TR 5906 5906 (Noether). Instead, various types of “third-party payors” (primarily public and private insurance entities) negotiate the prices prices in advance on a periodic basis, and pay the bulk of the hospitals’ charges. TR 480 (Mendonsa); TR 2457-58, 2461 (Haas-(Haas-Wilson); RX 1743 at 6-7. Private insurance companies then sell health care policies to employers and individuals, who pay premiums for the policies. TR 2461-62 (Haas-Wilson). Individual

⁸ We adopt the ALJ’s findings of fact to the extent those findings are not inconsistent with this opinion. In addition, unless otherwise noted, any Commission citation to any trial testimony, exhibit, or deposition segment in this opinion constitutes a determination by the Commission that the cited testimony, exhibit, or deposition segment is relevant, material, and reliable evidence, and therefore admitted into the record of this proceeding. 16 C.F.R. § 3.43(b). Each such determination shall be conclusive, with respect to determining the contents of the record of this proceeding, notwithstanding any objection or response thereto registered by either complaint counsel or counsel for respondent.

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members often also pay a co-payment amount or a deductible when they use hospital services. TR 477-78 (Mendonsa); TR 2464 (Haas-Wilson).

The primary public third-party payors are the federal government's Medicare and the joint federal and state Medicaid programs. Medicare provides health insurance for the elderly, and Medicaid provides coverage for low-income persons. TR 2454 (Haas-Wilson). ENH obtains slightly less than half of its revenues from patients who are covered by the Medicare or Medicaid programs. IDF ¶¶ 127, 134-35. We do not discuss the Medicare and Medicaid systems further because complaint counsel did not allege that the merger increased the prices paid by Medicare or Medicaid for hospital services.

Approximately half of ENH's revenues come from private insurers. IDF ¶ 134.⁹ The United States has a largely employer-based health care system in which a majority of consumers who have private health insurance obtain it through their employers. Typically, consumers select an insurance plan from one or more private insurance companies with which their employers have contracted. TR 2460-61 (Haas-Wilson).

The private health insurance market has changed substantially over the past two decades. In the 1980s, the predominant type of insurance in Chicago was indemnity insurance. IDF ¶ 153; TR 1831-32 (Hillebrand). In a typical indemnity plan, the consumer could select any hospital (or doctor), and the insurance company reimbursed the individual a set amount based on the care provided. IDF ¶ 155. Because indemnity plans allowed their insureds to select any hospital or provider, hospitals did not need to compete to be covered by the plans. TR 2466 (Haas-Wilson).

Concerns about rising costs, among other factors, gave rise to MCOs, which now account for the vast majority of private insurance

⁹ The remaining portions of ENH's volume are charity care and a very small percentage of patients who self-pay. IDF ¶ 137.

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insurance in the Chicago market. TR 1832-33 (Hillebrand). There are two broad categories of MCO plans: health maintenance organization plans (“HMOs”) and preferred provider organization plans (“PPOs”). An HMO plan provides coverage to members through a “network” of physicians, hospitals, and other health care providers that contract to furnish such services. RX 1743 at 6. 6. An HMO is generally a fully insured product: employers and consumers pay premiums to the provider of the HMO, and the provider assumes the risk that those premiums will be sufficient to cover the members’ healthcare expenses. TR 585 (Neary). Because the insurance company assumes the risk, HMO plans often have a smaller network of physicians and hospitals than do risk-sharing plans, and they provide benefits only to members who receive care from in-network providers. TR 1759-60 (Hillebrand); TR 477 (Mendonsa).

PPOs include elements of both managed care and fee-for-service fee-for-service arrangements.. RX 1743 at 6. A typical PPO plan has contracts with a range of health care providers that is larger than than the range of providers in an HMO network. TR 2460 (Haas-(Haas-Wilson). PPOs generally offer members substantial financial financial incentives to obtain their health care “in network” or from from “preferred providers.” TR 477-78 (Mendonsa); RX 1743 at 6. 6. PPO members, however, can obtain health care from other providers at additional cost. IDF ¶ 148; TR 477-78 (Mendonsa). Many MCOs offer both HMO and PPO plans. TR 477 (Mendonsa).¹⁰

Depending on the type of insurance plan, when consumers receive services from an in-network hospital, they pay a deductible deductible and/or a co-payment, RX 1743 at 6, which usually

¹⁰ There are also point of service plans (POS). A POS is a variation of a PPO that contracts with a limited number of hospitals and doctors and extends terms of coverage to enrollees based on terms that vary depending on the provider from which the enrollee seeks care. CFF ¶¶ 187-88.

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constitutes a small portion of the total price for the services that the patient receives. PPOs generally are more expensive than HMOs because they provide coverage or reimbursement for a larger set of providers. In the Chicago area, the use of HMOs has declined substantially in favor of PPOs. TR 1834 (Hillebrand); TR 479-80 (Mendonsa).

B. Competition Among Hospitals for MCO Contracts

MCOs enter into two basic types of contracts with hospitals – “per diem” and “discount off charges.” In per diem contracts, there is an all-inclusive per day charge, based on the class of services, for each day that the patient is in the hospital, regardless of the amount or the total cost of the services that the patient receives. IDF ¶ 178; JX 8 at 8-9. Under discount off charges contracts, the MCO agrees to pay the hospital a rate for each service performed. The paid rate is equal to the hospital’s list price of the service, discounted by an agreed upon percentage. IDF ¶ 173. The list prices are contained in the hospital’s “chargemaster.” IDF ¶ 175. Thus, the prices paid by MCOs increase as a hospital increases the prices in its chargemaster. All else being equal, MCOs usually prefer per diem contracts because they allow for greater certainty about MCOs’ costs. IDF ¶¶ 179-80; TR 5740 (Sirabian).

MCOs do not typically select every hospital in a geographic region for their HMO networks, IDF 158, and they do not designate every provider as preferred for their PPOs. IDF ¶¶ 158-67; 158-67; TR 2457-60 (Haas-Wilson). Rather, physicians and hospitals compete to be included in HMO and PPO networks. IDF ¶ 109. The central terms of competition are price, quality of service, service, and geographic proximity to the MCO’s members. IDF ¶¶ 109, 121. The use of a business model that potentially excludes some providers allows MCOs to leverage competing providers against each other to negotiate lower prices. TR 2470 (Haas-Wilson); TR 6189 (Noether). Through this competitive process, MCOs seek to assemble high-quality networks at competitive rates

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that include a sufficient number of hospitals and physicians to attract employers and their employees. IDF ¶¶ 109, 121, 158.

C. Competition Among MCOs to be Selected by Employers

As stated, a majority of people in the United States who have private health insurance obtain it through their employers. TR 2454 2454 (Haas-Wilson).¹¹ Typically, the employer selects which MCOs and plans to offer its employees. TR 2460-61 (Haas-Wilson). Because employees sometimes consider the quality of health care benefits when they decide where to accept employment, many employers try to provide health care plans that are attractive to their employees. IDF ¶ 120; TR 2407 (Elzinga). Thus, employer demand for MCO services is a partially derived demand from employee preferences. TR 5936-37 (Noether); TR 2407 (Elzinga). As a general matter, employees prefer health plans that offer a broad choice of hospitals (and physicians) that are geographically convenient for them and their families. TR 2461 (Haas-Wilson); TR 485 (Mendonsa); TR 568 (Mendonsa), *in camera*. At the same time, employees (and employers) want to limit the amount of money that they spend on employee health benefits. TR 2461 (Haas-Wilson).

Consequently, MCOs compete to have employers offer their plans based on price, quality, the geographic convenience of the hospitals and physicians in their networks, and other factors relevant to employees and employers. IDF ¶¶ 114, 117 252-53; TR 2407-08 (Elzinga); TR 2803 (Haas-Wilson), *in camera*. Similarly, because some employers offer their employees several plans from which to choose, TR 491 (Mendonsa), an MCO needs to offer an attractive

¹¹ As respondent notes, employers generally are self-insured or fully-insured. RFF ¶ 54. Self-insured employers are responsible for the actual medical expenses of their employees but pay MCOs to access and manage the network and to process claims. TR 480 (Mendonsa). Fully-insured employers are liable only for premiums but not for the actual healthcare dollars spent by employees. RX 1743 at 6.

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network to convince employees to enroll in its plan as opposed to a plan from one of its competitors. TR 2461 (Haas-Wilson); TR 5948 (Noether).

D. Consumer Harm from Increases in Hospital Prices

Consumers are harmed when hospital prices increase due to the exercise of market power, even though they usually do not pay directly the full price of a hospital visit. TR 239 (Ballengee), *in camera*; TR 483-84 (Mendonsa); TR 549 (Mendonsa), *in camera*. When a hospital succeeds in raising its prices to an MCO, the MCO generally passes on those costs to the employers, which in turn pass them on to the employees. TR 483-84 (Mendonsa); TR 171-72, 179, 196-97 (Ballengee); TR 2463 (Haas-Wilson). Similarly, self-insured employers often pass on higher hospital costs to their employees. IDF ¶ 189. Thus, if a hospital can increase its market power by merging with a close competitor, the resulting price increases harm consumers.

Significantly, consumers who use a particular hospital will not necessarily pay for all of a price increase imposed by that hospital. Much of the cost may be borne by consumers who always use other hospitals. This is because consumers usually pay only the deductible or co-payment when they use a hospital, and MCOs do not necessarily vary these amounts for in-network or preferred providers, even when there is substantial variation among these providers' prices to the MCO. TR 2464 (Haas-Wilson). Rather, MCOs often pass on the higher costs to employers and then consumers through higher premiums or across-the-board increases to deductibles and/or co-payment amounts. TR 483-84 (Mendonsa); TR 171-72 (Ballengee). This dynamic does not reduce the anticompetitive effects of hospital price increases to MCOs due to market power, but it does alter who incurs the costs of those effects.

E. Types of Hospital Services

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Hospitals provide a wide range of services, ranging from minor outpatient procedures to complex organ transplants and experimental treatments. TR 158-59 (Ballengee); TR 622 (Neary); TR 6159-60 (Noether). There is not precise agreement about how to categorize hospital services, but the record reflects that it is appropriate to classify hospital services into three broad categories: primary, secondary, and tertiary services. Primary services generally consist of internal medicine, obstetrics, and minor surgery. IDF ¶ 197; TR 6159 (Noether); TR 1293 (Neaman). Some primary services are provided on an outpatient basis. Outpatient services generally are considered to be any service for which a patient remains in the hospital for less than twenty-four hours. TR 302 (Newton); TR 144 (Ballengee).

Secondary services largely consist of inpatient medical services services provided by a specialist, including standard surgery, and generally require more skill, expertise, or equipment than primary care services. IDF ¶ 198; TR 1294 (Neaman); TR 6159 (Noether). Tertiary services refer to major surgical or medical procedures that that are done within a hospital setting. IDF ¶ 199; TR 1294 (Neaman).¹²

F. Parties**1. Evanston Northwestern Healthcare**

¹² There are even more complex medical services, which sometimes are referred to as “quaternary services.” TR 1294 (Neaman); TR 2009 (Hillebrand); TR 2491 (Haas-Wilson); TR 2701 (Haas-Wilson), in camera. The record does not indicate that there is a consensus about how to categorize these services, but they include procedures such as solid organ transplants and treatment for severe burns, TR 2491 (Haas-Wilson), and require very specific human and physical capital. TR 2701 (Haas-Wilson), in camera. Neither Evanston nor Highland Park provides these types of medical services. TR 298 (Newton); TR 1295, 1378 (Neaman); TR 2009-10 (Hillebrand); TR 2665 (Haas-Wilson). Other hospitals in the Chicago area, such as Northwestern Memorial Hospital and the University of Chicago, do offer these very advanced services. TR 1378 (Neaman).

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Evanston owned two hospitals, Evanston Hospital and Glenbrook Hospital (“Glenbrook”), prior to merging with Highland Park Hospital. Evanston Hospital is located in Evanston, Illinois. It is a 400-bed facility that provides a range of primary, secondary, and tertiary services. For example, Evanston offers obstetrical and pediatric services, psychiatric care, neurosurgery, radiation therapy, cardiology services, orthopedics, trauma centers, and the Kellogg Cancer Care Center. CX 84 at 8; CX 681 at 2; TR 299 (Newton); TR 1291-93 (Neaman); TR 2083-84 (Spaeth).

Glenbrook is a 125-bed facility located in Glenview, Illinois. IDF ¶¶ 2, 9, 11. Glenbrook provides primary and secondary services. IDF ¶ 12.

In fiscal year 1998, Evanston Hospital and Glenbrook together generated \$441 million in revenue. CX 84 at 16. That year, 51% of Evanston’s revenue came from private MCOs, 37% from Medicare and Medicaid, and 12% from other sources. CX 84 at 8.

2. Lakeland Health Services

Highland Park Hospital was the sole subsidiary of Lakeland Health Services, Inc. The hospital is located in Highland Park, Illinois, and has approximately 150 to 200 beds. IDF ¶¶ 20, 22. Before the merger, Highland Park offered primary and secondary services, but not tertiary services. IDF ¶¶ 22, 202, 203. The services offered included obstetrical service, a level II prenatal center, pediatric services, diagnostic services, a fertility center, psychiatric care, neurosurgery, radiation therapy, cardiology services, and a level II trauma center. CX 84 at 13, 15; CX 699 at 24; TR 299 (Newton); TR 2083-88 (Spaeth).

In fiscal year 1998, Highland Park generated \$101 million in revenue. CX 84 at 16. Forty-five percent of Highland Park’s revenues that year came from MCOs, 43% from Medicare and Medicaid, and 12% from other sources. CX 84 at 13.

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G. Other Hospitals in the Geographic Region

Evanston, Glenbrook, and Highland Park Hospitals are located in the affluent suburban towns north of Chicago, generally referred to as the North Shore suburbs. IDF ¶ 227; TR 516-17 (Mendonsa), *in camera*; TR 901-02 (Foucre); TR 360 (Newton); TR 602 (Neary). The North Shore suburbs start at Evanston and include Glencoe, Wilmette, Winnetka, Kenilworth, Highland Park, and Lake Forest. TR 162-63 (Ballengee); TR 484 (Mendonsa). Regarding the hospital coverage in the area, one of the MCO witnesses testified that a person traveling up the North Shore from Chicago “would stop at Evanston” and then “Highland Park would be the next hospital.” TR 1426 (Holt-Darcy).

The three ENH hospitals form a triangle, one long side of which runs along Lake Michigan between Highland Park and Evanston Hospitals. Evanston is approximately 13.7 miles and 27 minutes south of Highland Park. IDF ¶ 21. Glenbrook is located 12.6 miles and 26 minutes west of Evanston Hospital and approximately 7 miles southwest of Highland Park. IDF ¶ 10.

There are approximately 100 hospitals in the Chicago metropolitan area, TR 5982 (Noether), but no other hospitals within the triangle formed by the three ENH hospitals. TR 901-02 (Foucre); TR 167-68 (Ballengee). There are, however, other nearby hospitals, including nine hospitals that are closer to Evanston, Glenbrook, or Highland Park than they are to each other. RX 1912 at 20, 21, *in camera*; RB 29. These hospitals include:

1. Advocate Lutheran General

Advocate Lutheran General is 10.2 miles west of Evanston Hospital, approximately a 21-minute drive. IDF ¶ 272; RX 1912 at

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at 20, *in camera*. Advocate Lutheran General is a 521-bed hospital that provides primary, secondary, and tertiary care. IDF ¶¶ 273-74. Advocate Lutheran General is the largest hospital in the Advocate system, which itself consists of eight hospitals. IDF ¶ 273; RX 1503 at 22, *in camera*; RX 1912 at 60.

2. Rush North Shore

Rush North Shore is 3.7 miles southwest of Evanston Hospital, approximately a 9-minute drive. IDF ¶ 281; RX 1912 at 20, *in camera*. Rush North Shore has 150 to 200 beds and provides primary, secondary, and some level of tertiary services. IDF ¶ 282.

3. St. Francis

St. Francis is 3 miles south of Evanston Hospital, approximately an 8-minute drive. IDF ¶ 87; RX 1912 at 20, *in camera*. St. Francis has 300 to 400 beds. IDF 288. St. Francis provides primary, secondary, and some level of tertiary services. IDF ¶ 289.

4. Resurrection

Resurrection Medical Center is 12.1 miles southwest from Evanston, approximately a 25-minute drive. IDF ¶ 298; RX 1912 at 20, *in camera*. Resurrection has 350 beds. IDF ¶ 299; RX 1912 at 60, *in camera*.

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5. Holy Family

Holy Family is 11.3 miles west of Evanston, approximately a 23-minute drive. RX 1912 at 20-21, *in camera*. Holy Family has 260 staffed beds. IDF ¶ 305.

6. Swedish Covenant

Swedish Covenant is an urban hospital located 6.8 miles south of Evanston, approximately a 19-minute drive. IDF ¶ 306; RX 1912 at 20, *in camera*. Swedish Covenant has 325 beds, IDF ¶ 306, and provides primary, secondary, and tertiary services. CFF 1935.

7. Northwestern Memorial

Northwestern Memorial is located in downtown Chicago, roughly 13 miles south of Evanston, approximately a 26-minute drive. IDF ¶ 308; RX 1912 at 20, *in camera*. Northwestern has more than 700 beds, and provides primary, secondary, and tertiary services. IDF ¶ 308. Northwestern Memorial is affiliated with the Northwestern Medical School. *Id.*

8. Lake Forest

Lake Forest is 6.1 miles northwest of Highland Park, approximately a 13-minute drive. IDF ¶ 266. Lake Forest is a 142-bed hospital, and provides primary and secondary services, including a significant level of obstetric services. IDF ¶ 267; TR 1304 (Neaman).

9. Condell

Condell is 12.7 miles northwest of Highland Park, approximately approximately a 24-minute drive. IDF ¶ 293; RX 1912 at 20, *in*

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camera. Condell is a 163-bed hospital and provides primary, secondary, and some level of tertiary services. IDF ¶¶ 294-95.

H. Parties' Pre-Merger Objectives

The parties signed a letter of intent to merge on July 1, 1999, and entered into the merger agreement in October 1999. IDF ¶¶ 81, 83. The parties completed the merger on January 1, 2000. IDF ¶ 85. The record reflects, and we find, that the parties had three objectives for the merger – raising prices, achieving economies of scale, and developing new programs at Highland Park. Mark Neaman, who joined Evanston in 1973 and has served as its Chief Executive Officer since 1992, TR 1278 (Neaman), testified that he hoped that Evanston's merger with Highland Park would allow it to obtain better prices from MCOs. TR 1036 (Neaman). The parties' pre-merger business records state that Evanston's most senior officials thought that the merger would allow Evanston to do just that. At a January 4, 1999 meeting between Evanston and Highland Park's board members and medical staff leaders, Evanston representatives identified the merger as an opportunity to "strengthen negotiation capability with managed care companies through merged entities" and not to "compete with self" in covered zip codes (*e.g.*, 60% to 70% market shares) such as Evanston, Glenview, Highland Park, and Deerfield." CX 1 at 3. Likewise, the minutes of an April 5, 1999 meeting record an Evanston representative as saying that "[t]his would be an opportunity to join forces and grow together rather than compete with each other." CX 2 at 7. In September 29, 1999, Neaman told his managers and his Board that the merger would "[i]ncrease our leverage, limited as it might be, with the managed care players and help our negotiating posture." IDF ¶ 335; CX 1566 at 9.

Neaman and Ronald Spaeth, the President and Chief Executive Officer of Highland Park before the merger, also wrote that a goal of the transaction was to "strengthen their negotiating positions with managed care" organizations. CX 19 at 1; TR 1036-1036-37 (Neaman). A Spring 1999 report by Highland Park's

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Chairman explains: “Everybody progresses [sic] to see the community benefit that would be derived as well as the economic benefit of not being out there doing battle with one another in what what will be a common battle ground if you want to call it that.” CX CX 4 at 1. Most significantly, Spaeth’s bottom-line conclusion about about the transaction was that “it would be real [sic] tough for any of of the Fortune 40 companies in this area whose CEOs either use this this place [Highland Park] or that place [Evanston Hospital and Glenbrook] to walk from Evanston, Highland Park, Glenbrook and and 1700 of their doctors.” *Id.* at 2.

We find that the testimony of Mark Newton, a former senior official at Highland Park, also supports the conclusion that Highland Park thought that the transaction would give it greater leverage to negotiate higher prices from payors. Newton testified that, before the merger, he had prepared an outline for a strategic planning retreat that identified various ways that Highland Park could increase its market share. TR 345-49 (Newton). The document identified the possibility of a merger between Highland Park and Evanston, Northwest Community, Lake Forest, or Condell Hospitals. CX 1869 at 6. Newton concluded that the merger between Highland Park and Evanston would produce the entity with the greatest negotiating strength with payors based on “the array of services, the numbers of the medical staff, as well as the communities that were being served.” TR 350-51 (Newton). He explained that “[o]f the options that we had looked at in terms of merger . . . the power in the relevant market would be higher with Highland Park and Evanston than with those others.” TR 354 (Newton). The reasons included “the proximity of the institutions, the cultural relationships that exist in that community,[and] the placement of the medical staffs.” TR 354 (Newton).

Finally, we find that Evanston’s consultants also expressed confidence, prior to the closing, that the merger would give the combined company greater bargaining leverage with MCO customers. Evanston engaged the Bain consulting firm in the fall of

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of 1999 to assist in strategic planning related to the merger. TR 1159 1159 (Neaman). In an August 30, 1999 proposal letter from Bain to Neaman, Bain wrote: “As a consequence of the merger, ENH will have broad geographic coverage on the North Shore, with three three hospitals and an extensive physician network. The merger provides the opportunity to reduce costs, refocus activities at the three hospitals, shift activity from the overcrowded Evanston Hospital, and negotiate contracts with payors from a stronger position.” CX 2072 at 1. In October 1999, in a document entitled “Growth Opportunities from the Highland Park Merger,” Bain wrote that “[b]etter integration with the ENH Medical Group and the the addition of Highland Park will substantially improve ENH’s leverage.” CX 74 at 19.

In October and November of 1999, Bain reviewed and analyzed Evanston’s and Highland Park’s contracts. CX 74; CX 75. Bain concluded that the merger would enable Evanston to grow net income by increasing revenue, due in part to higher prices and greater market share and to reduce costs through economies of scale, elimination of duplicate costs, and capital investment savings. CX 74 at 3. Bain also determined that the combined Evanston and Highland Park Hospitals would have “significant leverage with payors as [it has] the largest [number of] admissions” among other Chicago area hospitals. CX 74 at 15. An Evanston senior official testified at trial that he felt that Bain’s analyses were accurate and helpful. TR 1161(Hillebrand).

I. ENH’s Post-Merger Price Increases

After the merger closed, ENH rapidly increased the prices that it charged to most of its MCO customers to the higher of Evanston’s Evanston’s or Highland Park’s pre-merger rate for a particular service. IDF ¶¶ 348-54. ENH then set about negotiating a single contract for all three of its hospitals with each MCO. IDF ¶¶ 355-66; 355-66; TR 1528 (Holt-Darcy), *in camera*. ENH did not offer the MCOs the option to enter into separate contracts for the hospitals, or to decline to use one or more of the three hospitals. IDF ¶¶ 355-

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355-66. In addition, ENH sought to raise its prices through the conversion of portions of some of its contracts from per diem to discount off charges payment structures. IDF ¶¶ 373-77.

The record reflects that ENH's post-merger negotiation strategy was highly successful. ENH negotiated with its MCO customers a single contract for all three of its hospitals with substantial price increases, and converted a number of its contracts from per diem to discount off charges structures. CX 5174 at 11, *in camera*; CX 5 at 5; TR 252 (Ballengee), *in camera*. In addition, from 2002 to 2003, ENH increased its chargemaster rates four times. IDF ¶ 384; RX 1687 at 3, *in camera*.

As we describe in detail below in our findings about the econometrics, the actual amount of ENH's price increases depends on the calculation method. Using data that included all patients in Illinois, complaint counsel's economist, Deborah Haas-Haas-Wilson, computed that from 1998 through 2002, ENH increased its *per day* average net prices by 48% for all patients; 46% for the commercial and self-pay patients; and 46% for commercial, self-pay, self-administered, and HMO patients. CX 6279 at 7, *in camera*.¹³ On a *per case* basis, the corresponding average net price increases from 1998 to 2002 were 30%, 27%, and 26%, respectively. *Id.*, *in camera*.

Using data from individual MCOs, Haas-Wilson calculated the level of ENH's *per case* post-merger average net price changes for Aetna, Blue Cross/Blue Shield ("BCBS"), Humana, United Healthcare of Illinois ("United"), and Great West. She determined that ENH increased its *per day* average net prices by the following amounts: Aetna (48% to 56%); BCBS (-12%(decrease) to 15%); Great West (79%); Humana (57% to

¹³ As we explain below, Haas-Wilson used various techniques to construct and estimate a "net price," which consisted of the sum of (1) the payment from the MCO to the hospital, and (2) the payment from the patient to the hospital.

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82%); and United (77% to 202%). CX 6279 at 3, *in camera*; CX 6282 at 5, *in camera*. The corresponding *per case* average net price increases were: Aetna (28% to 89%); BCBS (10% to 27%); Great West (42%); Humana (27% to 73%); and United (62% to 128%). CX 6279 at 3, 5, *in camera*. The ranges of price increases reflect that the price increases varied by the type of plan offered by the MCOs (*e.g.*, HMO or PPO).

Respondent's economist, Jonathan Baker, did not compute a market-wide price increase. Instead, Baker used two different methods to compute price changes from 1998 to 2003 for Aetna, BCBS, Humana, and United. The first calculation found the following *per case* average net price increases for Evanston, Glenbrook, and Highland Park: Aetna (35%); BCBS (13%); Humana (83%); and United (138%). RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. The *per case* average net price increase across all four payors was 42%. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. The second calculation found the following *per case* average net price increases for only Evanston and Glenbrook: Aetna (25%), BCBS (2%), Humana (60%), United (140%), and an average *per case* increase across all four payors of 29%. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*.¹⁴

Post-merger ENH documents indicate that ENH executives believed that the merger gave ENH the market power needed to achieve these price increases. The minutes of a September 27, 2000 meeting of the ENH board's finance committee state that ENH's

¹⁴ Baker also performed these calculations omitting obstetrics cases because, as discussed below, there were some ambiguities in the data with respect to obstetrics. The corresponding *per case* average net price increases for Evanston, Glenbrook, and Highland Park Hospitals were: Aetna 34%, BCBS 5%, Humana 84%, and United 111%, with an average across all four payors of 37%. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*. The corresponding *per case* price increases for only Evanston and Glenbrook were: Aetna 31%, BCBS 3%, Humana 82%, and United 124%, with an average across all four payors of 35%. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*.

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President Neaman attributed the price increases, at least in part, to the transaction: “[T]he larger market share created by adding Highland Park Hospital has translated to better managed care contracts.” CX 16 at 1. The next month, Neaman issued a memorandum entitled “Final Report – Merger Integration Activities” that stated: “Some \$24 million of revenue enhancements have been achieved – mostly via managed care renegotiations,” and “*none of this could have been achieved by either Evanston or Highland Park alone.* The ‘fighting unit’ of our three hospitals and 1600 physicians was instrumental in achieving these ends.” CX 17 at 1-2 (emphasis added).

Portions of the trial testimony from Highland Park’s officials were consistent with these documents. Highland Park’s CEO before the merger, Spaeth, contrasted the post-merger price increases against Highland Park’s pre-merger negotiations, testifying that before the merger he did not see an opportunity to raise rates. TR 2172-73 (Spaeth). Terry Chan, Highland Park’s primary negotiator before the merger, testified that the merger gave ENH additional bargaining power. TR 709-10 (Chan); IDF ¶ 367.

To summarize, we find that the documentary evidence and testimony support the conclusion that senior officials at Evanston and Highland Park anticipated that the merger would give them greater leverage to raise prices to MCOs, the merged firm did raise its prices to MCOs immediately and substantially after consummation of the transaction, and the same senior officials attributed the price increase in part to increased bargaining leverage with payors produced by the merger.

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J. MCO Testimony

Complaint counsel presented testimony from five MCOs at trial.¹⁵

1. Private Healthcare Systems (“PHCS”)

PHCS develops networks of hospitals, doctors, and other ancillary services, and markets these networks to insurance companies, third-party administrators, and employers. TR 142-43 (Ballengee). Jane Ballengee, PHCS’ Regional Vice President for Network Development, testified about PHCS’ post-merger negotiations with ENH. Ballengee was PHCS’ Territory Director for the Chicago region when PHCS renegotiated its contract with ENH after the merger, although she did not participate in the negotiations. TR 146-47 (Ballengee).

Throughout the 1990s, PHCS had negotiated new rates with Evanston approximately every one and one-half years. TR 168-69 (Ballengee). Ballengee testified that PHCS viewed Highland Park as as Evanston’s “primary alternative” and that, before the merger, PHCS believed that it could select Evanston or Highland Park and “work them off against each other.” TR 166-68 (Ballengee). Prior to to the merger, PHCS had never threatened to drop either Evanston or or Highland Park, but PHCS believed that its ability to do so was understood and that this ability restrained the hospitals’ prices. TR 171 (Ballengee). PHCS had dropped other hospitals from its

¹⁵ We limit our findings about the MCO testimony to the MCOs’ descriptions of the role played by the ENH hospitals in their networks, their post-merger negotiations with ENH, ENH’s post-merger price increases, and which hospitals the MCOs viewed as competitors to the ENH hospitals before and after the merger. Both sides have presented extensive evidence about the tone and the rhetoric used during the MCO negotiations. We have carefully reviewed and considered these portions of the record and, while such information can be probative in antitrust cases, we have concluded that in this case this testimony neither supports nor undermines the conclusion that the merger gave ENH market power.

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network when it was not satisfied with the offered prices. TR 154-56 154-56 (Ballengee). Ballengee further testified that if Evanston had had made unacceptable price demands pre-merger, PHCS could have eliminated it from the network and used Highland Park as the alternative, and vice-versa. TR 167 (Ballengee).

Ballengee testified that she believed that competition between Evanston and Highland Park had kept price increases to an average average of 4% to 8% for each contract renegotiation. TR 168-71 (Ballengee). By comparison, post-merger, ENH sought and obtained what Ballengee testified was approximately a 60% price increase, primarily through increases in Evanston's prices. TR 179 (Ballengee).¹⁶ Ballengee testified that PHCS accepted the increase because some of its customers had informed PHCS that they could not market their health plans without ENH in the network "[b]ecause there would be a large [geographic] area that would be uncovered." TR 179-81 (Ballengee). Ballengee's assessment of the market conditions is consistent with a document prepared for ENH by Bain at the time of the merger, which stated that ENH had "significant leverage in negotiations with PHCS as they have [a] strong North Shore presence and need us in their network." CX 1998 at 44.

On cross-examination, Ballengee also stated that she believed that Advocate Lutheran General and St. Francis were significant competitors to Evanston, and that Lake Forest was a significant competitor to Highland Park. TR 211-12 (Ballengee). She also stated that for purposes of forming a network, Advocate Lutheran and possibly Rush North Shore and Advocate Northside were comparable to Evanston. TR 191-93 (Ballengee).

¹⁶ Data analyzed by complaint counsel's economist appeared to show that, post-merger, ENH increased its prices to PHCS (as a percentage per case) approximately 60%. CX 6279 at 4-5 (62.3% as calculated using the data received from the FTC's Civil Investigative Demand to ENH and 59.6% as calculated using data received from the consulting firm NERA), *in camera*; TR 2522 (Haas-Wilson), *in camera*; CX 6279 at 4-5.

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We find that Ballengee's testimony, viewed in conjunction with with the Bain document, supports the conclusion that Evanston and Highland Park were close substitutes that likely constrained each other's pricing to PHCS before the merger. Ballengee's testimony that Advocate Lutheran General, St. Francis, and possibly possibly Rush North Shore and Advocate Northside were significant significant competitors to Evanston, and that Lake Forest was a significant competitor to Highland Park, does not undermine this conclusion. The issue is not whether other hospitals competed with with the merging parties, but whether they did so to a sufficient degree to offset the loss of competition caused by the merger. The fact that PHCS retained ENH after it substantially raised prices at a rate that exceeded the average rate increase of other hospitals, rather than drop ENH and use other hospitals, also supports the finding that, for PHCS, competition from these other hospitals was was not sufficient to constrain ENH from exercising market power.¹⁷

2. Aetna

Robert Mendonsa, who was an Aetna general manager responsible for sales and network contracting, testified about Aetna's Aetna's negotiations with ENH after the merger. TR 475-76 (Mendonsa). Prior to the merger, Evanston and Aetna had last negotiated a contract in 1996, and the prices that Aetna negotiated at at that time had remained in effect through 2000. IDF ¶ 437; TR 533-34, 563 (Mendonsa), *in camera*. Mendonsa testified that the ENH hospitals had been part of Aetna's network for many years because it was "extremely important" to include them. TR 516 (Mendonsa), *in camera*. Mendonsa also testified that it is very important to have hospital coverage in the North Shore suburbs

¹⁷ For the same reason, we find not particularly informative a PHCS statement to its customers during its post-merger negotiations with ENH, about the existence of other hospitals in the same geographic area as Evanston and Highland Park. RX 712 at 2-3. Further, Ballengee testified that her customers "made it very clear to [her] that they didn't believe that they could have a marketable network, that they could compete in the marketplace without having the new ENH entity in it." TR 180 (Ballengee).

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because executives of employers live there who are involved in the companies' decisions. TR 516-17 (Mendonsa), *in camera*. Mendonsa was concerned about the merger because it had resulted in "three extremely important hospitals negotiating together in a very important geography" and because it would "severely compromise[]" Aetna's ability to sell its plans without the three hospitals. TR 530, 518 (Mendonsa), *in camera*.

On January 18, 2000, ENH wrote a letter to Aetna, requesting that it assign Highland Park's rates to ENH until it negotiated a new hospital agreement with Aetna. RX 769 at ENH JL 2817. ENH's letter also contained an initial proposal for a new contract. *Id.*, *in camera*. Because Evanston's rates for Aetna had not increased since 1996, Mendonsa expected ENH to ask for a price increase of approximately 10%. TR 534 (Mendonsa). By Aetna's estimates, however, ENH sought a 65% increase. TR 533 (Mendonsa), *in camera*.

On March 14, 2000, ENH invoked the termination clause of the existing pre-merger contract, giving Aetna notice that it would terminate the contract if the parties could not reach an agreement. CX 123 at 1; TR 546-47, 531 (Mendonsa), *in camera*. In June 2000, 2000, Aetna and ENH ultimately agreed to a contract that Aetna calculated increased ENH's prices by approximately 45% to 47% over a three-year period. TR 539-40 (Mendonsa), *in camera*.¹⁸

Mendonsa testified that Aetna signed the post-merger contract with ENH because Aetna thought that people who lived in the communities around the ENH hospitals would not want to travel to other hospitals. TR 541-43 (Mendonsa), *in camera*. He explained explained that he believed that "[s]omeone that's going to Evanston Evanston is not going to drive all the way out to Park Ridge, which

¹⁸ Respondent does not dispute Aetna's arithmetic about the post-merger price increase, but argues that it is more reasonable to calculate the increase on an annual percentage basis starting in 1996. RRB 44.

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is where [Advocate] Lutheran General is, and . . . neither are they going to do that with Northwest Community Hospital.” TR 542 (Mendonsa), *in camera*. Mendonsa further testified that Aetna believed that it “couldn’t walk away” from ENH post-merger because it would have “devastated” Aetna and “shut down” its marketing to local employers. TR 518, 520 (Mendonsa), *in camera*.

In addition, Mendonsa testified that before the merger Evanston was “extremely desirable” and that Aetna’s “walk-away point would have been pretty high . . . [but that Aetna] would have walked away[] because we still had Highland Park and we had Northwestern in the city and we had coverage.” TR 530 (Mendonsa), *in camera*. He also stated that “there probably would have been a walk-away point with the two independently. But with the two together, that was a different conversation.” TR 520 (Mendonsa), *in camera*. Aetna had terminated hospital contracts in the past when it had concluded that the prices were too high. TR 544 (Mendonsa), *in camera*. To do so with ENH, however, “would have killed [Aetna’s] marketing to any middle market or national accounts.” TR 530 (Mendonsa), *in camera*.

On cross-examination, Mendonsa testified that Evanston competed with Northwestern and Lutheran hospitals on tertiary services, and that Evanston also competed with St. Francis and Rush North Shore. TR 561 (Mendonsa), *in camera*. Mendonsa also testified that Highland Park competed with Lake Forest. TR 562 (Mendonsa), *in camera*.

We find that Mendonsa’s testimony that Aetna could have walked from Evanston pre-merger “because [it] still had Highland Park and . . . Northwestern in the city,” TR 530 (Mendonsa), *in camera*, and that “[s]omeone that’s going to Evanston is not going to drive all the way out to Park Ridge, which is where [Advocate] Lutheran General is” located, TR 542 (Mendonsa), *in camera*, loosely suggests that Evanston and Highland Park were relatively close substitutes from Aetna’s perspective. His testimony that Evanston competed with Northwestern, Lutheran, St. Francis, and

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Rush North Shore, and that Highland Park competed with Lake Forest, neither supports nor undermines complaint counsel's case because it does not indicate whether competition from those hospitals could offset the loss of competition caused by the merger. merger.

3. One Health

Patrick Neary testified on behalf of One Health, which today is called Great West. When Evanston and Highland Park merged, Neary was Director of Network Development and Provider Relations, and he negotiated One Health's contract with ENH after the merger. TR 582 (Neary).

In December 1999, the month before the merger closed, Evanston contacted One Health to request the renegotiation of its contract. TR 594-95 (Neary). One Health's previous contracts with Evanston and Highland Park were from 1996 and 1995, respectively. TR 596-97 (Neary). Bain had advised Evanston of what Bain believed was a "substantial difference" between One Health's pre-merger rates at Highland Park and Evanston. CX 75 at 9-10.

Neary testified that he thought that, after the merger, One Health was not in a strong negotiating position because he believed that Evanston had purchased "its main competitor" that "drew patients from the same general area." TR 600-01 (Neary). Neary also testified that Advocate Lutheran General was "one of several" alternatives to ENH in 2000, along with St. Francis, Condell, and Northwestern Memorial. TR 631 (Neary).

Neary further stated "that it had been several years since the [Evanston Hospital] contracts had been renegotiated and that it was appropriate to . . . increase some of the rates," and One Health Health was willing to give a price increase based on an index. IDF ¶ 423; TR 608, 762-63 (Neary), *in camera*; CX 2085, *in camera*.

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When ENH requested a larger increase than One Health thought was warranted after the merger, however, One Health and ENH failed to reach an agreement. One Health believed that ENH had proposed an increase of “26% to 219% of the current rate agreements in place.” CX 2085, *in camera*; TR 762 (Neary), *in camera*. One Health allowed the contract to lapse on August 31, 2000. TR 609-11 (Neary).

Neary testified that, shortly after its contract with ENH lapsed, One Health’s customers started to complain about their lack of access to ENH, and that One Health’s membership reports reflected a loss of membership. IDF ¶¶ 427-28; TR 615-17 (Neary); *see also* TR 1452, 1487-88 (Dorsey). At that time, One Health also had in its network Condell, Lake Forest, Northwest Community, Advocate Lutheran General, Rush North Shore, and St. Francis. TR 611 (Neary); TR 1459 (Dorsey). One Health ultimately agreed in the second half of 2000 to a contract with ENH that contained price increases that were “similar” to those in ENH’s initial proposal. TR 763-64 (Neary), *in camera*.

On cross-examination, Neary testified that Advocate Lutheran General, St Francis, and Condell were “several” main alternatives to ENH. In addition, he testified that Northwestern Memorial Hospital was also an “alternative” to ENH. TR 630-31 (Neary).

Neary’s testimony that Evanston had purchased its “main competitor” and that One Health briefly had dropped ENH after ENH requested substantial price increases, and then entered into a contract with ENH at similar levels, provides some indication that pre-merger competition between Evanston and Highland Park prevented them from individually exercising market power. We assign only a small amount of weight to the testimony, however, because Neary provided less information about the substitutability of Evanston and Highland Park than did Ballengee and Mendonsa. Neary’s testimony about the existence of other “main” alternatives to ENH also lacks sufficient detail to allow for firm conclusions.

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Kevin Dorsey also testified about One Health's post-merger contract negotiations with ENH. Dorsey was employed at One Health from 1997 to 2003, first as a Director of Development and then as a Vice President. TR 1429-30 (Dorsey). Dorsey managed Neary and oversaw One Health's post-merger negotiations with ENH. Dorsey testified that One Health did not play one hospital off against another in negotiations, that he believed that Lake Forest was Highland Park's primary competitor, and that he viewed St. Francis as Evanston's primary competitor. TR 1470-72 (Dorsey). Dorsey's generalized testimony is not particularly informative because he supported it with only minimal supporting facts. TR 1470-72 (Dorsey).

4. Unicare

Lenore Holt-Darcy testified for Unicare. TR 1412-13 (Holt-Darcy). Holt-Darcy is a Unicare Regional Vice President. *Id.* (Holt-Darcy). At the time of the merger, Unicare had both an HMO and a PPO contract with Evanston. The HMO contract had been negotiated in 1994 and contained a one-year term, with automatic annual renewals. CX 5085; CX 5091. Either party could terminate the agreement with ninety days' notice. CX 5091. The PPO contract had been negotiated in 1999. TR 1548, 1599, 1604-05 (Holt-Darcy), *in camera*; CX 216 at 12.¹⁹

In 2000, Unicare entered into contract renegotiations with ENH. ENH. Holt-Darcy testified that Unicare preferred to have rate

¹⁹ At the time of the merger, Highland Park also had a PPO contract with Rush Prudential, which was negotiated in 1994. CX 215; CX 5076. This contract also renewed annually, with each party having the right to terminate the contract with ninety days' notice. CX 215 at 15. In 1998, Rush Prudential sought unsuccessfully to contract with Highland Park for its HMO plan. RX 392. While Highland Park did not have any contracts with Unicare before the merger, CX 114, Unicare acquired Rush Prudential in 1999. As a result, Unicare had access to Highland Park. *Id.*

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increases below 10%, but if a hospital's rates needed to "catch up," the annual rate increase could exceed 10%. TR 1503 (Holt-Darcy), *in camera*. Holt-Darcy added that before the merger, Unicare could have developed a network with "adequate coverage" of the North Shore region with Evanston or Highland Park, and a combination of other hospitals. TR 1517-19 (Holt-Darcy), *in camera*. Unicare did not need both Evanston and Highland Park to "serve the geography." *Id.* (Holt-Darcy), *in camera*.

The ALJ found that during the post-merger negotiations with Unicare, ENH officials stated that "[t]hey had sewn up" the North Shore suburbs for hospitals and physicians. IDF ¶ 455; *see also* TR 1546 (Holt-Darcy), *in camera*. The negotiations produced a contract on September 16, 2000, which contained substantial price increases. TR 1536, 1563-64 (Holt-Darcy), *in camera*. Holt-Darcy testified that the contract contained an 80% price increase in the rates that Evanston Hospital charged for Unicare's PPO, TR 1539-40, 1563 (Holt-Darcy), *in camera* and that prices for Unicare's HMO increased by 7%, 30%, and approximately 25% at Glenbrook, Highland Park, and Evanston Hospitals, respectively. TR 1543 (Holt-Darcy), *in camera*. Holt-Darcy also testified that Unicare had agreed to the substantial price increases because it viewed ENH as a "key provider," and that not to have ENH in the network could have caused major employers, such as Kraft, to select other health plans. TR 1551-53 (Holt-Darcy), *in camera*. Holt-Darcy further explained that the ENH hospitals "had a contiguous service area that would have been hard, painful, for [Unicare's] customers to see them leave." TR 1602 (Holt-Darcy), *in camera*.

On cross-examination, Holt-Darcy testified that Unicare does not not overtly play one hospital off against another during contract negotiations. TR 1593-94 (Holt-Darcy), *in camera*. She added, however, that it was not necessary to identify alternatives during negotiations because most hospitals know their competitors. TR 1602-03 (Holt-Darcy), *in camera*. Holt-Darcy also testified that Highland Park competes with Lake Forest and Condell Hospitals,

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and that Evanston competes with a significant number of tertiary-service hospitals in the Chicago area, including Rush North Shore, St. Francis, Loyola, University of Chicago, University of Illinois, and Northwestern Hospital. TR 1595-96 (Holt-Darcy), *in camera*.

Similar to Mendonsa's testimony, we find that Holt-Darcy's testimony that Unicare could have developed a network with "adequate coverage" of the North Shore region with either Evanston or Highland Park, and a combination of other hospitals, TR 1517-19 (Holt-Darcy), *in camera*, loosely supports the inference that there was significant pre-merger competition between Evanston and Highland Park. Her testimony about the significance of the "contiguous service area." TR 1602 (Holt-Darcy), *in camera*, of the ENH hospitals also suggests that Evanston and Highland Park were close geographic competitors, but because she offered relatively few specifics to support her testimony, we assign it only limited weight. Holt-Darcy's testimony on cross-examination about competition between Evanston and Highland Park and other hospitals is not particularly probative because it did not explain whether and, if so, why this competition was sufficient to defeat a price increase by ENH.

5. United

Jillian Foucre testified for United. Foucre worked at United from 1999 through 2004, and in August of 2001 became United's Chief Operating Officer. TR 877-78 (Foucre). Foucre managed a team that negotiated with United's network providers, including hospitals. TR 879 (Foucre).

United and ENH agreed on a new contract on January 1, 2000. TR 886-87 (Foucre). The new prices were substantially higher than in United's prior contract with Evanston. United's documents show that it believed that ENH's reimbursement rate (on allowed dollars *per day* basis) increased by 65.1% from 1999 to 2000, and by 28.7% from 2000 to 2001. TR 1076-78 (Foucre), *in camera*; CX

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CX 21 at 9, *in camera*. Foucre was not involved in the negotiation of the 2000 contract. The United employee who was responsible for the negotiations was deceased at the time of trial. TR 887 (Foucre).

In 2002, United analyzed ENH's prices, concluded that they were higher than United's average hospital reimbursement rate, and and sought to renegotiate them. TR 888, 890 (Foucre).²⁰ United decided that it could not afford to drop ENH because when you look look at the three hospitals that make up the Evanston Northwestern Northwestern Healthcare system and look at . . . the triangle that they create, that area of Chicago . . . is very heavily populated by some of the most affluent communities in the Chicago area, and a result of that, the senior executives and the decision-makers of not only our existing customers but also our prospective customers would be residing within that area, and because, while there might be hospitals to the south and to the north, there are no other facilities, it did not seem feasible that we could have a viable network without Evanston Northwestern Healthcare.

TR 901-02 (Foucre). Consequently, United did not believe that it could satisfy its customers without ENH, IDF ¶ 408; TR 901-02, 925-26 (Foucre), even though Lake Forest, Rush North Shore, St. Francis, and several other nearby hospitals were in its network at the time. IDF ¶ 408; TR 931-34 (Foucre).

Foucre testified that United was sufficiently concerned about ENH's price levels that she met with local large employers, including Kraft, to discuss them. TR 904 (Foucre). The customers advised Foucre that they did not believe that it was feasible to remove the ENH hospitals from the network. TR 905-06 (Foucre). In May 2003, United arranged a meeting between a number of local local employers and ENH officials to discuss the pricing levels. TR

²⁰ United had three objectives for the 2002 negotiations: (1) change the format of the contract; (2) increase the percentage of the total revenues that it paid to ENH on a per diem basis and reduce the percentage that it paid pursuant to discount off charges terms; and (3) reduce its total payments under the contract. TR 892 (Foucre).

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TR 908 (Foucre). In 2004, United and ENH agreed to a contract that reduced ENH's rates but, in United's view, did not eliminate ENH as an outlier in terms of its prices. TR 1103 (Foucre), *in camera*.

On cross-examination, Foucre testified that she viewed Condell and Lake Forest as the primary competitors to Highland Park, and that Evanston competes with Advocate Lutheran General, Rush North Shore, and St. Francis. TR 942-44 (Foucre). She testified that with respect to Evanston, "Lutheran General is the most comparable facility from type of services, quality of services, [and] size of facility; however, it is the furthest away. It's got a bit of geographic disadvantage, but it's not terribly far away." TR 944 (Foucre).

Foucre's testimony that hospitals to the north of Highland Park and the south of Evanston were less desirable to residents of the North Shore suburbs suggests that the geographic proximity of Highland Park and Evanston made them close competitors, but because the testimony lacks detail we assign it only modest weight. Foucre's very general testimony that Evanston and Highland Park competed with other hospitals, by itself, is not particularly informative.

K. ENH Officials' Testimony

Two of ENH's senior executives, Neaman and Spaeth, presented testimony about pre-merger competition among North Shore hospitals. Neaman testified in general terms that he did "[n]ot really" view Highland Park as a competitor to Evanston because Evanston was "a lot bigger than Highland Park . . . [and] offered a much broader array of services." TR 1306-07 (Neaman). He did not explain in detail, however, why Evanston and Highland Park were not close competitors for the large number of primary and secondary services that they both provided. Accordingly, we find that Neaman's testimony is not probative as to

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to the level of pre-merger competition between Evanston and Highland Park.

Spaeth testified that he considered Lake Forest Hospital to have have been Highland Park's "primary competitor" before the merger because they are only six miles apart and have "major overlap" between their medical staffs. TR 2239, 2163 (Spaeth).²¹ Spaeth also testified that Highland Park competed with Evanston for patients to the south of Highland Park, and that Evanston was competing for patients in Highland Park's core area. TR 2157, 2241 2241 (Spaeth). In addition, he testified that, after Lake Forest, Evanston was Highland Park's closest competitor:

Q. Let's talk about Highland Park's closest competitors before the merger beyond the market share that we just looked at for your core area. Leaving aside Lake Forest, Evanston was Highland Park's next closest competitor before the merger, correct?

A. Leaving aside Lake Forest? I believe they were, yes, they were among the next one or two competitors.

Q. They were the next closest competitor, correct?

A. They probably were.

* * * *

Lake Forest would be first because of the major overlap in medical staffs. There were probably 200-200-plus physicians that were on each other's staff.

²¹ Terry Chan, a Highland Park employee tasked with analyzing Evanston's and Highland Park's prices shortly before the merger, also testified that she viewed Lake Forest as Highland Park's closest competitor because there are many physicians who are on the staff of both hospitals. TR 730 (Chan).

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Then the next set of competitors clearly put Evanston

—

Q. Well, the next competitor clearly was Evanston, correct?

A. Yes.

TR 2162-63 (Spaeth).

On cross-examination by Respondent's counsel, Spaeth testified that he also viewed Lake Forest, Condell, Rush North Shore, Advocate Lutheran General, St. Francis, and the downtown Chicago hospitals (along with Evanston) as competitors to Highland Park because of their "reasonably close" geography and because "[t]hey are all certainly substitutable for Highland Park." TR 2239-40, 2299 (Spaeth). This competition, he explained, allowed MCOs to "go down the street" to Highland Park's competitors to find substitutes for Highland Park in their networks. TR 2299 (Spaeth). Lastly, Spaeth testified that Evanston and Highland Park did not offer similar services because "there is a vast difference between an academic medical center and a community hospital" and because Highland Park did not offer heart care, sophisticated neonatal care or pediatrics, major oncology surgery, or neurosurgery. TR 2285-86 (Spaeth).

We find that Spaeth's testimony that Evanston competed in Highland Park's core service area, and that Evanston was Highland Park's closest competitor (after Lake Forest), indicates that Evanston and Highland Park were close competitors for some services for patients who lived to the south of Highland Park and to the north of Evanston. The fact that Highland Park did not provide heart care or sophisticated neonatal care or pediatrics is not inconsistent with the existence of substantial competition between the two hospitals for primary and secondary services.

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L. Econometric Evidence

Complaint counsel and respondent each presented extensive econometric evidence. Complaint counsel's primary economist was Deborah Haas-Wilson, Professor of Economics at Smith College. Respondent's economists were Jonathan Baker, a Professor Professor of Law at American University and Senior Consultant at Charles River Associates Incorporated, and Monica Noether who was then the Vice President and Head of the Competition Practice at Charles River Associates.²²

The econometric analyses of complaint counsel and respondent were designed to determine whether ENH charged higher prices than the merging hospitals would have charged if the merger had not occurred, and, if so, whether the price increases were due to an increase in market power produced by the merger. To answer these questions, Haas-Wilson and Baker used a three-step process to predict the prices that ENH would have charged had the merger not occurred. First, they calculated the amount of ENH's post-merger average net price increases to MCOs. Their second step was a difference-in-differences analysis, which consisted of a comparison of ENH's pre- to post-merger change in average net price to the pre- to post-merger changes in average net price for various control groups. Their third step was a series of linear regressions using the same control groups.

Haas-Wilson ultimately concluded that, coincident with the merger, average net prices increased by higher-than-predicted levels for four of the five MCOs in the following ranges:²³ Aetna (21.3% to 32.5%); Humana (12.3% to 16.6%); United (75.3% to 93.2%); and Great West (25.1% to 39.5%). CX 6279 at 18-19, *in camera*; CX

²² Dr. Noether is currently the Head of the Litigation and Applied Economics Platform and Professor Baker is a Senior Consultant at CRA International, Inc., a successor corporation to Charles River Associates.

²³ The ranges are due to variations in the measured increases across econometric specifications.

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6282 at 6, *in camera*; TR 2619-31 (Haas-Wilson), *in camera*. The results were statistically significant. *Id.* For BCBS, Haas-Wilson found that ENH's actual post-merger average net prices were not statistically-significantly higher than her predicted post-merger average net ENH prices. CX 6279 at 18, *in camera*. Haas-Wilson also estimated that there were market-wide, higher-than-predicted merger-coincident average net price increases of 11% to 18%. CX 6279 at 20, *in camera*. She concluded that these price increases were due to market power created by the merger because she believed that she had factored out, through empirical and non-empirical analyses, the effects of the most likely competitively-benign explanations for the price increases. TR 2451, 2657 (Haas-Wilson); TR 2586-88, 2645-48, 2698-2733 (Haas-Wilson), *in camera*.

Baker also found substantial higher-than-predicted average net price increases in acute inpatient services of 9% or 10%. TR 4620 4645-46 (Baker), *in camera*; RX 2040 at 3, *in camera*; DX 7068 at 21, ¶ 47, *in camera*. Because respondent maintained that hospital-based outpatient services were also in the market, Baker also performed the same calculation for both inpatient and hospital-based outpatient services combined. Baker estimated a higher-than-predicted average net price increase of 11% or 12% for these services combined. TR 4602-03 (Baker); TR 4617-18 (Baker), *in camera*; DX 7068 at 21, ¶ 46, *in camera*. Baker testified that these estimates did not account for ENH's learning-about-demand and for potential post-merger changes in quality. TR 4602-03 (Baker). We address these issues below.

We describe the details of Haas-Wilson's and Baker's analyses separately, explain how they were similar and how they differed, and then state the findings and conclusions that we draw from their work.

1. Haas-Wilson's Empirical Analyses

Haas-Wilson tried to determine whether any of the following ten factors caused a post-merger price increase by ENH:

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1. increases in costs that also affected other hospitals in the Chicago area, TR 2482 (Haas-Wilson);
2. changes in regulation that also affected other hospitals in the Chicago area, TR 2483-84 (Haas-Wilson);
3. increases in hospital demand that affected other hospitals in the Chicago area, TR 2484 (Haas-Wilson);
4. increases in quality at ENH relative to other hospitals in the Chicago area, TR 2485 (Haas-Wilson);
5. changes in the mix of patients (*i.e.*, the complexity and type of the cases at each hospital) at ENH relative to other hospitals in the Chicago area that resulted in greater “resource intensity,” and thus greater costs, TR 2485-86 (Haas-Wilson); TR 2594 (Haas-Wilson), *in camera*;
6. changes in the mix of customers to more Medicare/Medicaid patients at ENH relative to other hospitals in the Chicago area, TR 2486 (Haas-Wilson);
7. increases in teaching intensity (*i.e.*, the number of residents and interns per bed) at ENH relative to other hospitals in the Chicago area, TR 2486-87 (Haas-Wilson); TR 2604 (Haas-Wilson), *in camera*;
8. decreases in the prices of outpatient services charged to MCOs, TR 2487-88 (Haas-Wilson);
9. ENH’s learning-about-demand for hospital services from Highland Park’s pricing data, TR 2488 (Haas-Wilson); and

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10. an increase in market power due to the merger, TR 2488-89 (Haas-Wilson).²⁴

Haas-Wilson used four data sources to conduct her analyses: (1) commercial payor claims data from MCOs in the Chicago area (“payor data”); (2) data received from the consulting firm NERA; (3) data received from the FTC’s Civil Investigative Demand to ENH; and (4) data from the Illinois Department of Public Health (“Illinois data”). TR 2495-500 (Haas-Wilson). Because only the payor and Illinois data were sufficiently comprehensive for Haas-Wilson to perform her regressions – which is the critical part of her analyses – we limit our discussion to Haas-Wilson’s analyses of these two data sets.

a. Simple Price Change Statistic

Haas-Wilson began her analysis by calculating a simple post-merger price statistic. TR 2489 (Haas-Wilson).

(1) Price Changes Calculated from the Payor Data

The payor data were relatively comprehensive. The data (a) covered a five-year period from 1998 to 2002, CX 6279 at 3, *in camera*;²⁵ (b) included data for the three ENH hospitals and many, if

²⁴ Haas-Wilson acknowledged that this was not an exhaustive list of potential explanations for the post-merger price increases at ENH. TR 2481 (Haas-Wilson). Other explanations would include: (a) an increase in demand at ENH relative to other hospitals, and (b) an increase in costs at ENH relative to other hospitals. TR 2681-82 (Haas-Wilson), *in camera*; TR 4650-53 (Baker), *in camera*.

²⁵ The exception was the data from Aetna, which ended in August 2002. TR 2512 (Haas-Wilson), *in camera*. Additionally, it appears from DX 7010 at 1, *in camera*, that the data from Humana also ended in August 2002.

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not all, of the other general acute care hospitals²⁶ from the Chicago metropolitan area; (c) were at the patient level for each hospital, and included the date of admission, the date of discharge, and in many cases the diagnosis, the age, and the gender of the patient; (d) included “the (dollar) amount that the managed care organization reimbursed the hospital for the care of the patient,” TR 2496-97 (Haas-Wilson), and the “diagnostic [or diagnosis] related group [“(DRG”)] indicating the nature of the hospital service,” DX 7068 at 15, *in camera*;²⁷ and (e) covered seven of the at least fourteen MCOs that appeared to have had contracts with the ENH hospitals; including Aetna, BCBS, Humana, and United. CX 6279 at 5, *in camera*.²⁸

Haas-Wilson used the payor data for Aetna, BCBS, Humana, and United purchases. Collectively, these four MCOs accounted for greater than 70% of ENH’s MCO patients on a *per case* basis in 2002, *see* CX 6279 at 5, *in camera*, but “less than 60 percent of MCO payments to ENH.” DX 7068 at 8, ¶ 20, *in camera*. By how

²⁶ The record does not appear to contain a complete list of the other hospitals covered by the payor data. Haas-Wilson described the data as including “information on . . . the care received at many hospitals in the Chicago area.” TR 2497 (Haas-Wilson). Later, she stated that her largest control group of hospitals “included all general acute care hospitals in the Chicago PMSA.” TR 2548 (Haas-Wilson), *in camera*. From this testimony, we can infer that the payor data included, at the very least, all general acute care hospitals in the Chicago PMSA. Haas-Wilson denoted the area covered by the hospitals as the PMSA. The Commission could not locate a definition of “PMSA” in the voluminous record, but presumably it stands for Primary Metropolitan Statistical Area.

²⁷ Diagnosis Related Groups (“DRGs”) refer to a system created for Medicare used to classify patients into groups expected to require similar hospital resources. There are roughly 500 DRGs. TR 2594 (Haas-Wilson), *in camera*; TR 5912-13 (Noether).

²⁸ For an unknown reason, the payor data for all four MCOs contained more mothers than babies for obstetrics cases, which Baker and Noether labeled the “missing babies” problem. TR 4625 (Baker), *in camera*; DX 7126 at 74, ¶ 184; *id.* at 103, ¶ 267. The record does not appear to indicate that Haas-Wilson addressed this issue. Baker and Noether dealt with this issue by implementing a correction and by omitting obstetrics cases (both mothers and babies) from some of their analyses. DX 7126 at 74-75, ¶¶ 185-186; TR 4628 (Baker), *in camera*; DX 7068 at 12, ¶ 29, *in camera*.

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much less than 60% is not specified in the record. Haas-Wilson also used payor data that covered Great West (formerly known as One Health).²⁹

For the payor data, Haas-Wilson delineated the pre- and post-merger periods for each MCO by the date of its first contract renegotiation after the merger. TR 2511 (Haas-Wilson), *in camera*. Consequently, each payor had different pre- and post-merger periods.³⁰ Haas-Wilson appeared to construct a hospital service “net price” that consisted of the sum of (1) the payment from the MCO to the hospital, and (2) the payment from the patient to the hospital. TR 2496-97, 2576, *in camera* (Haas-Wilson).³¹ From this measure, she apparently then calculated, on a per-patient basis, (1) an average net price *per case*, and (2) an average net price *per day*. TR 2514 (Haas-Wilson), *in camera*. We believe that the price-per-case metric is more relevant than the price-per-day calculations because presumably MCOs are more focused on their total cost for a for a procedure rather than the amount of time that it takes to

²⁹ The Great West data included payments only from the MCOs to the hospitals but not from the patients to the hospitals, while the other payors included the total payments to the hospitals. TR 2576 (Haas-Wilson), *in camera*. Haas-Wilson testified that the Great West data “does not allow me to look at the total reimbursement to the hospital for inpatient care,” but she did not explain why she used the data. *Id.* (Haas-Wilson), *in camera*.

³⁰ For United, the contract effective date was January 1, 2000, which is the same date as the merger. TR 2512 (Haas-Wilson), *in camera*. For Aetna, the contract effective date was June 1, 2000. TR 2512 (Haas-Wilson), *in camera*. The record does not appear to indicate the contract effective dates for BCBS, Humana, and Great West. According to DX 7010 at 1, *in camera*, however, it appears that the contract effective date for the BCBS HMO was July 1, 2000, and the effective dates for the BCBS PPO and the Managed Care Network Provider plans were January 1, 2001; Humana and Great West had contract effective dates of September 15, 2000, and January 1, 2001, respectively.

³¹ Baker and Noether also appear to have constructed a total “net” price, which consisted of the payment made by the payor to the hospital, and any payment made directly by the patient. DX 7126 at 76.

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perform. Consequently, we report Haas-Wilson's *per case* calculations in text, and her *per day* calculations in footnotes.

Haas-Wilson calculated that ENH's average net price *per case* increased post-merger for all five of the MCOs that she examined: Aetna (28% to 89%); BCBS (10% to 27%); Humana (27% to 73%); 73%); United (62% to 128%), CX 6279 at 3, *in camera*; and Great Great West (42%), CX 6282 at 5, *in camera*. The ranges of percentages reflect that Haas-Wilson performed the calculations for for multiple plans for the MCOs.³²

(2) Price Changes Calculated from the Illinois Data

The Illinois data also were relatively comprehensive. The data set contained data on all patients from all hospitals in Illinois for the the periods 1998-99 and 2001-02. TR 2500 (Haas-Wilson); CX 6279 6279 at 7, *in camera*. Unlike the payor data, which contained data for individual MCOs, the Illinois data set identified the payor by general categories of payment types: commercial insurance, self-pay, self-pay, or HMO, as well as others. TR 2532 (Haas-Wilson), *in camera*; CX 6279 at 7, *in camera*. The data also contained only list list prices from the chargemaster (*i.e.*, gross payments) but not the net prices (*i.e.*, negotiated prices or net payments). TR 2500 (Haas-Wilson). Haas-Wilson dealt with this limitation by using Medicare cost reports to derive an estimate of the net prices. TR 2527 (Haas-Wilson), *in camera*. The Medicare cost reports contain aggregate data on both net payments and gross payments by

³² Haas-Wilson also calculated the increase in ENH's average net price per day post-merger for each of the MCOs' plans: Aetna (48% to 56%); BCBS (-12% (decrease) to 15%); Humana (57% to 82%); United (77% to 202%), CX 6279 at 3, *in camera*; and Great West (79%), CX 6282 at 5, *in camera*.

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hospitals for inpatient and outpatient services. IDF ¶ 576.³³ Haas-Wilson calculated the ratio of the net receipts of the hospitals to their gross billing amounts and then multiplied that ratio by the billing information in the Illinois data set to estimate the actual net price. TR 2529 (Haas-Wilson), *in camera*. Haas-Wilson testified that, while there is potential bias in such an approach, any bias would be small. TR 2529-30 (Haas-Wilson), *in camera*; IDF ¶ 579.

For the Illinois data, Haas-Wilson calculated the post-merger increases in the average net price *per case* for three broad categories of patients: all patients (30%); commercial and self-pay patients (27%); and commercial, self-pay, self-administered, and HMO patients (26%). CX 6279 at 7, *in camera*.³⁴

b. Difference-in-Differences Analysis

Haas-Wilson correctly recognized that her calculations of the simple changes in average net price using the payor and Illinois data data sets did not demonstrate that the changes in net prices resulted from post-merger market power because they did not control for other factors that might explain the increases. TR 2540-2540-41 (Haas-Wilson), *in camera*. Haas-Wilson's second step was to use a difference-in-differences ("DID") analysis to attempt to control for her first three competitively-benign potential causes of the price increases: changes in cost, demand, and regulation

³³ "The Medicare cost reports are reports that hospitals are required to file with the Federal Government if they receive Medicare dollars." TR 2527 (Haas-Wilson), *in camera*. They include "information on both net payments and gross payments by hospital for inpatient and outpatient services." TR 2529 (Haas-Wilson), *in camera*. The reports also appear to have included "the percent of patients receiving care at [each] hospital that are covered by Medicaid or the percent of patients at [each] hospital that are covered by Medicare." TR 2600 (Haas-Wilson), *in camera*.

³⁴ The average net per day price increases were: all patients (48%); commercial and self-pay patients (46%); and commercial, self-pay, self-administered, and HMO patients (46%). CX 6279 at 7, *in camera*.

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common across both ENH and her control groups. TR 2542-44 (Haas-Wilson), *in camera*. The DID analysis consisted of a comparison of ENH's pre- to post-merger change in average net price to the pre- to post-merger changes in average net price for each each of three control groups. TR 2546-47 (Haas-Wilson), *in camera*; *camera*; DX 7027 at 1. Haas-Wilson compared the average percentage *changes* in ENH's prices to those of the control groups because hospitals are differentiated and thus a simple cross-section cross-section comparison of price *levels* may be less informative. TR TR 2492-95 (Haas-Wilson). (Baker also measured percentage changes in ENH's prices. RX 2040 at 1-3, *in camera*.)

The reasoning underlying this approach was that changes in cost, demand, and regulation probably had a simultaneous and equal impact on the net prices charged by the ENH hospitals and hospitals that were similarly situated. If so, and if the control groups were reasonable and there were no other changes, her DID analysis enabled her to factor out the influence of the three competitively-benign variables. TR 2548 (Haas-Wilson), *in camera*.

Haas-Wilson used three control groups for her DID analyses: (1) (1) all general acute care hospitals in the Chicago PMSA;³⁵ (2) all general acute care hospitals in the Chicago PMSA that were not involved in a merger between 1996 and 2002; and (3) all general acute care hospitals in the Chicago PMSA involved in some teaching activity during the study period. TR 2548-49 (Haas-Wilson), *in camera*. The purpose of using multiple control groups is that if results are consistent across a number of different econometric specifications, all other things equal, the regression analyses are more likely to be correct.³⁶

³⁵ As stated, "PMSA" presumably refers to Primary Metropolitan Statistical Area.

³⁶ For more on specification tests, see G.S. MADDALA, INTRODUCTION TO ECONOMETRICS, Ch. 12 (2d ed. 1992).

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For the payor data, Haas-Wilson excluded hospitals with fewer than 100 admissions, during both the pre- and post-merger periods, for each payor plan.³⁷ Consequently, a control group might be composed of different hospitals depending on the particular payor plan. TR 2557, 2560 (Haas-Wilson), *in camera*.

Using the payor data, Haas-Wilson tried to use the DID analysis to determine whether changes in cost, demand, or regulatory changes common across both ENH and her control groups explained all of ENH's post-merger increases in average net net price. CX 6279 at 8-9, *in camera*; CX 6282 at 5, *in camera*; TR 2583 (Haas-Wilson), *in camera*. Haas-Wilson found that ENH's ENH's post-merger average net price *per case* increased, at statistically significant levels, for most of the payors' plans by more more than that of the control groups: Aetna (30% to 73%); BCBS' HMO and PPO (1% to 16%); Humana (5% to 53%); United (34% to to 113%); and Great West (13% to 27%). CX 6279 at 9, *in camera*; *camera*; CX 6282 at 5, *in camera*. The ranges reflect Haas-Wilson's use of different control groups and plans.³⁸ The only payor plan that

³⁷ Haas-Wilson explained that she "selected only those hospitals that had more than 100 admissions in both pre- and post-merger periods" in order to "make sure that outlier admissions wouldn't drive the result at any particular hospital. By 'outlier admission,' [she] mean[t] an admission where the price, because someone had to stay an especially long time in the hospital, was extremely high, much higher than average." TR 2556-57 (Haas-Wilson), *in camera*.

³⁸ At varying levels of statistical significance, Haas-Wilson also found that ENH's post-merger average net price per day increased for most payor plans beyond that of the control groups: Aetna (18% to 45%); BCBS' PPO (1% to 4%); Humana (34% to 71%); United (43% to 167%); and Great West (57% to 58%). CX 6279 at 8, *in camera*; CX 6282 at 5, *in camera*. The only payor plans that did not experience at least one statistically significant increase in average net price per day beyond the control groups were BCBS' HMO and POS plans, which experienced a 1% to 38% decrease. CX 6279 at 8, *in camera*. The Commission calculated these price changes from CX 6279 at 8 and 9, *in camera*, by subtracting from the figures in the "ENH" column either the "Chicago PMSA," the "Non-Merging Chicago," or the "Teaching Chicago" column.

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did not experience at least one statistically significant increase in average net price *per case* beyond the control groups was BCBS' POS plan, which experienced a 12% to 15% decrease. CX 6279 at 9, *in camera*.

Haas-Wilson's application of the DID methodology to the Illinois data produced consistent results, as she again found statistically significant increases in ENH's post-merger average net net prices beyond that of the control groups.³⁹ The average net price *per case* increases for the three categories of patients were as follows: all patients (21% across all three control groups); commercial and self-pay patients (14% to 16%, depending on the control group); and commercial, self-pay, self-administered, and HMO patients (13% to 15%, depending on the control group). CX 6279 at 11, *in camera*.⁴⁰ These results were all statistically significant at the one percent level. Thus, Haas-Wilson concluded that her DID analysis using the Illinois data also supported rejection of the first three competitively-benign hypotheses for an increase in average net prices. TR 2585-86 (Haas-Wilson), *in camera*.

She also used the DID framework to test whether a decrease in in the average net price of outpatient services (her eighth potential alternative) was the cause of the substantial post-merger price

³⁹ Again, Haas-Wilson excluded hospitals with fewer than 100 admissions during both the pre- and post-merger period. CX 6279 at 10-11, *in camera*.

⁴⁰ These numbers were calculated from CX 6279 at 11, *in camera*, by subtracting from the figures in the "ENH" column either the "Chicago PMSA Control Hospitals," the "Non-Merging Chicago Control Hospitals," or the "Teaching Chicago Control Hospitals" column. The average net price per day increases for the three categories of patients were: all patients (34%, across all three control groups); commercial and self-pay patients (26% to 29%, depending on the control group); and commercial, self-pay, self-administered, and HMO patients (27% to 29%, depending on the control group). CX 6279 at 10, *in camera*. These numbers were calculated from CX 6279 at 10, *in camera* by subtracting from the "ENH" column either the "Chicago PMSA Control Hospitals," the "Non-Merging Chicago Control Hospitals," or the "Teaching Chicago Control Hospitals" column.

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increases at the ENH hospitals. TR 2607 (Haas-Wilson), *in camera*. The record indicates that MCOs negotiate the prices of both inpatient and outpatient services at the same time. Thus an MCO might agree to higher prices for inpatient services in exchange for reduced prices for outpatient services. Using the payor data only (because the Illinois data did not contain sufficient information on outpatient cases), Haas-Wilson found that the average net prices for outpatient services at ENH increased by at least as much as they did at hospitals in her control groups. CX 6279 at 17, *in camera*. These results, which were statistically significant, implied that the measures of the average net price changes for inpatient cases alone likely would understate the total post-merger price increases at ENH, if the case mix of outpatient services at ENH did not increase relative to the control groups. TR 2610-15 (Haas-Wilson), *in camera*.

Finally, Haas-Wilson used the DID method to determine whether changes in patient mix customer mix, and teaching intensity intensity were significantly different between ENH and the control control hospitals (*i.e.*, her explanations five, six, and seven). CX 6279 at 13-16, *in camera*; TR 2594-2606 (Haas-Wilson), *in camera*. Patient mix measured the complexity (and type) of the cases cases at each hospital, TR 2594 (Haas-Wilson), *in camera*;⁴¹ customer mix measured the percentage of patients receiving Medicare or Medicaid assistance at each hospital, TR 2600 (Haas-Wilson), *in camera*; and teaching intensity measured the number of residents and interns per bed at each hospital, TR 2604 (Haas-Wilson), *in camera*. The results indicated that changes in patient mix customer mix, and teaching intensity differed significantly between ENH and the control hospitals and, therefore, that these factors could explain some of ENH's post-

⁴¹ Haas-Wilson used four different measures for patient mix: All Patient Refined DRGs ("APRDRGs"), APRDRGs with a "length of stay" variable, DRG weights, and DRG weights with a "length of stay" variable. TR 2622-23 (Haas-Wilson), *in camera*.

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post-merger price increases. TR 2607 (Haas-Wilson), *in camera*. Depending on the data set, the payor, the plan, and the control group, the percentage changes in case mix complexity at ENH differed substantially from those at the control group hospitals (from 9% below to 45% above).⁴² CX 6279 at 13, *in camera*. The average net price increases in the percent of patients on Medicaid and Medicare were greater at ENH (45% and 12%, respectively) than they were at hospitals in the control groups (30% to 34% and 7% to 8%, respectively, depending on the control group). *Id.* at 15, 15, *in camera*. The increase in teaching intensity was greater at ENH (32%) than it was at hospitals in the teaching hospital control group (8%). *Id.* at 16, *in camera*.

Haas-Wilson's finding that patient mix, customer mix, and teaching intensity differed between ENH and the control groups potentially invalidated her earlier use of the DID methodology to reject shared cost, demand, and regulation changes as explanations for the post-merger price increases. This is because her rejection of shared cost, demand, and regulation changes as explanations for the post-merger price increases was premised on the the ENH hospitals and the control groups having equivalent patient mix, customer mix, and teaching intensity.⁴³ Nonetheless, as we now explain, this flaw does not invalidate Haas-Wilson's ultimate conclusion because her linear regression results, which did control for patient mix, customer mix, and teaching intensity, also implicitly eliminated shared cost, demand, and regulation changes as sufficient explanations for the post-merger price increases.

⁴² Again, the Commission calculated these percentages from the data on CX 6279 at 13, *in camera*, and CX 6279 at 14, *in camera*, by subtracting from the "ENH" column either the "Chicago PMSA Control Hospitals," the "Non-Merging Chicago PMSA Control Hospitals," or the "Teaching Chicago Control Hospitals" column.

⁴³ Haas-Wilson's DID analysis suffers from "omitted variable bias." This problem occurs when a regression omits a relevant explanatory variable. See WILLIAM H. GREENE, *ECONOMETRIC ANALYSIS* 334-37 (4th ed. 2000). Her subsequent regressions demonstrated that the variables she omitted were relevant.

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c. Linear Regression Analysis

Haas-Wilson's third step was to apply a linear regression model to test whether changes in patient mix, customer mix, and teaching intensity explained ENH's post-merger increase in net prices. TR 2615 (Haas-Wilson), *in camera*; DX 7056 at 1. Regression is a statistical technique used to characterize the relationship between a variable of interest, such as price, and several other variables, such as changes in teaching intensity or increases in market concentration. Linear least squares regression, one of the most common forms of regression, characterizes the relationship by (1) assuming that it can be expressed as a straight line and (2) choosing a line of "best fit" that minimizes the sum of the squared differences between the predicted values (those on the line) and the actual values of the variable of interest. *See* Maddala, *supra* note 36, Ch. 3.

Haas-Wilson's regressions tested for whether changes in patient mix, customer mix, and teaching intensity explained ENH's ENH's post-merger increases in net prices, and also implicitly, by using control groups, tested for whether market-wide changes in cost, demand, and regulation could explain the price increases. In Haas-Wilson's regression model, net prices at ENH and the control control hospitals were the dependent variables, and patient mix, customer mix, and teaching intensity were included in the independent variables. TR 2619 (Haas-Wilson), *in camera*. Using both the payor data and the Illinois data, Haas-Wilson regressed ENH's and the control groups' *per case* net prices on patient mix, customer mix, teaching intensity, and a dummy variable for the merger.⁴⁴ DX 7056 at 1; TR 2619-22 (Haas-Wilson), *in camera*. Haas-Wilson used the same three control groups of hospitals as with

⁴⁴ Haas-Wilson's exclusive use of per case prices for her regression model (rather than per day prices) can be inferred by referencing CX 6279 at 19, *in camera*, and CX 6282 at 6, *in camera*.

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with her DID analysis. TR 2620 (Haas-Wilson), *in camera*. She used four different measures of patient mix, which she regarded as a specification test. TR 2622-23 (Haas-Wilson), *in camera*.⁴⁵ She ran the regressions separately for the payor data and the Illinois data. TR 2621-22 (Haas-Wilson), *in camera*.

Tellingly, Haas-Wilson's regressions for the payor data indicated that ENH's actual post-merger average net prices, at varying levels of statistical significance, were higher than her predicted post-merger ENH average net prices for four of the five payors: Aetna (21.3% to 32.5%); Humana (12.3% to 16.6%); United (75.3% to 93.2%); and Great-West (25.1% to 39.5%). CX 6279 at 18-19, *in camera*; CX 6282 at 6, *in camera*; TR 2619-31 (Haas-Wilson); *in camera*. The ranges reflect Haas-Wilson's use of different control groups and measures of resource intensity. For BCBS, Haas-Wilson found that ENH's actual post-merger average net prices were not statistically-significantly higher than her predicted post-merger average net ENH prices. CX 6279 at 18, *in camera*.

Haas-Wilson found similarly higher-than-predicted increases in ENH's average net price using the Illinois data for all three categories of patients: all patients (13.2% to 17%, depending on the control group and measure of resource intensity); commercial and self-pay patients (11.1% to 17.0%, depending on the control group and measure of resource intensity); and commercial, self-pay, self-administered, and HMO patients (11.9% to 17.9%, depending on the control group and measure of resource intensity). These results were statistically significant at the one percent level. *Id.* at 20, *in camera*.

d. Learning-About-Demand/Changes in Quality

⁴⁵ Again, Haas-Wilson used four different measures of patient mix: APRDRGs, APRDRGs with a "length of stay" variable, DRG weights, and DRG weights with a "length of stay" variable. TR 2622-23 (Haas-Wilson), *in camera*.

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Haas-Wilson did not formulate empirical tests to evaluate Respondent's position that Evanston's learning about market demand from Highland Park's pricing data and improvements to Highland Park (factors four and nine) were responsible for the substantially higher-than-predicted merger-coincident price increases. TR 2586 (Haas-Wilson), *in camera*. She testified correctly that devising an econometric model to test for the learning-about-demand hypothesis is very difficult. TR 2643-44 (Haas-Wilson), *in camera*. Haas-Wilson rejected Respondent's learning-about-demand argument and Respondent's argument about improvements to Highland Park based on other portions of the record. TR 2586-88, 2645-48, 2698-2732 (Haas-Wilson), *in camera*; DX 7046, *in camera*; DX 7047, *in camera*; DX 7057, *in camera*; DX 7058, *in camera*; DX 7060, *in camera*; DX 7061 *in camera*. We do not discuss this portion of Haas-Wilson's testimony because, as discussed below, the Commission has determined, based on its own review of the record (including many of the portions that Haas-Wilson relied upon), that neither possibility is a plausible explanation for ENH's higher-than-predicted merger-coincident price increases.

2. Baker's Empirical Analyses

Baker used the same basic methodology as Haas-Wilson to analyze the changes in ENH's prices to MCOs against the price changes of various control groups. Significantly, like Haas-Wilson, Baker found substantial higher-than-predicted merger-coincident price increases for ENH.

Baker, however, differed from Haas-Wilson in how he organized the data and in limiting his analysis to the payor data. First, Baker calculated prices only on a *per case* basis, while Haas-Wilson used both *per case* and *per day* prices in the majority of her analysis. TR 4628-29 (Baker), *in camera*. Second, consistent with Respondent's position that the relevant product market includes inpatient and hospital-based outpatient services,

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Baker used both inpatient and outpatient cases (together) to measure price, although, for comparison with Haas-Wilson, Baker also performed his analysis using only inpatient cases.⁴⁶ TR 4620 (Baker), *in camera*; DX 7068 at 10, ¶25, *in camera*.

Third, Baker and Noether defined the post-merger period as the time after January 1, 2000, while Haas-Wilson used each payor's contract renegotiation date as the start of the post-merger period. TR 4635 (Baker), *in camera*; DX 7068 at 9, ¶23, *in camera*. Baker testified that using the date of the merger as the starting point of the post-merger period was a more accurate method of calculating the post-merger price increases. TR 4636-67 (Baker), *in camera*.

Fourth, Baker and Noether analyzed the data at the payor level for Aetna, BCBS, Humana, and United, but testified only on the results averaged across all payors. TR 4621, 4631-32 (Baker), *in camera*; DX 7068 at 8, ¶20, *in camera*; *id.* at 10, ¶24, *in camera*. Baker testified that he preferred using the overall price changes because he believed that it was more reliable, and also more appropriate given that complaint counsel had alleged that the relevant market involved the entire managed care market. TR 4648 (Baker), *in camera*.

a. Simple Price Change Statistic

To calculate the simple price change statistic, Baker used two different measures of price: (a) "ENH constructed," which was used to examine price increases across Evanston, Glenbrook, and Highland Park Hospitals taken together; and (b) "ENH," which was used to examine price increases only at Evanston and Glenbrook Hospitals but not Highland Park Hospital. TR 4633 (Baker), *in camera*; DX 7068 at 10-11, ¶26, *in camera*.

⁴⁶ No data were available on the case mix of outpatient cases. Baker and Noether dealt with this issue by assuming that the case mix changes for both inpatient and outpatient cases were identical. TR 4642-43 (Baker), *in camera*.

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Baker found that inpatient average net prices increased across all all four payors after the merger using both the “ENH” and “ENH constructed” measures. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. Using the “ENH constructed” measure, Baker calculated calculated the following average net price increases by ENH: Aetna Aetna (35%); BCBS (13%); Humana (83%); and United (138%). RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. Overall, the four payors experienced an average 42% inpatient price increase from ENH. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. Using the “ENH” measure, Baker calculated the following average average net price increases by ENH: Aetna (25%); BCBS (2%); Humana (60%); and United (140%). RX 2040 at 1, *in camera*; DX DX 7068 at 43, *in camera*. Overall, the four payors experienced an an average 29% inpatient net price increase from ENH. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*.⁴⁷ Baker did not report levels of statistical significance for any of these calculations. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*.

⁴⁷ Baker also performed these calculations omitting obstetrics cases because of the “missing babies” problem. The corresponding per case average net price increases for “ENH constructed” (i.e., Evanston, Glenbrook, and Highland Park Hospitals) were: Aetna (34%); BCBS (5%); Humana (84%); and United (111%), with an average net price increase across all four payors of 37%. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*. The corresponding per case average net price increases for “ENH” (only Evanston and Glenbrook) were: Aetna (31%); BCBS (3%); Humana (82%); and United (124%), with an average across all four payors of 35%. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*.

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b. Difference-in-Differences Analysis

Next, to control for factors that could change prices across all hospitals, Baker differenced ENH's price change with a control group's price change. Baker used a control group of eighteen hospitals that Noether selected. DX 7126 at 71, ¶ 174; TR 4637-38 4637-38 (Baker), *in camera*; DX 8039, *in camera*. Noether did not explain with precision how she chose the eighteen hospitals, and her list does not match any set of hospitals in any particular document or any particular industry standard. TR 6149-51 (Noether). Again, using the "ENH constructed" measure, after differencing, Baker found that ENH's average net prices increased above those of the control group at Aetna by 26%, at Humana by 58%, and at United by 103%. Baker found that BCBS' prices did not increase. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. The combined average net price increase by ENH for all four payors was 25% above that of the control group.⁴⁸

Using the "ENH" measure, Baker found average net price increases to three of the payors and a price decrease for BCBS. After differencing, Baker found that ENH's average net prices increased above that of the control group at Aetna by 16%, at Humana by 35%, and at United by 105%. Baker found that BCBS' average net prices decreased by 11%. RX 2040 at 1, *in camera*; DX 7068 at 43, *in camera*. With the "ENH" measure, the average net ENH price increase for all four payors was 12% above above that of the control group.⁴⁹

⁴⁸ Again, Baker performed these calculations omitting obstetrics cases. The corresponding per case average net price increases above the control group were: Aetna (26%); Humana (61%); United (83%); and a decrease of 3% for BCBS. The corresponding average net price increase across all four payors of 23% above that of the control group. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*.

⁴⁹ The corresponding per case ENH average net price increases above the control group, omitting obstetrics, were: Aetna (23%); Humana (59%); United (96%); and a decrease of 5% for BCBS. The corresponding combined price increase for all four payors was 21% above that of the control group. RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*.

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Again, Baker did not report the statistical significance of any of these differences. Presumably, if the increases were *not* statistically significant, Baker would have had an incentive to disclose that information. Regardless, Baker's DID results, like Haas-Wilson's, are not particularly informative because (1) they do not account for the substantial changes that Haas-Wilson found in case mix, patient mix, customer mix, and teaching intensity between ENH and other hospitals and, (2) as explained below, his DID results differed substantially from his linear regression results.

c. Linear Regression Analysis

The third step in Baker's analysis is probative. As with Haas-Haas-Wilson, Baker's third step was a regression model, which he used to control for changes in cost, demand, and regulation common to both ENH and hospitals in his control group. Because Baker was unable to adjust for variations in outpatient cases, he included only inpatient cases in his regression analysis. TR 4642 (Baker), *in camera*; DX 7068 at 15, *in camera*. Baker also used his regression to control for a range of variables that could affect price, including a patient's age, gender, length of stay, type of health care plan, and hospital. DX 7068 at 16, ¶ 38, *in camera*.⁵⁰ To control for changes in case mix, Baker estimated his model separately for each DRG and for each payor. *Id.*, *in camera*.⁵¹ Baker then calculated a weighted average ENH net price change over all the DRGs. *Id.* at 17, ¶ 39, *in camera*. Significantly, from this regression model, Baker concluded that, relative to the control group, ENH's inpatient average net prices increased by 9% or 10% more than the predicted level, depending on whether obstetrics cases

⁵⁰ Differing slightly from his earlier work, Baker used the natural logarithm of prices, rather than the prices themselves, as the dependent variable. RX 2040 at 3, *in camera*; DX 7068 at 45, *in camera*.

⁵¹ Haas-Wilson used different specifications to control for changes in case mix. Presumably she could have used an identical specification but chose not to.

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were included. *Id.* at 19-20, ¶ 43, *in camera*; RX 2040 at 3, *in camera*; DX 7068 at 45, *in camera*. For inpatient and outpatient cases combined, Baker found that average net prices increased by higher-than-predicted levels of 11% or 12%. TR 4602-03 (Baker); DX 7068 at 21, *in camera*. As before, Baker did not report statistical significance, which is very unusual for regression results. One can presume again that Baker's results were statistically significant because, if the results were insignificant, Baker would have had a strong incentive to report this.

3. Summary and Findings of Fact Concerning the Econometrics

We find that the econometric work of both Haas-Wilson and Baker supports our finding that the higher-than-predicted merger-merger-coincident increases in ENH's prices reflect the exercise of of market power caused by the merger. The economic testimony is marked by both agreement and disagreement over the correct way to to estimate the price changes associated with the merger, but significantly for purposes of resolving this case, the results of the analyses differed very little.⁵² Every empirical analysis conducted by Haas-Wilson and Baker found higher-than-predicted merger-coincident increases in ENH's average net price for Humana and United. All but one of the empirical analyses conducted by Haas-Wilson and Baker found higher-than-predicted merger-coincident increases in ENH's average net price for Aetna. Nearly every empirical test found little or no unexplained merger-coincident average net price increase for BCBS.

In addition, Haas-Wilson's calculation of average market-wide changes in net price for all payors and Baker's calculation of the average net price increase for Aetna, BCBS, Humana, and United,

⁵² There are essentially four different regression analyses: Haas-Wilson's regressions using the Illinois Data, Haas-Wilson's regressions using the payor data, Baker's regressions using the payor data, and Baker's learning-about-demand regressions, described *infra* 43-45, which also relied on the payor data.

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produced very similar results. As we discuss in our findings about Respondent's "learning-about-demand" argument, only when Baker used a particularly contrived and narrow control group of six academic hospitals was he able to account for the merger-merger-coincident price increases.

Haas-Wilson's work demonstrated that Aetna, Humana, United, and Great West likely experienced higher-than-predicted price increases as a result of the merger, while BCBS did not. TR 2501, 2540 (Haas-Wilson), *in camera*. Using the payor data, the magnitude of the estimated average net price increase beyond that of the control groups ranged from 12.3% to 93.2%, depending on the payor and the control group used for the regression. CX 6279 at 18-19, *in camera*. Using the Illinois data, Haas-Wilson estimated that the merger caused market-wide average net price increases of 11% to 18%. *Id.* at 20 *in camera*.

Baker obtained very similar results. Again, Baker calculated that, relative to his control groups, average net inpatient prices across the four MCOs that he examined increased by 9% or 10% more than the predicted level due to the merger. TR 4620, 4645-46 (Baker), *in camera*; RX 2040 at 3, *in camera*; DX 7068 at 21, ¶ 47, *in camera*.

Respondent briefly maintains that the Commission cannot rely on the econometrics because they were based on "imperfect" data. RB 50. Data inevitably have some flaws, and Haas-Wilson acknowledged that the data were not perfect. TR 2496-500 (Haas-Wilson). The question is whether the data are sufficiently reliable that they are suitable for analysis. Both Haas-Wilson and Baker relied heavily on the payor data, and the record indicates that that this reliance was sensible because the data were comprehensive enough to permit sound analyses. The data contained information from many (if not all) of the acute care hospitals in the Chicago metropolitan area from 1998 to 2002, and included data from more than 70% of ENH's MCO patients on a per

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per case basis in 2002. See CX 6279 at 5, *in camera*. Further, Baker obviously felt sufficiently confident about the data to use them for most of his econometric analysis. The fact that Haas-Wilson obtained similar results from her regressions using the Illinois data also suggests that the payor data, as well as the Illinois data, were sufficiently reliable to instill confidence in Haas-Wilson's and Baker's results.

We also reject Respondent's argument that Haas-Wilson did not account for every possible factor that might explain ENH's substantially higher-than-predicted merger-coincident price increases, such as increases in marketing or advertising. RB 57. Rarely is it possible to consider every imaginable factor that might cause a price increase, and that is not necessary to have confidence in the results of econometric analysis. The issue is whether Haas-Wilson (and Baker) took into account the factors that were reasonably likely to have caused the substantial post-merger price increases. We find that both of them ruled out those other factors with econometric analysis. Further, as we describe below, the parties' documents and the balance of the record indicate that it is very unlikely that the higher-than-predicted portions of the price increases were due to other competitively-benign causes.

It is true that neither Haas-Wilson nor Baker provided the Commission with their exact econometric model, and Haas-Wilson Haas-Wilson did not provide a full explanation of how she calculated prices from the Illinois data. If the results of the regressions were more mixed, this lack of detail might make us less less confident about their reliability. However, except for our rejection of a portion of the results obtained from Baker's narrow "learning-about-demand" six-hospital control group (discussed below), we need not pick and choose among the economists' various various regressions, or the data sources, because they all produced essentially the same result: there were substantial higher-than-higher-than-predicted merger-coincident average net price increases, increases, and it is likely that a significant portion of these increases

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increases did not result from the most likely competitively-benign causes. The consistent results of such a wide range of tests utilized by both sides' experts, combined with our other findings of fact, warrant our finding that it is very likely that the unexplained portions of the merger-coincident price increases were due to ENH's exercising market power created by the merger.

M. Learning-About-Demand

Respondent vigorously maintains that ENH's post-merger increases in the prices for Evanston Hospital were caused by ENH's obtaining information about Highland Park's prices during the due diligence process, rather than the exercise of market power. RB 47-59. This information allegedly showed ENH that some of Evanston's pre-merger prices were below those charged by Highland Park. RB 18 47-59. Respondent argues that because Evanston offered more "comprehensive and advanced" services than Highland Park, and because more advanced hospitals allegedly receive higher prices, Evanston concluded that its pre-merger prices were below competitive rates. RB 51. If Evanston had been charging competitive prices, respondent reasons, its pre-merger prices would have exceeded those charged by Highland Park. RB 50-51.

As we discuss in our legal analysis, respondent does not cite any case in which a party has argued that its price increases are an attempt to correct a systematic failure to charge competitive prices, and our research has not produced any such authorities. As we also discuss, we need not resolve all of the doctrinal issues associated with Respondent's argument because none of the four types of evidence offered by respondent to support the learning-about-demand position indicates that Evanston was systematically charging below-competitive prices to MCOs before the merger. We also note at the outset of our analysis that Respondent's learning-about-demand argument does not apply to the

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the merger-coincident price increases at Highland Park, which respondent appears largely to attribute to post-merger improvements in quality at the hospital. RB 51.

1. ENH Officials' Testimony

Evanston's Chief Operating Officer, Jeffrey Hillebrand, testified that from 1990 to 1998 Evanston's strategy was to have a relationship with every health insurer, and that this goal affected Evanston's negotiating style. TR 1835 (Hillebrand). He also testified that during the 1990s there were fewer financial pressures on hospitals; that Evanston had a target rate of return; and that "as long as we were able to achieve that, management and our board felt that whatever pricing we were getting was sufficient." TR 1836 (Hillebrand). According to Hillebrand, Evanston did not renegotiate a number of its contracts for approximately five years before the merger, TR 1850 (Hillebrand), which purportedly resulted in Evanston's "short-changing itself for years in negotiations with MCOs." RRB 49.

Respondent assigns some of the responsibility for its all-inclusive strategy with MCOs to Jack Sirabian, who was Evanston's principal negotiator from 1990 to 2000 and in that position reported to Hillebrand. TR 5697-98, 5701 (Sirabian). Sirabian and Kim Ogden of Bain testified that Sirabian wanted to have Evanston included in every network, lacked negotiation experience and support staff, and "was not comfortable taking a tough stand." TR 5697-98 (Sirabian); RX 2047 at 34 (Ogden).

Respondent asserts that it hired Bain in 1999 to conduct an analysis of its contracts and assist it with the merger. Bain's analysis purportedly demonstrated that Highland Park had higher rates than Evanston for the majority of its MCO contracts. Hillebrand testified that he was surprised and "embarrassed" to learn this fact. TR 1853 (Hillebrand). Neaman similarly testified that that he was "shocked" by the purported price disparity between

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Evanston's and Highland Park's prices. TR 1344-45 (Neaman). Based on Bain's conclusions, ENH decided that it would use more aggressive negotiating tactics with MCOs, including risking being dropped from the MCOs' networks. TR 1854-55 (Hillebrand); TR 1218 (Neaman).

The testimony by Hillebrand, Sirabian, and Neaman is not persuasive. First, respondent stated in the proposed findings of fact submitted to the ALJ that during the 1990s Hillebrand participated in negotiations with larger MCOs, such as BCBS, which caused Sirabian to pay "closer attention" to these pre-merger pre-merger contract negotiations and resulted in contracts with higher prices. RFF ¶¶ 604, 757; RB 52; see also TR 1700, 1836 (Hillebrand). As a result, ENH did not need to impose a "relative post-merger price increase" on BCBS. RB 52. Thus, the import of Respondent's argument is that Evanston allowed Sirabian to forgo millions of dollars for the better part of a decade for those contracts that he negotiated alone, but charged market rates when Hillebrand (to whom Sirabian reported) participated in the negotiations. This argument and the supporting testimony lack credibility.⁵³

Second, Neaman testified that Hillebrand was an effective negotiator, with a good understanding of the marketplace and Evanston's relationships with health plans. TR 1220 (Neaman).

⁵³ Respondent also claims that it needed to raise its prices in 2000 because it faced new financial pressures, including that the Balanced Budget Act reduced its revenues and MCOs began to exert increased negotiating pressure. RB 49 (citing RFF ¶¶ 106, 110, 624, 630-33, 637). These events were not unique to respondent; they affected many hospitals, including Highland Park. Respondent asserts in its proposed findings of fact that Highland Park also felt the impact of the Balanced Budget Act, RFF ¶ 632, and Neaman testified that Balanced Budget Act cuts had hurt Highland Park's financial performance, TR 1137 (Neaman), *in camera*. Respondent does claim that the Balanced Budget Act hit hospitals like Evanston harder because it had more clinical lines of service and teaching programs. RB 16. Respondent, however, cites only a few lines of conclusory testimony in support of this assertion. RFF ¶¶ 628-29.

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Neaman also testified that he never criticized Hillebrand about Evanston's pre-merger contracts with health plans. TR 1220 (Neaman). While not dispositive, such testimony contradicts Respondent's argument.

Third, for those contracts that Sirabian allowed to remain in effect for a number of years without renegotiation, the record indicates that it is equally plausible that the prevailing competitive environment would not have allowed Evanston to raise prices. Spaeth testified that during the 1990s, Highland Park had "multi-year, no change contracts" and that before the merger he did not see an opportunity for Highland Park to raise prices. TR 2182, 2172-73 (Spaeth). As the ALJ found, "[t]he fact that Highland Park executives were concerned about contract terminations pre[-]merger [if they raised rates] is illustrative of the competitive environment that existed before 2000 and stands in contrast to the [post-merger] actions of ENH officials who, given their competitive situation, were not constrained by such prospects in their renegotiations with managed care representatives" ID 166.

Finally, Respondent's learning-about-demand argument is difficult to square with Respondent's position that Evanston was and is a state-of-the-art hospital, with superior management, that consistently provided high-quality services. RB 7. Respondent maintains that despite these many attributes, Evanston could not set prices at market levels for some MCOs. In contrast, respondent respondent maintains that Highland Park failed to address quality issues properly, provided poor services to the point that it was threatening patient safety, was in severe financial distress, and would have deteriorated without the merger. RB 8-9, 63-67, 69. Despite these alleged shortcomings, Respondent's learning-about-learning-about-demand argument rests on the premise that Highland Park officials were proficient at setting the hospital's profit-maximizing price. This logical discrepancy is not determinative, but

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when viewed in conjunction with the totality of the other evidence, supports rejecting Respondent's learning-about-demand position.⁵⁴

2. Baker's Learning-About-Demand Analysis

Baker sought to show through econometrics that at least some portion of ENH's post-merger price increases was due to ENH's learning that it had under-priced the market. Baker's work, however, partially undermines Respondent's position. To test Respondent's learning-about-demand position, Baker performed a regression analysis that was conceptually similar to the regression model that he used to measure the post-merger net price changes. TR 4665-67 (Baker), *in camera*; DX 7068 at 29-30, ¶¶ 60-61, *in camera*. The primary difference was that, in his first regression, Baker used an eighteen-hospital control group; his learning-about-demand regression used a control group that consisted of only six hospitals selected by Noether, which Noether termed an "academic" group. DX 7068 at 27-30, ¶¶ 58-61, *in camera*; RX 2040 at 4, *in camera*; DX 7068 at 46, *in camera*. Baker's rationale was that the information on market demand that ENH had obtained from the merger would enable it to price up to but not above the average prices charged by this group of hospitals, which Noether claimed were peers to Evanston. TR 5993-6000 (Noether); DX 7068 at 27, ¶ 56-57, *in camera*.

Baker estimated the average difference in the net prices between Evanston and each of the six academic hospitals for each year, after controlling for variation in the mix of patients across hospitals. DX 7068 at 28-29, ¶ 60, *in camera*. Baker then calculated the weighted

⁵⁴ There is also an overall lack of merit to respondent's contention that some of the MCO witnesses supported its learning-about-demand argument because they agreed that some of their contracts with Evanston were outdated. As the ALJ correctly found, these witnesses also testified that they thought that ENH's post-merger price increases far exceeded reasonable market price benchmarks. ID 172; IDF ¶¶ 392-456.

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average across the six hospitals of these predicted average differences. Baker found that the average net price (combining the four MCOs in his sample: United, Humana, BCBS, and Aetna) at ENH did not exceed the predicted level as compared to the control group. TR 4809-11 (Baker), *in camera*; RX 2040 at 4, *in camera*; DX 7068 at 30-31, 46, *in camera*. In contrast to all of his prior results, Baker also reported the statistical significance of his results.⁵⁵

Baker's regressions with the six-hospital control group are not reliable, however, because, as the ALJ found, and we agree, the narrow academic control group is highly flawed. The academic control group consisted of Advocate Lutheran General, Advocate Northside, Northwestern Memorial, Rush-Presbyterian-St. Luke, Loyola, and the University of Chicago. TR 6000 (Noether). Noether selected her academic control group based on three criteria: teaching intensity (rate of residents to beds); number of staffed beds; and breadth of services (number of DRGs). IDF ¶ 808; TR 5993-95 (Noether). Noether included in her academic control group only hospitals with at least 370 DRGs, more than .25 residents per bed, and more than 300 staffed beds. IDF ¶ 808; TR 5993-95.

Noether's criteria appear to be somewhat arbitrary and designed designed to exclude a number of hospitals that likely are Evanston's Evanston's peers. The teaching intensity classification is consistent consistent with the Medicare Payment Advisory Commission's ("MedPac") provision that defines a "major teaching hospital" as a a hospital with "at least .25 residents per bed," but the DRG and number of bed criteria are not based on any specific established industry metric. IDF ¶¶ 809, 814, 817. The control group also included four of the most expensive hospitals in the city. Northwestern Memorial, University of Chicago, Rush-Presbyterian-Rush-Presbyterian-St. Luke, and Loyola each had higher average

⁵⁵ The Commission could not determine whether Baker's learning-about-demand regression analysis included obstetrics cases.

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reimbursement *per case* than did Evanston. RX 1912 at 147, 150, *in camera*. Conversely, the control group excluded less expensive hospitals that could handle most of the cases handled by Evanston. Evanston. IDF ¶ 819; RX 1912 at 60; *id.* at 147-52, *in camera*.

Additionally, four hospitals in the control group had a higher breadth of services (*i.e.*, number of DRGs) than did Evanston. IDF ¶¶ 821, 824-25; RX 1912 at 44, *in camera*. Also, four of the hospitals performed significant numbers of solid organ transplants, transplants, and two of them treated a significant number of extensive burn injuries. TR 2702 (Haas-Wilson), *in camera*; DX 7058, *in camera*. Evanston did not provide either service. TR 1378 (Neaman). Four of the six hospitals in the control group had a substantially greater number of residents per bed (*i.e.*, more teaching intensity) than did Evanston. RX 1912 at 60. At the time, Evanston had 0.3386 residents per bed, while Loyola University had 0.6060 residents per bed, Northwestern Memorial had 0.5670 residents per bed, Rush-Presbyterian-St. Luke's had .7606 residents per bed, and University of Chicago had 0.7938 residents per bed. IDF ¶ 827; RX 1912 at 60.⁵⁶

Further casting doubt on Noether's criteria for selecting the narrow control group is that her standards resulted in the exclusion of two hospitals – Louis A. Weiss Hospital and St. Francis Hospital – that met the MedPac criteria for a major teaching hospital but that, according to Noether's calculations, charged average prices below those charged by ENH from 2000 to 2003. TR 5921-22, 6170-71 (Noether); RX 1912 at 60; *id.* at 148, 151, *in camera*. Similarly, Noether excluded a number of hospitals that had a higher case mix index than did ENH, which she calculated

⁵⁶ Moreover, three MCO witnesses testified that Evanston was not an academic hospital. TR 621 (Neary); TR 1444 (Dorsey); TR 936 (Foucre). We find this testimony to be credible. Further, none of the Bain documents upon which respondent relies so heavily, *infra* 46-47, references these very high-end academic hospitals as the appropriate benchmark for Evanston's prices. TR 2052-58 (Hillebrand).

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charged average prices below those charged by ENH from 2001 to 2003. TR 6168, 6170-72 (Noether); RX 1912 at 25; RX 1912 at 148-49, 151-52, *in camera*. These hospitals were Alexian Brothers Medical Center, Northwest Community Hospital, and St. Francis Medical Center. TR 6168, 6170-72 (Noether); RX 1912 at 26, 148-49, 151-52, *in camera*.⁵⁷

Even assuming that Baker's and Noether's narrow academic control group was valid (which it is not), Baker's regressions still partially undermine Respondent's argument because he computed that Evanston's post-merger prices to both Humana and United were significantly higher than he predicted they would have been without the merger. TR 4682-85 (Baker), *in camera*; RX 2040 at 4, 4, *in camera*; DX 7068 at 46, *in camera*. For Humana, Baker computed that in 2002 the net prices ENH charged were 21% higher higher than he predicted they would have been had the merger not occurred. RX 2040 at 4, *in camera*; DX 7068 at 46, *in camera*. For United, the net prices ENH charged in 2002 and 2003 were higher by 35% and 29%, respectively. RX 2040 at 4, *in camera*; DX 7068 at 46, *in camera*.⁵⁸ The results for United are particularly significant because respondent repeatedly cites United as its primary example of a contract under which ENH's pre-merger prices were substantially below market. *E.g.*, RB 52.

⁵⁷ Noether also excluded from her academic control group a number of hospitals that she listed as "best practice competitors" in her expert report, including Hinsdale Hospital, Christ Hospital, and MacNeil Hospital. TR 6152 (Noether); DX 7126 at 50. Conversely, Noether included in the academic control group Loyola University Medical Center and Rush-Presbyterian-St. Luke's Medical Center, which are not listed in the documents that she relied on in her report to identify Evanston's competitors. TR 6153-54 (Noether).

⁵⁸ The Commission computed the numbers through straightforward calculations of the percentage differences in rows 7 vs. 9 (Humana) and rows 10 vs. 12 (United) in RX 2040 at 4, *in camera*; or DX 7068 at 46 (Table 4), *in camera*. The calculations are the following: Humana in 2002 – 21% = $(\$9,683 - \$7,993)/\$7,993$; United in 2002 – 35% = $(\$10,373 - \$7,708)/\$7,708$; United in 2003 – 29% = $(\$11,479 - \$8,906)/\$8,906$. RX 2040 at 4, *in camera*; DX 7068 at 46 (Table 4), *in camera*.

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Baker's findings for Aetna and BCBS were more favorable to ENH. He found that the prices ENH charged to these two payors were not statistically higher than prices at the academic hospitals. These results are not informative, however, because of Baker's use of the flawed narrow control group.

3. Comparisons of Evanston's and Highland Park's Prices

Respondent also tried to support its learning-about-demand position by introducing evidence that purportedly showed that Evanston charged lower prices than those charged by Highland Park for a number of MCOs before the merger. We find that this evidence does not support Respondent's argument.

First, it is not entirely clear whether respondent is correct that Evanston's theoretical equilibrium price was systematically higher than Highland Park's, particularly for the primary and secondary services that both hospitals provided. Highland Park is located in the wealthiest part of the North Shore suburbs. TR 320-21 (Newton). Several of the MCOs explained that it was important to include Highland Park in their networks because many high-level officials who selected their company's health plans lived in Highland Park and wanted access to the local hospital. As One Health's Neary explained:

[I]n my opinion, . . . Highland Park knew that they had these influential people who were living in their community who would not be satisfied with a network that didn't have Highland Park in their . . . healthcare plan. So, Highland Park had that as basically negotiating leverage, and they were able to say that these folks want us in their network, so you need to contract with us at higher rates.

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TR 605-06 (Neary). Given the MCOs' desire to satisfy major corporate decision-makers, some MCOs may have been willing to pay Highland Park higher rates than they would pay to Evanston.

Assuming that Evanston's theoretical, equilibrium price was greater than Highland Park's price, Respondent's pricing evidence that purported to show that Evanston's pre-merger prices were often below Highland Park's prices is not persuasive. Noether compared Evanston's and Highland Park's 1999 *per diem* rates for a number of payors at a number of different hospitals. RX 1912 at 34, *in camera*. The results showed that Highland Park's prices were higher than Evanston's for all the payors except BCBS and Unicare. TR 6079, 6088 (Noether). Noether's results are flawed because, as she argued (and we agree), price *per case* is likely a more meaningful measure of price than price *per day*. DX 7126-104. Also, Noether's table does not report statistical significance. RX 1912 at 34, *in camera*.

In addition, Haas-Wilson's calculations showed that pre-merger pre-merger prices were higher at Evanston than they were at Highland Park. TR 2646 (Haas-Wilson), *in camera*; DX 7047 at 1, 1, *in camera*. Baker implicitly arrived at the same conclusion as Haas-Wilson. TR 4744-47 (Baker), *in camera*. As the ALJ found, Baker calculated the average percentage price increase following the the merger for four health plans – Aetna, BCBS, Humana, and United – using two methodologies: (1) comparing Evanston's and Glenbrook's pre-merger prices to the ENH post-merger prices; and and (2) comparing Evanston's, Glenbrook's, and Highland Park's combined pre-merger prices (Baker's "constructed prices") to the ENH post-merger prices. IDF ¶ 795 (citing TR 4633 (Baker), *in camera*). The constructed price calculation (which includes the pre-merger prices at Highland Park) showed a larger average post-post-merger price increase than his calculation for the price increase increase (both with and without obstetrics) for just Evanston and Glenbrook. RX 2040 at 1-2, *in camera*; DX 7068 at 43-44, *in camera*. It follows that because the post-merger price increases were were larger when Baker included Highland Park's prices in his

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calculations, Highland Park's average prices were lower than the average prices at Evanston and Glenbrook before the merger. TR 4744-47 (Baker), *in camera*. And finally, ENH's Sirabian testified that no more than one-third of Highland Park's contracts had higher higher rates than those contained in Evanston's contracts. TR 5717 5717 (Sirabian).

Respondent attempts to dismiss Haas-Wilson's and Baker's calculations on the ground that they were based on econometric analyses that controlled for various factors, such as case mix, rather than the nominal contract rates. RB 50. Respondent appears to argue that even if Evanston's prices, when adjusted for these relevant factors, were higher than those charged by Highland Park, ENH and some MCOs believed that they were lower based on a review of the nominal "*contract rates*," RB 50 (emphasis added), and therefore that Respondent's merger-coincident price increases could not have been due to market power. This reasoning is unconvincing. Even if we assume that Evanston's unadjusted prices were below Highland Park's, ultimately, business decisions are made based on actual rather than nominal prices. For example, we would not expect job seekers to decide between various employment opportunities using only nominal (*i.e.*, "unadjusted") wages; rather, we would expect them to consider the quality of the work, training opportunities, potential bonuses, the number of vacation days, and other factors along with wages. Therefore, we find that the appropriate way to compare prices is by controlling for the appropriate variables, which is the approach used by Haas-Wilson and Baker.

Respondent also argued that Bain concluded that Highland Park had higher prices for certain contracts. *E.g.*, RX 652; RX 684; 684; RX 1995, *in camera*. In several of these documents, Bain compared what it described as the "non-adjusted" contract terms of of Evanston's and Highland Park's pre-merger contracts. RX 684 at at 6. As the ALJ correctly found, the actual revenues received by a hospital are a function of both the discount rate in the contract and

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the hospital's chargemaster. IDF ¶ 789-93; ID 173. A hospital with a higher chargemaster can have a lower discount rate and still charge higher prices. IDF ¶ 789-93; ID 173. Further, even the Bain documents that purport to compare Evanston's and Highland Park's contracts on an "adjusted" basis do not identify with precision the methodology that Bain used to make this determination. RX 1995 at 8, *in camera*. Therefore, the pre-merger pricing analyses that Bain performed shed relatively little light on Respondent's learning-about-demand position. *Id.*

Finally, respondent cites Terry Chan's assessment about the relationship between Evanston's and Highland Park's prices before the merger. As the Highland Park employee tasked with analyzing the two hospitals' prices shortly before the merger, Chan authored a September 24, 1999 memo that stated that Highland Park's contract rates "seem[ed] to be higher" than those charged by Evanston, but she acknowledged that her analysis did not include "information on [Evanston's] charges and case mix." TR 715 (Chan); RX 620 at 1, *in camera*. Chan also qualified her subsequent assessment that if Highland Park had applied the rates contained in Evanston's contract rates in the previous year, Highland Park would have earned approximately \$5 million less in inpatient revenue and \$8 million less in outpatient revenue, RX 625 at 8294; RX 674 at 17915, with the caveat that "[f]uture environments under [Evanston's] pricing structure and case mix might yield different results." RX 674 at 17915. Chan noted in other memos that the "gross" rates in Evanston's chargemaster were expected to be higher than those in the chargemaster used by Highland Park, RX 663 at 016939, *in camera*, and that "ENH's charge master . . . is expected to generate higher gross charges than [the] gross charges generated by Highland Park Hospital's current chargemaster." CX 1373 at 14, *in camera*. These observations suggest that the net prices charged by Evanston may have been higher than those for Highland Park.

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4. Comparison of Evanston's Prices and Other Hospitals' Prices

Finally, Noether attempted to validate ENH's learning-about-demand argument by comparing Evanston's average pre- and post-merger price levels with the average prices of groups of what she termed "community" and "academic" hospitals. TR 5993 (Noether). Her premise was that if Evanston had learned that its prices were low coincident with the merger, she would expect Evanston's price to move from the average community hospital price to the average academic hospital price. TR 6060 (Noether), *in camera*. Noether reported her results using graphical plots of prices. RX 1912 at 62-75, 108-52, *in camera*. In Noether's graphs, ENH's price appeared to move closer to the academic average price for a number of payors, but not all payors.

Noether's price comparisons are unreliable, however, because they use the flawed academic control group. Further, even assuming that the control group is reasonable (which it is not) and that Noether's calculations are correct, standing alone they do not support Respondent's learning-about-demand position because they are equally consistent with the post-merger exercise of market power by ENH.

5. Summary of Findings of Fact on Learning-About-Demand

While no one type of evidence in the record is dispositive, we find that the totality of the record warrants rejecting Respondent's position that ENH's learning-about-demand explains the substantially higher-than-predicted merger-coincident price increases.

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N. Post-Merger Improvements and Cost Reductions**1. Merger-Specificity**

As stated above, in addition to believing that the merger would and did allow ENH to raise prices to MCOs, Evanston's senior officials viewed the merger as an opportunity to achieve cost cost reductions and economies of scale in various clinical and administrative areas,⁵⁹ and to provide an additional teaching site for Evanston and Northwestern University Medical School. CX 359 at 22. Highland Park officials saw the merger as an opportunity for an infusion of capital at a time when the hospital was experiencing reduced income. TR 1327-28 (Neaman); TR 2266 (Spaeth). Those officials also viewed Evanston as an experienced partner that could help Highland Park implement new programs and enhance existing services – in particular cardiac surgery and oncology. TR 2273-74 (Spaeth); CX 6305 at 7. At Highland Park's insistence, the merging parties' letter of intent included specific commitments to implement these programs. RX 567 at 10, 12-13; CX 6305 at 9-10.

Shortly after the merger, ENH established a cardiac surgery program at Highland Park and an interventional cardiology program program that supplemented Highland Park's existing diagnostic cardiology program. IDF ¶¶ 952, 961. In mid-2000, ENH expanded expanded Highland Park's existing oncology services by opening the the Kellogg Cancer Care Center at Highland Park, which provided a provided a multi-disciplinary approach to cancer care and brought together an array of oncology services in a single location. IDF ¶ 921. ENH also established a residency training program in family medicine at Highland Park, and obtained academic appointments at at Northwestern University Medical School for approximately sixty

⁵⁹ Highland Park's transaction counsel also advised Highland Park's board that, although the merger might produce cost savings, "such savings are not the highest priority of the transaction" and "[t]he financial condition of both parties is such that neither require [sic] a financial reason for such affiliation." CX 1923 at 2; TR 5840 (Kaufman); IDF ¶¶ 1039-40.

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Highland Park physicians, enabling them to participate in teaching activities (principally at Evanston). IDF ¶¶ 988, 990; TR 3124-25 (Romano), *in camera*.

In addition, ENH improved Highland Park's physical facilities – *e.g.*, it constructed a new ambulatory care center, renovated the emergency department, and expanded the on-site laboratory – and upgraded some equipment. IDF ¶¶ 911-20, 929, 935-36, 941-43, 962 962 968. ENH also replaced all three hospitals' existing electronic medical records systems with an integrated, entirely paperless computerized system called EPIC. IDF 976-81.⁶⁰ All told, ENH spent approximately \$120 million to make these changes at Highland Park. TR 1250, 1350 (Neary).

Complaint counsel and respondent each presented the testimony of a healthcare quality expert, who identified three widely recognized measures of quality: structure (*e.g.*, facilities, staffing), process (*e.g.*, surgical procedures, medication regimens), and outcome (*e.g.*, mortality). TR 2986-87 (Romano); TR 5143-45 (Chassin). ENH's evidence focused principally on structural changes (as well as some process changes) made by ENH, which its expert, Dr. Mark Chassin, testified constituted quality improvements because they “increase the likelihood of desired health outcomes.” TR 5141 (Chassin). Complaint counsel's expert, Dr. Patrick Romano, focused principally on outcome measures. For the most part, ENH did not endeavor to show that the claimed improvements have actually improved health care outcomes at Highland Park.

The ALJ found that ENH did not present any quantifiable evidence that improvements at Highland Park enhanced competition, competition, ID 177, and that ENH failed to show that quality

⁶⁰ EPIC is a software system for managing patient records for both hospitals and physicians. It includes a physician order entry system and clinical decision support systems. IDF ¶¶ 978-79.

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improved across the combined ENH system (not just at Highland Park) and relative to other hospitals. ID 179-81. The ALJ found that that Highland Park could have achieved the vast majority of the claimed improvements without the merger. ID 182-92.

Our findings of fact differ in some respects from those of the ALJ, but we agree with the ALJ that Highland Park could have made the large majority of the quality improvements asserted by ENH without the merger. The record shows, and we find, that Highland Park was considered to be an excellent community hospital before the merger. IDF ¶¶ 850-52; TR 2095-98 (Spaeth); TR 4382 (Dragon); TR 5087-88 (Ankin). Highland Park had plans in place to improve its quality and expand services further without a merger, including many of the same improvements that ENH credits to the merger. Highland Park planned, for instance, to develop a cardiac surgery program in affiliation with Evanston or another hospital. IDF ¶¶ 952-59. In fact, in early 1999, Highland Park and Evanston entered into an agreement to develop a joint cardiac surgery program at Highland Park, with the understanding that implementation of the program did not depend on a merger. IDF ¶¶ 958-59. This agreement was similar to the affiliation agreements that ENH has with two other community hospitals – Swedish Covenant and Weiss – where it currently runs successful cardiac surgery programs without a merger. IDF ¶ 957; TR 4442-44, 4527-28 (Rosengart). Highland Park planned to improve its interventional cardiology services by expanding the diagnostic capabilities of its existing cardiac catheterization lab and to provide emergent angioplasty with the planned cardiac surgery program. IDF ¶ 964.

Highland Park also had plans to enhance its existing “center for excellence” in oncology by launching a joint comprehensive oncology program with an institution other than Evanston, without a merger. IDF ¶¶ 924-28. In late 1997, Evanston’s CEO wrote to Highland Park’s CEO:

Our interest and expertise in developing an oncology oncology program with you along the same lines as

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with cardiac surgery, is extremely high . . . [H]aving the proven track record of already expanding our oncology program at both Glenbrook Hospital and Swedish Covenant Hospital, we believe we have developed a successful model that could rather quickly be implemented at your institution.

CX 1865 at 2. Evanston also considered partnering with organizations other than Highland Park. IDF ¶ 925.

Additionally, Highland Park's strategic plans in 1998 and 1999 identified plans to enhance clinical services in maternal/fetal health, orthopedics, surgical services, and behavioral services; to improve physician collaboration; to improve workflow in all departments with particular focuses on radiology, cardiology, laboratory, and physical medicine; and to utilize technology to expand access to information to physician offices. CX 1868 at 13, 16, 18; CX 1908 at 13-14, 18, 20; IDF ¶¶ 869-70. In March 1999, Highland Park's finance committee approved a long-range capital budget of \$43 million for investments in strategic initiatives and master plan items such as cardiology services, ambulatory services, oncology, assisted living, and facility expansion, and \$65 million for hospital construction, routine capital, and information technology. CX 545 at 3; IDF ¶¶ 872-74.

Prior to the merger, Highland Park already had begun to make a number of the improvements that ENH contends the merger produced. For instance, in early 1998, Highland Park initiated an effort to improve the quality of care provided in its obstetrics and gynecology ("OB/GYN") department by inviting the American College of Obstetricians and Gynecologists ("ACOG") to conduct an on-site review of its birthing center and make recommendations for improvements. Highland Park then undertook a comprehensive effort to implement these recommendations and address the issues that ACOG had identified. IDF ¶¶ 883-86 (citing TR 3152-54 (Romano), *in camera*);

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camera); TR 389-93 (Newton). Highland Park also began the process of improving its nursing staff by hiring new, more effective effective nursing leaders and initiating a comprehensive effort to train, retain, and reward its nurses, and to improve communications communications between nurses and physicians. IDF ¶¶ 908-10; TR TR 3746-49 (Krasner); TR 5479-80 (Chassin); CX 6265 at 19, 21, *in in camera*. Before the merger, Highland Park also undertook an internal review of its quality assurance and quality improvement programs to identify ways to enhance these programs. IDF ¶ 898. The resulting report laid out a number of planned initiatives for improvements, including some of the same types of improvements that ENH asserts were produced by the merger. RX 417.⁶¹

The record also shows that a number of the changes that ENH made at Highland Park after the merger merely reflect emerging trends in the industry, rather than benefits unique to the merger. IDF IDF ¶ 895 (quality assurance program); IDF ¶¶ 901-02 (quality improvement program); IDF ¶ 950 (decentralized dispensation of medication); IDF ¶ 973 (use of intensivists); IDF ¶ 983 (electronic medical records systems); TR 3840-41 (Silver) (in-house physician physician coverage in obstetrics departments). Further, since the time of the merger, there has been a growing consensus regarding how best to monitor and improve healthcare quality measures that Highland Park likely would have incorporated into its quality assurance and quality improvement programs had it not merged with with Evanston. TR 2998-99, 3003-04 (Romano). And while respondent criticizes pre-merger Highland Park for not having had an intensivist program or a completely paperless electronic medical

⁶¹ For example, the report included recommendations that Highland Park consider developing an interdisciplinary steering committee to focus on operations and quality issues; develop a mechanism to improve reporting of adverse events; develop and adopt additional treatment protocols to address co-morbidity and complications; review the quality tracking indicators used by Highland Park and identify critical indicators that ought to be tracked; and improve usage of national benchmarks. RX 417; *see also* CX 99 at 3 (outlining Highland Park's plans, *inter alia*, to develop additional care maps that incorporate national benchmark data).

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medical records system, ENH's decision to implement these programs at Highland Park was largely influenced by the publication, in 1999 and 2000, of recommendations by the Institute of Medicine and the Leapfrog Group. TR 4065-66 (Wagner); TR 5079-87 (Ankin). In short, the record does not contain sufficient evidence to conclude that had it not merged with Evanston, Highland Park could not, or would not, have been responsive to these emerging trends as well.

In this respect, we disagree with the ALJ's decision that ENH's installation of EPIC at Highland Park in late 2003 was a merger-specific quality improvement. Prior to the merger, Highland Park was exploring ways to improve its information technology. CX 94 at 2-3; CX 1908 at 20. Although the ALJ concluded that Highland Park was unlikely, on its own, to have installed EPIC (in part because Highland Park already had an "excellent" electronic medical records system, and because, as a standalone hospital, it would not have had the same need as Evanston to integrate records from three hospitals, ID 190-91), Highland Park likely would have continued to improve its operations by investing in current information technology – if not EPIC, then through other appropriate systems.⁶²

We find only one merger-specific improvement: the medical staff staff integration and affiliation with a teaching hospital. The record shows that ENH physicians in several specialties now rotate through all three hospitals, and that ENH facilitated faculty appointments at Northwestern Medical School for approximately 60 Highland Park physicians, who now participate in teaching activities at Evanston (for example, by giving "didactic lectures" to medical students receiving their training at Evanston). IDF ¶¶

⁶² Complaint counsel's health care quality expert testified that there are no barriers other than cost for a community hospital to install EPIC, and some hospitals of similar size to Highland Park have partnered together to share the costs of installing and maintaining the system. TR 3162-63 (Romano), *in camera*.

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989-90; TR 3588-90 (Victor). The merger has not, however, transformed Highland Park (which has only one residency program, program, in family medicine) into a teaching hospital. IDF ¶¶ 988, 992. While studies have apparently shown that teaching hospitals have lower risk-adjusted mortality rates in certain clinical areas, there is no literature that shows that merely being owned by a teaching hospital is associated with improved quality of care. IDF ¶¶ 993; TR 3121-25 (Romano), *in camera*. ENH's health care quality expert testified that the integration of medical staff and academic affiliation provides Highland Park physicians with greater opportunities to upgrade their skills and keeps them "on their toes." TR 5373-78 (Chassin). But this does not constitute verifiable evidence that any such improvement is of sufficient magnitude to offset the competitive harm that demonstrably has resulted from the merger.

2. Effect of Highland Park Improvements on Demand

Respondent also maintains that some portion of the higher-than-predicted merger-coincident price increases computed by both Haas-Wilson and Baker was caused by increased demand for Highland Park's services due to post-merger improvements, and thus does not reflect the exercise of market power. RB 51, 58-59, 62, 72. We also find that the record does not support this assertion. Just as it is incorrect to conclude that nominal price increases by themselves reflect market power, it is also wrong to assume that nominal increases in quality are likely to lead to greater demand for the improved service. The relevant questions are whether Highland Park's quality improved relative to that of other hospitals, *and*, if so, whether such above-market improvements increased demand for the hospital's services.

As the ALJ found, quality of medical care is not easily defined or measured, ID 179, and this difficulty is reflected in the differing approaches of complaint counsel's and Respondent's health care experts. The record is ambiguous as to whether Highland Park's services improved more quickly than services at other hospitals in

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the Chicago area. If they did, however, they likely did so by only a modest amount. The Joint Commission on Accreditation of Healthcare Organizations (“JCAHO”) regularly evaluates overall hospital quality nationally, including at Highland Park and Evanston, and JCAHO accreditation is necessary to qualify for Medicare, as well as for most managed care plans. ID 181. JCAHO assigns hospitals scores based on approximately 1200 elements of hospital performance. *Id.* In 1999, Highland Park received a preliminary score of 95 and a final score of 96. *Id.* In 2002, Highland Park received a JCAHO score of 94, a slight decline from 1999. *Id.* Further, as we have already found, a number of the post-merger changes at Highland Park reflect emerging trends in the industry.

A comparison of the rate of Highland Park’s improvement to that of other hospitals is not critical, however, because even if the quality of care at Highland Park improved at a faster rate, the record does not support a finding that these improvements increased demand for Highland Park’s services. Again, hospital quality is difficult to measure, and demand for the services of one hospital compared to another is the product of a number of factors. Consequently, it does not follow that relative increases in the quality of one hospital always produce rapid increases in demand for that hospital’s services.

Here, the record indicates that relative demand for Highland Park’s services did not increase during the time period covered by the record. As the ALJ found, the record establishes that at the time that ENH increased its prices, ENH did not mention that its price increases to MCOs were due to improvements at Highland Park. IDF ¶ 840. Hillebrand testified that he did not tell MCOs that that the substantial post-merger price increases were a function of improved quality at Highland Park. IDF ¶ 842; ID 178. Similarly, Neaman testified that he never saw any documents correlating the higher prices with the quality changes at Highland Park. IDF ¶ 843; 843; ID 178. Even after ENH implemented changes at Highland Park, ENH never identified any improvements at Highland Park to

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to MCOs (other than in a single press release). IDF ¶¶ 841-47; ID 178. We agree with the ALJ that if relative quality improvements were what drove ENH's substantial post-merger price increases, logic suggests that ENH at least would have informed some MCOs MCOs on an individual basis about the improvements. ID 178.

Such communications never occurred. The MCO representatives testified that the topic of quality improvements at Highland Park never came up during contract negotiations. IDF ¶¶ 844-47; ID 178. The MCOs also testified that they were not aware of a significant increase in quality at Highland Park after the merger. IDF ¶¶ 846-47, 851; ID 181. Additionally, many of the price increases were instituted in 2000, before some of the improvements were made. IDF ¶¶ 911, 916, 966, 981.

In short, we find that the record does not support the conclusion that Highland Park's higher-than-predicted merger-coincident price increases were due to increased demand for Highland Park's services relative to those offered by other hospitals. Rather, as the ALJ found, "the totality of the evidence strongly suggests that Respondent's quality-of-care argument is a *post hoc* attempt to justify its post-merger price increases found to exist even by its own expert." ID 179 (emphasis in original).

V. CONCLUSIONS OF LAW

A. Section 7 of the Clayton Act

Section 7 of the Clayton Act prohibits the acquisition of assets "in any line of commerce or in any activity affecting commerce in any section of the country, [where] the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18. 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)). "Ephemeral possibilities" of

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anticompetitive effects, however, are not sufficient. *United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 623 (1974).

Merger enforcement is directed at market power. *Heinz Co.*, 246 F.3d at 713; *Merger Guidelines* § 0.1 (“[M]ergers should not be permitted to create or enhance market power or to facilitate its exercise.”). The courts analyze whether a merger will produce or increase market power through the use of the now-familiar sequential approach. The plaintiff first establishes the relevant market, which itself consists of the relevant product and geographic markets. *See United States v. Baker Hughes Inc.*, 908 F. 2d 981 982-83 (D.C. Cir. 1990). Typically, the next step is to assess whether the transaction would produce a significant increase in concentration in the relevant market. *Id.* If the plaintiff makes such a showing, there is a structural “presumption” that the merger will substantially lessen competition. *See Heinz*, 246 F. 3d at 715; *Baker Hughes*, 908 F. 2d at 982-83. The burden of production then shifts to the defendant to produce evidence that shows that the market share statistics do not reflect the merger’s probable effects on competition. *See Baker Hughes*, 908 F.2d at 982-83. If the defendant successfully rebuts the structural presumption of illegality, “the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the [government’s] ultimate burden of persuasion.” *Id.*

In practice, courts apply the burden-shifting paradigm by defining the relevant market, and then determining “the transaction’s probable effect on competition in the product and geographic markets.” *United States v. Sungard Data Sys., Inc.*, 172 F. Supp. 2d 172, 181 (D.D.C. 2001); *see also Marine Bancorp., Bancorp., Inc.*, 418 U.S. at 618-23. In addition to examining evidence of existing competition between the merging parties and other firms, an integral part of the competitive effects analysis is determining whether new entry or expansion is likely to offset any reduction in competition between the merging firms. *See FTC v.*

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Cardinal Health, Inc., 12 F. Supp. 2d 34, 58 (D.D.C. 1998) (citing *Merger Guidelines* § 3.0); *FTC v. Staples, Inc.*, 970 F. Supp. 1066, 1086 (D.D.C. 1997).

If a court finds that a transaction is likely to produce a substantial reduction in competition that will not be averted by entry, courts generally consider whether efficiencies are likely to offset the reduction in competition. Although the Supreme Court held in *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 579 (1967), that “[p]ossible economies cannot be used as a defense to illegality,” subsequent lower court decisions have stated that “whether an acquisition would yield significant efficiencies in the relevant market is an important consideration in predicting whether the acquisition would substantially lessen competition.” *FTC v. University Health, Inc.*, 938 F.2d 1206, 1222 (11th Cir. 1991); *see also* *Cardinal Health*, 12 F. Supp. 2d at 61. In *University Health*, 938 F.2d at 1223, the Eleventh Circuit held that a defendant could potentially overcome a “presumption that a proposed acquisition would substantially lessen competition [by] . . . demonstrat[ing] that the intended acquisition would result in significant economies and that these economies ultimately would benefit competition and, hence consumers.” The *Merger Guidelines* also recognize the role of efficiencies in determining the competitive effects of a transaction, stating that “[e]fficiencies generated through merger can enhance the merged firm’s ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products.” *Merger Guidelines* § 4.

Although 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. *See Baker Hughes*, 908 F.2d at 984 (Section 7 inquiry is of a “comprehensive nature”). In the recently published *Commentary on the Horizontal Merger Guidelines* (“*Merger Guidelines Commentary*”), the Federal Trade Commission and the Department

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Department of Justice's Antitrust Division emphasized "that the Agencies apply [] an integrated approach to merger review . . . [rather than] a linear, step-by-step progression that invariably starts starts with market definition and ends with efficiencies or failing assets."⁶³

Count I of the complaint alleges that the merger violated Section 7 of the Clayton Act in specified relevant product and geographic markets. Count II does not allege a particular relevant market; instead it alleges that the transaction violated the Clayton Act because the merger enabled ENH to raise its prices to private payors above the prices that the hospitals would have charged absent the merger. Under this count, complaint counsel maintains that it is not necessary to prove the relevant market because direct effects evidence shows that the transaction reduced competition substantially. CB 5. We first determine whether the record establishes that the transaction reduced competition substantially within a relevant antitrust market under Count I and then address complaint counsel's thesis that it is possible to establish liability under Section 7 solely through the analysis of direct effects evidence under Count II.

⁶³ FEDERAL TRADE COMM'N & U.S. DEP'T OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 2 (2006), *available at* <http://www.ftc.gov/os/2006/03/CommentaryontheHorizontalMergerGuidelinesMarch2006.pdf>.

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B. Defining the Relevant Market**1. Relevant Product Market**

The “boundaries of a product market are determined by 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; *see also United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 395 (1956). “Interchangeability 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*, 131 F. Supp. 2d 151, 157 (D.D.C. 2000) (citing *du Pont*, 351 U.S. at 393).

The *Merger Guidelines* use a related type of market definition test. Under the 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 (“SSNIP”) and not lose an amount of its sales to alternative products that would make the price increase unprofitable. *Merger Guidelines* § 1.11. If so, then the proposed market constitutes a relevant product market. *Id.* The agencies often use a SSNIP amount equal to a 5% price increase, although this varies depending on the nature of the market. *Id.*; *see Staples*, 970 F. Supp. at 1076 n.8. The *Merger Guidelines* provide that “what constitutes a ‘small but significant and nontransitory’ increase in price will depend on the nature of the industry, and the Agency at times may use a price increase that is larger or smaller than five percent.” *Merger Guidelines* § 1.11.

Courts are not required to follow the *Merger Guidelines*’ approach, but many modern courts have applied either the hypothetical monopolist test or some related test that defines markets by determining the set of products over which a dominant or or monopolist firm could exercise market power. *See, e.g., United*

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States v. Microsoft Corp., 253 F.3d 34, 81 (D.C. Cir. 2001) (“To establish a dangerous probability of success, plaintiffs must as a threshold matter show that the browser market can be monopolized, monopolized, *i.e.*, that a hypothetical monopolist in that market could enjoy market power.”); *Coastal Fuels, Inc. v. Caribbean Petroleum Corp.*, 79 F.3d 182, 198 (1st Cir. 1996) (“The touchstone touchstone of market definition is whether a hypothetical monopolist monopolist could raise prices.”); *Sungard*, 172 F. Supp. 2d at 182, 186-92 (citing the Guidelines’ hypothetical monopolist test approvingly); *Swedish Match*, 131 F. Supp. 2d at 160-61 & n.8 (paraphrasing *Merger Guidelines* and informally applying the hypothetical monopolist test). The authors of the leading treatise also generally endorse the hypothetical monopolist approach. *See* II Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, *Antitrust Antitrust Law* ¶¶ 530a, 536, at 180-82 (2d ed. 2002).⁶⁴

Complaint counsel asserts that the relevant product market is “general acute care hospital services, including primary, secondary, and tertiary services, sold to MCOs.” CB 37. Respondent argues, although not very strenuously, that the product market also includes “hospital-based” outpatient services because MCOs purchase both inpatient and outpatient services from hospitals. RB 26-27 & n.3. Respondent does not include non-hospital-based outpatient services in its relevant product market. *Id.*

The ALJ held that the record established that the relevant product market is that for acute inpatient hospital services, and we agree. ID 132-34. Current and former Evanston and Highland Park Park executives testified that ENH set inpatient rates independently of its outpatient rates and without concern that patients would switch to outpatient services. IDF ¶ 209; TR 330-31 330-31 (Newton); TR 1210-11 (Neaman). ENH’s Hillebrand

⁶⁴ *See generally* Gregory J. Werden, *The 1982 Merger Guidelines and the Ascent of the Hypothetical Monopolist Paradigm*, 71 ANTITRUST L.J. 253 (2003).

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testified that he believed that inpatient hospital prices do not alter customer decisions to seek outpatient services because the physician physician makes that determination. TR 1755-56 (Hillebrand). Such Such pricing independence is strong evidence that the two sets of services are not in the same market because it suggests that there is a is a low cross-elasticity of demand between inpatient and outpatient outpatient services. *Cf. United States v. Archer-Daniels-Midland Co.*, 866 F.2d 242, 248 (8th Cir. 1988) (finding that sugar and high-high-fructose corn syrup not in the same product market in the absence of “evidence . . . demonstrating a high cross-elasticity of demand” between them).

Additionally, Noether testified that inpatient and outpatient services are not substitutes for patients and that MCOs cannot offer offer their patients outpatient services as a substitute for inpatient services when the patients need inpatient services. TR 6194 (Noether). Finally, the MCO witnesses who testified on the issue also stated that they could not, as a practical matter, substitute inpatient for outpatient services. TR 1422-23 (Holt-Darcy); TR 538-538-39, *in camera* (Mendonsa); TR 591-92, 594-95 (Neary).⁶⁵

Respondent’s position that outpatient services are in the market market is also inconsistent with all modern hospital merger cases. The courts have held repeatedly that acute inpatient hospital services services are a “cluster of services” that constitute a relevant product product market. *See, e.g., FTC v. Freeman Hosp.*, 69 F.3d 260, 268 268 (8th Cir. 1995); *University Health*, 938 F.2d at 1211-12; *United United States v. Rockford Mem’l Corp.*, 898 F.2d 1278, 1284 (7th Cir. Cir. 1990); *United States v. Long Island Jewish Med. Ctr.*, 983 F. Supp. 121, 138-40 (E.D.N.Y. 1997); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1290-91 (W.D. Mich. 1996). The rationale rationale is that while “the treatments offered to patients within this

⁶⁵ Our descriptions of the testimony from Neaman, Hillebrand, Noether, Holt-Darcy, Mendonsa, and Neary are part of the Commission’s findings of fact. We did not include them in our findings of fact in Part IV only for ease of presentation.

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cluster of services are not substitutes for one another . . . the services and resources that hospitals provide tend to be similar across a wide range of primary, secondary, and tertiary inpatient services.” *California v. Sutter Health Sys.*, 130 F. Supp. 2d 1109, 1119 (N.D. Cal. 2001). The record does not support our departing from this long line of cases.

Respondent argues incorrectly that complaint counsel’s “focus on MCOs as the consumers” warrants including hospital-based outpatient services in the market because MCOs simultaneously negotiate with hospitals for both inpatient and outpatient services. As the Seventh Circuit explained in *Rockford Mem’l*, the fact that a customer purchases two sets of services from a supplier does not automatically lead to the conclusion that the two products are substitutes, or that one acts as a competitive constraint on the other. 898 F.2d at 1284.⁶⁶

In short, we conclude that the evidence in the record establishes that the relevant product market is acute inpatient hospital services. We also find that even if we included hospital-hospital-based outpatient services in the relevant product market, as

⁶⁶ One could argue that there is no more substitutability between different types of inpatient services (e.g., a tonsillectomy and a heart transplant) than there is between inpatient and outpatient services, and that would certainly be correct. However, this does not justify including hospital-based outpatient services in the relevant product market, as respondent proposes. The record is not clear on the issue, but it is very likely that there are some types of outpatient services for which hospitals compete only with other hospitals, and other types of outpatient services for which hospitals compete with both hospitals and non-hospital providers. Respondent appears to agree because it limited the types of outpatient services that it included in its proposed product market to those provided by hospitals. RB 26-27 & n.3. If it were feasible to isolate the outpatient services that only hospitals provide, then it might make sense to define a broader “hospital services” product market, as respondent suggests. Such segmentation, however, is not practical here; nor is it necessary because, as the ALJ implicitly found, there plainly is a substantial volume of inpatient services for which neither hospital-based nor non-hospital-based outpatient services are substitutes. IDF ¶¶ 206, 207, 209-11.

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respondent proposes, it would not alter the outcome of this case. As we found above, both sides' economists determined that ENH's post-merger price increases for inpatient services were not offset by reductions (or smaller increases) in ENH's prices for outpatient services. Baker actually calculated larger higher-than-predicted average merger-coincident net price increases for inpatient and hospital-based outpatient services combined (11% or 12%), than he did for inpatient services alone (9% or 10%). DX 7068 at 21, *in camera*.

2. Relevant Geographic Market

The geographic market is “the ‘area of effective competition . . . in which the seller operates, and to which the purchaser can practicably turn for supplies.’” *United States v. Philadelphia Nat’l Bank*, 374 U.S. 321, 359 (1963) (quoting *Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 327 (1961)). The *Merger Guidelines* use the same hypothetical-monopolist approach to define the geographic market as they do for product market definition, stating that the relevant geographic market is a region in which a hypothetical monopolist could “profitably impose at least a ‘small but significant and nontransitory’ increase in price, holding constant the terms of sale for all products produced elsewhere.” *Merger Guidelines* § 1.21.

Complaint counsel asserts that the geographic market is the “geographic triangle formed by the three ENH hospitals.” CB 38. Respondent does not specify a precise geographic market but maintains that it is much larger.⁶⁷ Whereas the north-south axis of

⁶⁷ Respondent, of course, does not have the burden of proving the relevant product or geographic markets. Respondent cites a number of hospital merger cases in which the courts have defined geographic markets to include a county or several counties. RB 27-28. Precedent is a relevant consideration in defining markets, and we have partially relied on precedent to define the relevant product market. However, market definition fundamentally is a question of fact. This is particularly the case for geographic market definition, where population density, traffic patterns, and socio-economic factors vary substantially from region to region.

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complaint counsel's market is approximately 13.7 miles, Respondent's market has a north-south axis of at least 36 miles, and includes hospitals such as Condell (approximately 13 miles north of Highland Park and 25 miles north of Evanston) and Northwestern Memorial (approximately 13 miles south of Evanston and 26 miles from Highland Park). RB 28-30. The record is less clear about the respective lengths of the east-west axes of complaint counsel's and Respondent's geographic markets, although it appears from a map in Respondent's brief that Respondent's axis is at least approximately one-third longer. *See* RB 29.

The ALJ defined the geographic market as the region covered by the three ENH hospitals and four other hospitals – Lake Forest, Advocate Lutheran General, Rush North Shore, and St. Francis. The ALJ found that “it is highly probable that *the four non-ENH hospitals in the geographic market would have the ability to constrain prices at ENH*, either now or in the future, and could be utilized by managed care organizations to create alternate hospital networks.” ID 144 (emphasis added). To the extent that the ALJ held that MCOs could defeat a post-merger anticompetitive price increase by ENH by using one or more of these four other hospitals, we reject this holding. Indeed, such a holding is inconsistent with the ALJ's ultimate conclusion that the merger enabled ENH to exercise market power. Moreover, the ALJ's opinion reflects that he made his conclusions about the geographic market through rough inferences from the MCOs' testimony and documents, and by making very general findings about driving distances. ID 142-43. The ALJ's technique did not address the central issue in defining geographic markets – over what geographic region could a hypothetical monopolist impose a SSNIP.⁶⁸

⁶⁸ We also find infirm the ALJ's reliance on a portion of a survey conducted by Lake Forest Hospital about consumers' willingness to travel for various types of hospital services, ID 142-43, because it is not possible to evaluate with confidence the survey's reliability from the document alone.

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As discussed above, some of the MCO testimony partially supports complaint counsel's assertion that Evanston and Highland Park were close substitutes for some MCOs, and, therefore that the triangle formed by the ENH hospitals might constitute a geographic market. Standing alone, however, the MCO testimony was not precise enough to allow the Commission to draw firm conclusions. Conversely, the testimony from Respondent's executives was not sufficiently detailed to conclude that the relevant geographic market is much broader than the market alleged by complaint counsel.

Because it is not possible to define the geographic market solely through the testimony of the MCOs or Respondent's executives, the question is whether the Commission can define the market based on the econometric evidence, which established that ENH could and did impose substantially higher-than-predicted merger-coincident price increases – 11% to 18% higher as computed by Haas-Wilson and 9% or 10% higher as computed by Baker. These price increases are larger than the 5% SSNIP that is often used under the Guidelines to define a market. *See Merger Guidelines* § 1.11.

Respondent describes the concept of defining a relevant market based on analysis of post-merger price increases as “circular” “circular” and a “tautology.” RRB 48-49. As we explain, defining markets based on such pricing evidence does not reflect a flawed circular analysis, but rather the fundamental relationship between market definition and competitive effects analysis in unilateral effects cases involving differentiated product markets. Complaint counsel, while alleging a geographic market, maintains that it is not necessary to define the relevant geographic market because, here, it is possible to show through direct evidence that the merger enabled ENH to exercise market power unilaterally. This argument, too, implicitly derives from the connection between market definition and competitive effects analysis in unilateral effects cases that

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involve differentiated products. To explain, we turn to discussing unilateral effects analysis.

3. Market Definition and Unilateral Effects

Modern merger analysis examines whether a merger is likely to lead to either or both coordinated and unilateral anticompetitive effects. Coordinated effects are reductions in competition caused by express or tacit interaction by the firms in a market, such as coordination on levels of price or output. *See Merger Guidelines* § 2.1. Generally, coordination is more likely in markets with homogeneous products because it is easier for competitors to reach agreement on the terms of coordination and to detect or punish deviations from those terms. *See id.* § 2.11. Determining that a merger has enabled the merged firm to raise prices does not necessarily aid in defining the relevant market in a coordinated effects case because the fact of the price increase may not readily enable the identification of the rivals in the market with which the merged firm is coordinating.

Unilateral effects are different. They result when a merger leads to higher prices due to the loss of competition between the two merging firms, independent of the action of other firms in the market. *See United States v. Oracle Corp.*, 331 F. Supp. 2d 1098, 1113 (N.D. Cal. 2004); *Merger Guidelines* § 2.2. There are a number of different types of unilateral effects.⁶⁹ Both complaint counsel and respondent agree that the type of unilateral effect that is relevant here is a reduction in competition in a differentiated product

⁶⁹ The Areeda treatise classifies unilateral effects into four different types: “(a) creating a monopoly or dominant firm; (b) perpetuating a monopoly or dominant firm by eliminating a nascent rival; (c) giving one firm more secure control of its ‘niche’ in a product-differentiated market; or (d) strengthening a firm’s power to make noncompetitive bids that buyers will be unable to refuse.” IV PHILLIP E. AREEDA, HERBERT HOVENKAMP & JOHN L. SOLOW, *ANTITRUST LAW* ¶ 910, at 55-56 (2d ed. 2006).

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market, meaning that the products under examination are not perfect substitutes for one another. *See generally Merger Guidelines* § 2.21.

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. *Id.* As the agencies explained in the *Merger Guidelines*, anticompetitive unilateral effects occur when a sufficient amount of the sales loss due to a post-merger price increase is diverted to the product of the merger partner to make the price increase profitable. *Id.* Thus, whether a firm can profitably increase its prices unilaterally after a merger depends in part on the degree to which customers switch to the product of the other merged firm, as opposed to switching to products of third-party firms. *See id.* § 2.21. The likelihood of unilateral effects in differentiated product markets also depends on the degree to which non-merging firms will “reposition” their products post-merger to make them closer substitutes to those of the merging parties. *Id.* Unilateral effects are less likely if other firms can quickly redesign or reformulate their products after a merger. *See id.*⁷⁰

⁷⁰ Thus, the *Merger Guidelines* provide that substantial unilateral price elevation in a market for differentiated products requires that there “[1] 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, and [2] that repositioning of the non-parties’ product lines to replace the localized competition lost through the merger be unlikely.” *Merger Guidelines* § 2.21. The leading treatise contains a similar description of the factors relevant to assessing the likelihood of unilateral effects:

The degree to which a merger in a product-differentiated market might facilitate a unilateral price increase depends on (1) the relative “closeness” in product space of the merging firms to one another; (2) the relative distance between the post-merger firm’s product offering and the offerings of others in the market; and (3) the relative inability of other firms to redesign their products to make them close to the output of the merging firms.

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The portion of sales that constitute “a significant share of sales” sales” (and the number of customers that produce such sales) varies by market, and is a function of the relative closeness of the merging parties’ products or services, versus those of other competitors, and the relative margins of the merging firms. *See* IV Areeda, Hovenkamp & Solow, *supra* note 69, ¶ 914a, at 67; *id.* ¶ 914h, at 80-83; *Merger Guidelines* § 2.21. Notably, it is not necessary for the merged firms to be the closest substitutes for all customers, or even a majority of customers. IV Areeda, Hovenkamp & Solow, *supra* note 69 ¶ 914h, at 82. Instead, what matters is that customers purchase enough of the merged firm’s products after a post-merger price increase to make the increase profitable. *See id.*; *see also Merger Guidelines Commentary* 27 (“A merger may produce significant unilateral effects even though a large majority of the substitution away from each merging product goes to non-merging products.”)⁷¹

Because the focus of the analysis is on the unilateral loss of “localized” competition between the merging parties, there are substantial factual and analytical overlaps between the market definition process and competitive effects analysis in unilateral effects cases. Again, a market is the smallest possible group of competing products (or geographic area) over which a hypothetical monopolist that sells those products (or competes in that area) could profitably impose a SSNIP. *Merger Guidelines* §§ 1.11, 1.21. Thus, if a merger enables the combined firm unilaterally

IV AREEDA, HOVENKAMP & SOLOW, *supra* note 69, ¶ 914a, at 67.

⁷¹ *See also* Jonathan B. Baker & Carl Shapiro, Reinforcing Horizontal Merger Enforcement 10 (June 2007), available at <http://faculty.haas.berkeley.edu/shapiro/mergerpolicy.pdf> (“[U]nilateral effects will arise so long as some customers of one of the merging firms consider its merger partner’s product as their second choice, even if more of the firm’s customers consider a third firm’s products to be their second choice.”).

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unilaterally to raise prices by a SSNIP for a non-transitory period due to the loss of competition between the merging parties, the merger plainly is anticompetitive, and the merging firms comprise a relevant antitrust market because the merged entity is considered to be a “monopolist” under the Guidelines. As the authors of the leading treatise explain:

In cases where a merger facilitates a significant “unilateral” price increase for a grouping of sales that was not a distinctive-looking market prior to the merger, the appropriate conclusion is that the merger has facilitated the emergence of a new grouping of sales capable of being classified as a relevant market. *This formulation meets the statutory requirement that the effect of a merger is anticompetitive in some “line of commerce” and in some “section of the country.”*

IV Areeda, Hovenkamp & Solow, *supra* note 69 ¶ 913b, at 64 (emphasis added);⁷² *see also* Gregory J. Werden, *Simulating the Effects of Differentiated Product Mergers: A Practical Alternative to Structural Merger Policy*, 5 *George Mason L. Rev.* 363, 384 & n.97 (1997) (“If the products of the merging firms are next-closest substitutes for each other and the [merger] simulations predict price increases of at least 5%, then the

⁷² The authors make the same point in the section of the treatise that discusses the criteria for identifying the likelihood that a merger will produce a unilateral price increase: “To the extent that . . . a merger enables the post-merger firm profitably to assess a significant price increase without losing sales to other firms, we would say that the merger facilitates the emergence of a new grouping of sales, or relevant market, in which the merging firms have either a monopoly or else a dominant share.” IV AREEDA, HOVENKAMP & SOLOW, *supra* note 69, ¶ 914f, at 77.

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Horizontal Merger Guidelines would support a market consisting of just the merging firms.”).⁷³

The district court’s analysis in *Staples* is instructive. The district court determined that office “superstores” constituted a relevant antitrust product market, relying heavily on its finding that that Staples’ and Office Depot’s pricing was disciplined more by the the presence of other superstores than by that of office supply stores stores generally. *Staples*, 970 F. Supp. at 1075-76, 1078. Staples’ prices were 13% lower in geographic markets where it competed

⁷³ Respondent suggests that the government must show that the combined firm will have a dominant or monopoly share of the relevant market to establish that a merger is likely to cause anticompetitive unilateral effects in a differentiated product market. RB 37-38. This argument is incorrect, regardless of whether markets are defined through the Merger Guidelines’ approach, or by making general assessments about the functional substitutability of products or services. As Professor Baker explains:

[S]mall increases in concentration can generate higher prices in the localized competition model of mergers among sellers of differentiated products The reason: two brands may be close substitutes even if both have low market shares.

Jonathan B. Baker, *Unilateral Competitive Effects Theories in Merger Analysis*, 11 ANTITRUST 21, 25 (1997) (emphasis added). Professor Baker made the same point in an article that he recently co-authored with Professor Carl Shapiro: the notion that “a plaintiff must demonstrate that the merging parties would enjoy a post-merger monopoly or dominant position [to raise prices unilaterally] . . . is incorrect and constitutes a clear error in economic reasoning.” Baker & Shapiro, *supra* note 71, at 10 (citations and quotations omitted); see also Gregory J. Werden, *Simulating Unilateral Effects from Differentiated Markets*, 11 ANTITRUST 27 (1997) (“ . . . [C]ourts often delineate very broad relevant markets, yielding small market shares. But shares of these broad markets do not indicate what really matters – how often consumers of the product(s) of either merging firm view a product of the other merging firm as their next-best substitute, and how close other substitutes are in such cases.”).

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with Office Depot and OfficeMax than in markets where it did not face superstore competition.⁷⁴ *Id.* at 1075-76.

When the court turned to the competitive effects analysis, it looked at the same pricing evidence that it relied on to define the product market, explaining that “[m]uch of the evidence already discussed with respect to defining the relevant product market also also indicates that the merger would likely have an anti-competitive anti-competitive effect.” *Id.* at 1082. The court further explained that that “the evidence of the defendants’ own current pricing practices, practices, for example, shows that an office superstore chain facing facing no competition from other superstores has the ability to *profitably raise prices* for consumable office supplies above competitive levels,” *id.* (emphasis added), which also is essentially essentially the central issue examined in defining a relevant market. market. Logically, the court could have started its analysis by examining the transaction’s likely competitive effects, determined that competition between the firms reduced prices by more than a SSNIP, and then concluded that office superstores are a relevant product market under the *Merger Guidelines*.⁷⁵

⁷⁴ The data also showed that Office Depot’s prices were more than 5% higher in markets where it did not face superstore competition than in the markets where Office Depot competed with other superstores. *Staples*, 970 F. Supp. at 1077.

⁷⁵ Practitioners have offered a similar assessment of the relationship between direct price-effects evidence and market definition in unilateral effects cases:

If the Guidelines were not so wedded to the prima facie case developed for coordinated effects cases, the Division might have started with its econometric analysis. It might have argued that the combination of [Oracle and Peoplesoft] was going to raise price between 9.7 and 13.6 percent. The Division might have argued that the prima facie case is just an indirect means of proving the competitive effect it has established directly. So it is not really important to know the market definition and the market share. But if the court feels that it needs to have market definitions, those follow from the competitive effects.

Marc G. Schildkraut, *Oracle and the Future of Unilateral Effects*, 19 ANTITRUST 24 (2005) (emphasis added).

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This case is somewhat different from *Staples* because prices in the hospital market are determined through bilateral bargaining. In bargaining markets, prices and other conditions of sale are set through individual negotiations between a buyer and seller. See *Merger Guidelines Commentary* 34. Because of the nature of the price-setting mechanism, bargaining markets can result in different prices for the same product, depending on the alternatives available to the negotiating parties.

Contrary to Respondent's position, RRB 11, bargaining markets are quite common and fully consistent with unilateral effects theory. See *Merger Guidelines Commentary* 34-36. And most most economists who have recently studied the issue have concluded that bargaining models are appropriate for hospital markets because bilateral negotiations between MCOs and hospitals determine prices that often are unique to the particular negotiation.⁷⁶ The record in this case also demonstrates that hospital prices in the Chicago market are set through bilateral negotiations. CFF 245-83; TR 2470 (Haas-Wilson); TR 6189 (Noether); RB 51.

The principles of unilateral effects analysis apply to bargaining bargaining markets, but their application is somewhat different in a bargaining than in a single-price market. The unilateral exercise of of market power in a single-price market harms all customers because they each pay a higher price for the good or service. In a bargaining market, a merger may allow the merged firm to exercise exercise market power against a subset of customers who view the merging parties as their first and second choices, while the transaction will have no effect on other customers who do not view the merging firms as close alternatives or who have substantial "buy-side" market power. One or both of these possibilities likely

⁷⁶ See generally Cory Capps et al., Competition and Market Power in Option Demand Markets, 34 RAND J. ECON. 737 (2003); Robert Town & Gregory Vistnes, Hospital Competition in HMO Networks, 20 J. HEALTH ECON. 733 (2001).

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explains, for example, why ENH appears to have been unable to exercise market power against BCBS after the merger.

The potential for a merger in a bargaining market to have disparate effects on different customers potentially creates sticky and unsettled issues for merger analysis, most significantly, determining the percentage of a merged firm's revenues that must come from customers who are harmed by the merger for the transaction to violate Section 7. The Commission need not delve into this issue in this case because, as we found above and discuss further below, the record demonstrates that the merger likely gave ENH sufficient market power to increase the average price that it charged to all MCOs.

We are mindful of the potential in both bargaining and non-bargaining markets for defining overly narrow markets in cases involving differentiated products. "Demonstrating that the merging parties' products are differentiated is not sufficient" to define a market, and there is a risk that "'localized competition' analysis [will] devolve into an unstructured submarket-type analysis." *See Oracle*, 331 F. Supp. 2d at 1119 (quoting IV Areeda, Areeda, Hovenkamp & Solow, *supra* note 69, ¶ 914a, at 60); *see also du Pont*, 351 U.S. at 393 (cautioning against viewing a manufacturer of every non-standardized commodity as having market power). At the same time, "a relevant market in an antitrust antitrust case may be smaller than a layperson would normally consider to be a market." *Oracle*, 331 F. Supp. 2d at 1119; *cf. Staples*, 970 F. Supp. at 1074 (defining "office supply superstores" product market). Further, a set of products can constitute an antitrust market even when it is not possible to delineate a traditional "clean break" around the products or to devise a traditional market definition label. The keys to protecting against incorrectly narrow markets are, first, not to assume that a firm has economic power merely because its products are differentiated from those of its competitors; and, second, to ensure that the touchstone principle of market definition is satisfied: that the degree of "product differentiation [is] sufficient to sustain a

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small but significant and non-transitory price increase.” *Oracle*, 331 F. Supp. 2d at 1120.⁷⁷

Thus, here, if complaint counsel has proven that the significant higher-than-predicted post-merger price increases resulted from market power gained through the merger, then complaint counsel has correctly defined the geographic market as the triangle formed by the three ENH hospitals. We turn now to the competitive effects analysis to determine whether the merger did enable ENH to exercise market power.

C. Competitive Effects

Courts reviewing mergers pursuant to a Section 7 challenge assess the totality of the circumstances, weighing a variety of factors to determine the transaction’s effects on competition. *See Baker Hughes*, 908 F.2d at 984. We start our analysis with the extensive econometric evidence submitted by complaint counsel and respondent, and then discuss the other evidence.

1. Econometric Evidence

⁷⁷ We are, of course, aware that some lawyers and economists have argued that the agencies and courts should focus solely on analyzing a transaction’s likely competitive effects, and not define markets, in unilateral effects cases involving differentiated products due to the fact that, viewed in isolation, market shares often are not always informative about the competitive proximity of the merging firms’ products. We also recognize that market definition can take on a conclusory quality in unilateral effects cases involving differentiated products because of the analytical and factual overlaps between the market definition and competitive effects analysis. See Jonathan B. Baker, *Stepping Out in an Old Brown Shoe: In Qualified Praise of Submarkets*, 68 ANTITRUST L.J. 203, 217 (1997). As we discuss in our treatment of Count II of the complaint, these and other considerations may justify holding at some point that it is not necessary to define a relevant market in certain Section 7 cases. Here, however, we need not decide this issue because, as we explain, it is readily possible to define the relevant product and geographic markets.

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It is undisputed that ENH substantially and immediately raised its prices after the merger. Nominal price increases, however, do not by themselves establish the exercise of market power. Accordingly, as described above, Haas-Wilson and Baker sought to determine whether the post-merger increases were due to market power produced by the merger by calculating the amounts of ENH's post-merger price increases, and then running a series of regressions to filter out the effects of the most likely competitively-benign factors that could have caused prices to rise after the merger.

First, both Haas-Wilson and Baker found that ENH substantially increased the actual prices that ENH charged to its customers. Haas-Wilson calculated, using the payor data, that ENH's ENH's average net price *per case* increased post-merger for all five of the MCOs that she examined: Aetna (28% to 89%); BCBS (10% to 27%); Humana (27% to 73%); United (62% to 128%); and Great West (42%). CX 6279 at 3, *in camera*; CX 6282 at 5, *in camera*.⁷⁸ Using the Illinois data, Haas-Wilson calculated the post-merger increases in the average net price *per case* for three broad categories of patients: all patients (30%); commercial and self-pay patients (27%); and commercial, self-pay, self-administered, and HMO patients (26%). CX 6279 at 7, *in camera*. Similarly, Baker, using two different methods to calculate the price increases, found that ENH substantially raised its average net prices after the merger to the four payors that he examined: Aetna (25%, 35%); BCBS (2%, 13%); Humana (60%, 83%); and United (140%, 138%). RX 2040 at 4, *in camera*; DX 7068 at 43, *in camera*.⁷⁹ The two different percentage amounts reflect that Baker used two different methods to calculate the price increases.

⁷⁸ The ranges of the price increases for Aetna, BCBS, Humana, and United reflect that ENH raised prices by different levels for these MCOs' various plans.

⁷⁹ Baker also performed these calculations omitting obstetrics cases. The corresponding results were that ENH increased its prices to the four payors by the following amounts: Aetna (31%, 34%); BCBS (3%, 5%); Humana (82%, 84%); and United (124%, 111%). RX 2040 at 2, *in camera*; DX 7068 at 44, *in camera*.

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Haas-Wilson next ran regressions using two data sources (the payor and the Illinois data) and three control groups, while Baker used only the payor data and two control groups. Although Haas-Wilson and Baker used different regression equations and different control groups, their calculations produced similar results. Haas-Wilson found, using the payor data, statistically-significantly higher-than-predicted post-merger ENH average net prices for four of the five payors: Aetna (21.3% to 32.5%); Humana (12.3% to 16.6%); United (75.3% to 93.2%); and Great West (25.1% to 39.5%). CX 6279 at 18-19, *in camera*; CX 6282 at 6, *in camera*; TR 2619-31 (Haas-Wilson), *in camera*. The percentage ranges reflect the use of different control groups and measures of resource intensity. For BCBS, Haas-Wilson found that ENH's actual post-merger average net prices were not statistically-significantly higher than her predicted post-merger average net ENH prices.

Haas-Wilson also found statistically-significantly higher-than-predicted increases in average net price using the Illinois data: all patients (13.2% to 17%); commercial and self-pay patients (11.1% to 17.0%); and commercial, self-pay, self-administered, and HMO patients (11.9% to 17.9%). CX 6279 at 30, *in camera*. Again, the percentage ranges reflect the use of different control groups and measures of resource intensity.

Finally, Baker's regressions found average net price increases of 9% or 10% for the four payors that he examined, relative to his eighteen-hospital control group, depending on whether obstetrics cases were included. RX 2040 at 3, *in camera*; DX 7068 at 45, *in camera*; DX 7068 at 19-20, ¶ 43, *in camera*. In addition to the factors ruled out by Haas-Wilson, Baker's model also controlled for patient age, gender, length of stay, type of health care plan, and hospital.⁸⁰

⁸⁰ As described *supra* 43-45, we find that Baker's regressions using the narrow six-hospital academic control group are unreliable because the control group was not reasonable.

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Because Haas-Wilson and Baker ruled out the most likely competitively-benign explanations for a substantial portion of the merger-coincident price increases, the size of the increases and the congruence of their results strongly suggest that the price increases were due to an increase in market power caused by the merger. As we found above, and discuss further below, the record does not support Respondent's position that Evanston's learning-about-demand or increased demand for Highland Park's services as a result of post-merger improvements explains these portions of the merger-coincident price increases.

2. Documents and MCO Testimony

The documentary evidence bolsters the conclusion that the higher-than-predicted merger-coincident price increases that both sides' economists found were caused by market power produced by the merger. As both the ALJ and we have found, the merging parties' documents reflect that a primary motivation of the senior officials in agreeing to merge the hospitals was to increase their bargaining leverage with MCOs in order to raise prices. The records of a January 4, 1999 meeting between Evanston's and Highland Park's board members and medical staff leaders state that Evanston representatives viewed the merger as an opportunity to not "compete with self" in covered zip codes (*e.g.*, 60% to 70% market shares) such as Evanston, Glenview, Highland Park, and Deerfield," CX 1 at 3, all of which are in the triangle. Similarly, the minutes of an April 5, 1999 meeting record an Evanston representative's statement that the merger "would be an opportunity to join forces and grow together rather than compete with each other." CX 2 at 7. After the merger, ENH's Neaman tied the post-merger price increases in part back to greater negotiating leverage produced by the merger, telling the ENH board's finance committee that "the larger market share created by adding Highland Park Hospital has translated to better managed care contracts." CX 16 at 1.

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The bottom-line conclusion of Highland Park's Spaeth was that the way to "push back on the managed care phenomenon and get rates back to where they ought to be [was to become] 'big enough,'" at which point "it would be real tough for any of the Fortune 40 companies in this area whose CEOs either use this place or that place to walk from Evanston, Highland Park, [and] Glenbrook." CX 4 at 2. It is difficult to imagine a clearer example of an executive using everyday language to explain how a merger will produce a firm that can exercise market power and whose services constitute a relevant antitrust market. Spaeth clearly thought that the merged firm would be able to raise prices because its customers would not be inclined to leave the ENH hospitals for other providers.

Respondent's efforts to downplay the significance of its documents are not persuasive. RB 59-62. The documents are probative because they reflect the merging parties' unvarnished contemporaneous analyses of the parties' market positions by their most senior officials. The statements are not simple bravado or unsubstantiated hyperbole from middle managers or sales representatives.

Respondent's argument that "intent" does not establish a Section 7 violation is correct, but beside the point. RB 59-60. The documents are probative not because they reflect the *desire* of Neaman and Spaeth to raise prices, but because they contain the informed analysis of experienced executives about when, why, and how the transaction would enable the merged hospitals to increase prices. Antitrust courts frequently rely on such evidence. *See, e.g., Cardinal Health*, 12 F. Supp. 2d at 63-64 (relying on statements of senior executives that merger would reduce excess capacity and curb downward pricing pressures). We disagree with respondent that it does not "matter whether ENH executives later tied the merger to price increases." RB 59. Antitrust courts often rely on the conclusions of senior executives about the goals and effects of their actions. *See, e.g., Microsoft*, 253 F.3d at 77 ("Microsoft's internal documents and deposition testimony confirm both the

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anticompetitive effect and intent of its actions.”); *University Health*, 938 F.2d at 1220 n.27 (relying on evidence showing that the “appellees, *by their own admissions*, intend[ed] to eliminate competition through the proposed [hospital] acquisition”) (emphasis in original).

Respondent’s effort to expand upon the plain meaning of the documents also is not persuasive. Respondent argues, for example, that the merging parties’ use of the phrase “leverage” in one document was shorthand for seeking to obtain fair market value for their services. RB 61. Shortly before the merger, Evanston CEO Neaman told his managers and his board that the merger would “[i]ncrease our leverage . . . with the managed care players.” IDF ¶ 335; CX 1566 at 9 (emphasis added). This language reflects that Neaman thought that the merger would give Evanston additional bargaining power, not that the merger would allow Evanston to exercise bargaining leverage that it already possessed.

Finally, we reject Respondent’s implied position that reliance on the documents to infer anticompetitive effects is improper because the documents also indicate that the merging parties thought that the transaction would produce efficiencies. RB 60. Although some of the documents state that the merging parties thought that the merger would be efficient, this does not diminish the fact that the documents also reflect the parties’ expectation that the transaction would increase (and in their view that it had increased) the combined entity’s ability to raise prices. The exercise of market power and the achievement of efficiencies are not mutually exclusive or inconsistent.⁸¹

The MCO testimony also provides some (albeit modest) support for the conclusion that the higher-than-predicted merger-

⁸¹ We analyze below whether the transaction enabled efficiencies and improvements that offset the anticompetitive effects of an increase in market power.

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merger-coincident price increases were due to market power, and it certainly is not inconsistent with that conclusion. The MCOs' testimony suggests that they were reluctant to drop the ENH hospitals because they were highly desirable hospitals that served the North Shore suburbs. Aetna's Mendonsa testified that he was concerned about the merger because it had resulted in "three extremely important hospitals negotiating together in a very important geography." TR 530, 518 (Mendonsa), *in camera*. Similarly, United's witness explained that the ENH hospitals were geographically significant because "when you look at the three hospitals that make up the Evanston Northwestern Healthcare system and look at . . . the triangle that they create, . . . it is very heavily populated by some of the most affluent communities in the the Chicago area . . . and because while there might be hospitals to to the south and to the north, there are no other facilities [within the the triangle], it did not seem feasible that we could have a viable network without Evanston Northwestern Healthcare." TR 901-02 (Foucre). Unicare's Holt-Darcy likewise testified about the strategic significance of the "contiguous service area" covered by the three ENH hospitals. TR 1602 (Holt-Darcy), *in camera*.

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3. Respondent's Positions

Respondent offers a series of arguments as to why the Commission should conclude that factors other than market power caused the higher-than-predicted merger-coincident price increases. We address each argument in turn, and conclude that none of them is valid.

a. Learning-About-Demand

Respondent's primary rebuttal to the econometrics is its contention that a significant portion of the merger-coincident price increases resulted from Evanston's learning from Highland Park that Evanston supposedly was charging prices that were below what respondent terms "the fully-informed competitive level." RB 48. Respondent essentially is arguing that complaint counsel's case reflects a "reverse" version of the *Cellophane* fallacy.⁸² Respondent, in essence, maintains that complaint counsel has defined the market too narrowly by applying a SSNIP to a price that is below the theoretical competitive level, and thus wrongly concluded that ENH's ability profitably to impose such a price increase is due to market power.

Respondent cites no case to support its argument.⁸³ Instead, respondent refers the Commission to a treatise and several articles

⁸² The "Cellophane fallacy" derives from the Supreme Court's decision in *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377 (1956), in which the Supreme Court assessed the existence of market power by defendant du Pont by using as a baseline the existing supracompetitive price of a food wrap, rather than examining the profitability of a price increase from the baseline of a competitive price for the product. This analytical error caused the Court to find the absence of market power in a situation where the defendant already had been exercising market power.

⁸³ Respondent asserts that the ALJ found that "Complaint Counsel failed to prove that ENH's post-merger prices exceeded competitive levels" and that this finding is dispositive in respondent's favor. RB 1 (citing ID 155). Respondent appears to be referring to the ALJ's statement that "Complaint Counsel did not attempt to compare ENH's price increases to a competitive level." ID 155. As the

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for the uncontroversial proposition that information about competitors' prices can be costly to acquire, and as a result firms may not always price at fully-informed levels at all times. RB 48 n.8; RRB 2. While obviously true, it does not follow that firms systematically and substantially undercharge the majority of their customers for years, which is what respondent is claiming Evanston Evanston did in the 1990s.

The lack of authority for Respondent's novel learning-about-demand position is not surprising. The argument runs at least partially counter to the *Merger Guidelines*. As respondent correctly points out, the *Merger Guidelines* provide that market power "is the ability profitably to maintain prices above *competitive levels* for a significant period of time." *Merger Guidelines* § 0.1 (emphasis added). What respondent neglects to mention, however, is that the antitrust enforcement agencies typically apply the hypothetical monopolist test by "using prevailing prices of the products of the merging firms and possible substitutes for such products." *Id.* § 1.11. The *Merger Guidelines* do mention two circumstances in which the agencies will use a price different from the prevailing price – (1) when pre-merger circumstances suggest that coordinated interaction has occurred and (2) in cases in which it is possible to predict changes in the prevailing prices with reasonable reliability. *Id.* Here, both complaint counsel and respondent agree that coordination among competitors is not at issue. And the econometric analysis used by Respondent's and complaint counsel's economists accounted for future changes in the prevailing price by factoring out the effects of the most likely competitively-benign factors that would cause prices to rise.

ALJ found, and as we agree, it is appropriate to determine that price increases reflect the exercise of market power by ruling out competitively-benign reasons for the price increases. On the same page to which respondent refers, the ALJ found that the "evidence therefore demonstrates that the relative price increases were the result of ENH's enhanced market power, achieved through elimination of a competitor as a consequence of the merger." *Id.*

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In addition, while we are not aware of any court that has specifically discussed the appropriate baseline price to use for the hypothetical monopolist test or to measure the exercise of market power, courts have looked to actual prices when defining markets. *Olin Corp. v. FTC*, 986 F.2d 1295, 1300-02 (9th Cir. 1993) (applying *Merger Guidelines* and using actual prices); *Sungard*, 172 F. Supp. 2d at 186-92 (analyzing customer testimony about actual prices regarding possibility of 5% to 10% price increase); *Staples*, 970 F. Supp. at 1076-77 (using actual prices); *New York v. Kraft Gen. Foods, Inc.*, 926 F. Supp. 321, 332-34, 359-61 (S.D.N.Y. 1995) (applying *Merger Guidelines* and referring back to previous analysis of relevant product market that contained references to actual customer prices); *FTC v. Owens-Illinois, Inc.*, 681 F. Supp. 27, 38-47 (D.D.C. 1988) (same), *vacated as moot*, 850 F.2d 694 (D.C. 1998); *see also CF Indus. v. Surface Transport Bd.*, 255 F.3d 816, 824 (D.C. Cir. 2001) (“[N]ormal assumption in examining assertions of market power is that the current price is at least the competitive price.”).

Respondent’s argument also raises a number of practical issues. It will almost always be true in markets where firms submit non-public bids or offers, such as hospital markets, that access by one firm to another firm’s prices will provide insight into the demand structure that could allow a firm to price more closely to theoretical, long-run equilibrium levels on a sustained basis. It is also very likely, however, that systematic access by firms to their competitors’ pricing can undermine firms’ incentives to price aggressively and can facilitate collusion. Customers often do not share one provider’s prices with another competing provider for this very reason. Presumably, Evanston did not know Highland Park’s prices until Evanston received them during the due diligence process because MCOs thought that sharing the pricing data might reduce Evanston’s incentives to compete aggressively for their business. Thus, caution is warranted before assigning procompetitive or competitively neutral effects to competitors’ learning about each other’s pricing strategies.

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through mergers, and even more caution is needed when those mergers result in substantial price increases.

We need not resolve all of the doctrinal or practical challenges presented by Respondent's learning-about-demand argument, however, because, as we have discussed in detail in our findings of fact, giving respondent all benefit of the doubt, we agree with the ALJ that the facts in the record do not support the argument. First, the testimony of the ENH executives that their business and negotiating strategy caused them not to obtain competitive prices in negotiations with MCOs during the 1990s lacks credibility. Second, Evanston's decision not to renegotiate certain contracts during the 1990s is equally consistent with Evanston's deciding that it could not obtain higher prices. Third, Respondent's learning-about-demand argument hinges heavily on the purported gap between Evanston's pre-merger prices and those charged by Highland Park. As we found, while not unambiguous, the weight of the record evidence suggests that this gap did not exist.

In addition, Baker's regressions partially undermine the argument because even when he used an unrealistically narrow control group to test the learning-about-demand position, he found that ENH's post-merger prices to both Humana and United were statistically-significantly higher than the predicted levels.⁸⁴ TR 4739, 4743, 4682-85 (Baker), *in camera*; RX 2040 at 4, *in camera*; DX 7068 at 46, *in camera*. For Humana, the average net prices that ENH charged were 21% higher in 2002 than he predicted they

⁸⁴ We find it somewhat surprising that Baker chose to report the statistical significance of these results. We presume that this is due to the fact that when he originally reported the results before correcting a mathematical error, he explicitly reported that the results were not statistically significant. DX 7067 at 45, *in camera*.

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would have been had the merger not occurred, and for United they were higher by 35% and 29% in 2002 and 2003, respectively.⁸⁵

As we also found above, Respondent's learning-about-demand argument is difficult to square with a number of Respondent's other positions. Respondent alleges that Evanston was and is a state-of-the-art hospital, with superior management, that consistently provided high-quality services. RFF ¶ 3. Yet respondent also maintains that Evanston's most senior officials did not set prices at market levels for certain MCOs while simultaneously charging market rates for other MCOs, such as BCBS and Cigna. In contrast, respondent maintains that Highland Park provided such poor services that it was threatening patient safety, and that Highland Park was in severe financial distress, but at the same time was highly proficient at setting a profit-maximizing price. Again, this logical discrepancy is not determinative, but when viewed in conjunction with the totality of the other evidence, it supports our rejection of Respondent's position that Evanston was systematically charging below-competitive rates before the merger.⁸⁶

b. Lack of Decline in Output

Respondent also argues vigorously that complaint counsel's position that the merger allowed supracompetitive pricing is deficient because complaint counsel did not show a decline in output. RB 56; RRB 5, 23-25. We disagree with Respondent's

⁸⁵ The Commission computed the numbers through straightforward calculations of the percentage differences in rows 7 vs. 9 (Humana), and rows 10 vs. 12 (United), in RX 2040 at 4, *in camera*; and DX 7068 at 46 (Table 4), *in camera*.

⁸⁶ As described *supra* at 41, the learning-about-demand argument does not apply to the post-merger price increases at Highland Park. Respondent's primary rebuttal to the econometrics as to Highland Park's price increases is that they reflect increased demand for Highland Park's services due to alleged post-merger improvements in the quality of the hospital. We address this argument, *infra*, at 70-72.

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reasoning. First, strictly speaking, the issue is not whether Respondent's output declined in nominal terms, but whether it declined from what it would have been but for the merger. Despite a merger-induced increase in ENH's market power, its nominal level level of output still could have grown if demand for hospital services services in the Chicago area increased.

More fundamentally, respondent incorrectly assumes that there is a relatively constant relationship in the hospital market between quantity and price. The record reflects that this is not the case. When MCOs negotiate with hospitals, for the most part they are faced with an all-or-nothing decision about whether to include the hospital in their network because, as Hillebrand testified, it is "very, very difficult" for an MCO to steer its PPO members to particular in-plan hospitals through differential pricing. IDF ¶ 169; TR 1760-63, 1766 (Hillebrand). Steering also is not an option for HMO plans because HMOs charge members uniform rates for all hospitals in their networks and preclude members from using other hospitals. Thus, generally, output declines only after the hospital exceeds the price at which the MCO is willing to enter into any contract with the hospital, at which point the output drops very substantially. In other words, there is a substantial range of prices, including prices at supracompetitive levels, over which an MCO will decide to include a hospital in its networks without a material change in the level of the hospital's services demanded by the MCO. The fact that complaint counsel did not prove a drop in market-wide output thus is not a deficiency in complaint counsel's case.

c. Quality Improvements at Highland Park

Respondent also argues that some portion of the merger-merger-coincident price increases computed by both Haas-Wilson and Baker was caused by increased demand for Highland Park's services due to post-merger improvements, rather than market power. RB 58-59, 62, 72. Complaint counsel responds that the ALJ

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ALJ found no evidence that the quality of care improved at ENH relative to other hospitals and, therefore, that Haas-Wilson's and Baker's estimates of the merger-coincident price increases do not require adjustment. CB 51.

Courts in merger cases usually consider efficiencies, including quality improvements, after the government has shown that the transaction is likely to reduce competition. *See Heinz*, 246 F.3d at 715, 720. Once the government has done so, the defendant can show that the loss of competition will not harm consumers by demonstrating that the transaction will produce "significant economies and that these economies ultimately would benefit competition and, hence, consumers." *University Health*, 938 F.2d at 1223; *see Merger Guidelines* § 4.0 ("To make the requisite determination, the Agency considers whether cognizable efficiencies likely would be sufficient to reverse the merger's potential to harm consumers in the relevant market, *e.g.*, by preventing price increases in that market."). The defendant has the burden of production to show that efficiencies offset any likely anticompetitive effects of the increase in market power produced by the merger. *See Heinz*, 246 F.3d at 715, 720 (finding that, to rebut presumptions of harm based on high concentration levels, defendants need to prove extraordinary efficiencies); *Staples*, 970 F. Supp. at 1088-89 (finding that defendants can use efficiency evidence to rebut presumption that merger will substantially lessen competition).

Because of the manner in which complaint counsel presented its case, however, here the issue of quality improvements at Highland Park is also relevant to determining whether the transaction increased the merging parties' market power. Complaint Counsel sought to prove that the merger increased ENH's market power by showing that there were large post-merger price increases that are not attributable to the most plausible competitively-benign factors. Respondent correctly points out that one such plausible factor is that MCO demand for Highland Park's services might have increased if (for whatever

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reason) the quality of Highland Park's services improved after the merger. RB 51. More formally, it is possible that the MCO demand curve for ENH's services might have shifted outward after the merger relative to demand for other hospitals due to a relative increase in the quality of the services at Highland Park.

As we have found, however, the record does not support Respondent's argument that improvements in quality at Highland Park caused the merger-coincident price increases at the hospital. First, because Evanston is more than twice the size of Highland Park, IDF ¶¶ 5, 22; ID 180, and generated roughly four times more revenue, CX 84 at 16, the large majority of commerce affected by ENH's substantial post-merger price increases was from Evanston's services, not those of Highland Park. Thus, even if respondent is correct that MCO demand for Highland Park's services increased after the merger due to quality improvements, such increased demand likely accounted for well short of half of the substantial higher-than-predicted merger-coincident price increases identified by both Haas-Wilson and Baker.

Second, the record is ambiguous as to whether quality at Highland Park improved relative to that of other hospitals after the merger. As we and the ALJ have found, however, even if Highland Park's quality improved relative to that of other hospitals, hospitals, the record supports a finding that it did not increase demand for Highland Park's services. ID 179. ENH did not mention to MCOs that its price increases were due to improvements at Highland Park, IDF ¶¶ 840, 842; ID 178, and Neaman testified that he never saw any documents correlating the higher prices with the quality changes at Highland Park. IDF ¶ 843; 843; ID 178. Other than a single press release mentioning planned clinical service improvements, ENH never identified any improvements at Highland Park to MCOs. IDF ¶¶ 841-47; ID 178. 178. The MCO witnesses also testified that the topic of quality improvements at Highland Park never came up during contract negotiations, IDF ¶¶ 844-47; ID 178, and that they were not aware

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aware of a significant increase in quality at Highland Park after the merger. IDF ¶¶ 846-47, 851; ID 181.

d. Merger Guidelines' Unilateral Effects Standards

Respondent also argues that complaint counsel has not satisfied the requirements for establishing that a merger enabled the combined firm unilaterally to exercise market power. Citing the *Merger Guidelines, In re R.R. Donnelley & Sons Co.*, 120 F.T.C. 36, 195 (1995), and several other authorities, respondent argues that establishing a likelihood of unilateral effects requires showing that (1) the merging firms are viewed as the first and second choices by (2) customers accounting for significant sales in the relevant market. RRB 3-5. Respondent maintains that complaint counsel did not and could not introduce such evidence because Evanston was much larger than Highland Park, and was a teaching facility that offered a greater breadth of medical services than did Highland Park. RB 42-43. Respondent also maintains that Evanston and Highland Park were geographically dissimilar because at least eight hospitals to the south of Evanston and two hospitals to the north of Highland Park are closer to Evanston and Highland Park, respectively, than Evanston and Highland Park are to each other. RB 43.

Respondent's position is not persuasive. An MCO's demand for hospital services is largely derived from an aggregation of the preferences of its employer and employee members. TR 5936-37 (Noether). When a hospital increases its price, the MCO can retain the hospital in its network and pay the higher price or drop the hospital and replace it with another hospital or some combination of hospitals. TR 2470 (Haas-Wilson).⁸⁷ If the MCO drops the hospital, it may cause some members who have a strong

⁸⁷ See Town & Vistnes, *supra* note 76, at 734-36, 752; see also Gregory Vistnes, Hospitals, Mergers, and Two-State Competition, 67 ANTITRUST L.J. 671, 686 (2000).

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preference for that hospital to switch to another MCO, and cause employers with a significant number of such members to drop the MCO altogether. 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. increase. TR 2475 (Haas-Wilson).⁸⁸ For example, Bain advised ENH that it likely could increase its prices to PHCS due to the "significant leverage [that ENH had] in negotiations with PHCS as [PHCS] ha[s] [a] strong North Shore presence and need[s] [ENH] in their network." CX 1998 at 44. Thus, whether the MCO decides to drop a hospital that raises its prices depends on a potentially complex assessment of the preferences of its employer and membership base.

The record reflects that Evanston and Highland Park likely were close substitutes for MCOs' members and employers, and thus for the MCOs. Evanston and Highland Park provided comparable primary and secondary services. TR 1291-93 (Neaman); CX 84 at 13, 15; TR 299 (Newton); TR 2083-88 (Spaeth). As Neaman testified, Evanston provided "[a]ll kinds of services, both inpatient and outpatient, sort of the basics, such as obstetrics, all the way up to the more intensive services, such as cardio-angiogenesis." TR 1291 (Neaman). That Highland Park did not provide the tertiary services provided by Evanston does not negate the interchangeability of the two hospitals' primary and secondary services, such as basic obstetrics and general surgery. Respondent's implied argument to the contrary is at odds with common sense and its own documents, which reflect pre-merger competition between Evanston and Highland Park. In addition, the district court in *Long Island Jewish Medical Center* rejected an argument similar to Respondent's position; the court held that two defendant merging academic hospitals (that provided tertiary services) competed with nearby community hospitals in the provision of primary and secondary care. 983 F. Supp. at 138-39.

⁸⁸ See Town & Vistnes, *supra* note 76, at 734, 737.

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Respondent's position that the two hospitals were highly differentiated geographically has somewhat more force, but also is ultimately unpersuasive. Respondent argues that a number of other hospitals are closer to Evanston and Highland Park than the merging hospitals are to each other. RB 43. Respondent appears to side-step the fact that geographic substitutability is a function not merely of the geographic relationship of hospitals to each other, but also of the relationship of the hospitals to MCOs' members. It is undisputed that there is an approximately thirteen-mile-long space between Evanston and Highland Park in which there are no other hospitals, and that no other hospitals are located within the geographic triangle formed by the ENH hospitals. Thus, it is likely that a significant number of MCO members who live in the triangle view Evanston and Highland Park as their preferred choices from a geographic perspective, and, therefore, that the financial cost to an MCO of removing the ENH hospitals from its network would exceed that of absorbing the price increase and spreading it over a larger membership base.

This conclusion is bolstered by ENH's ability successfully to charge substantially higher-than-predicted price increases to the MCOs after the merger. The MCO testimony also partially supports this determination. United's Jillian Foucre testified that Evanston and Highland Park would be the preferred choices of executives who lived in the triangle made up by the North Shore suburbs, and that executives who lived within the area made up by the triangle would not want to travel greater distances north or south to go to hospitals. TR 901-02 (Foucre). Aetna's Mendonsa testified that he thought that people who lived in the communities around the ENH hospitals would not want to travel to other hospitals, explaining that "[s]omeone that's going to Evanston is not going to drive all the way out to Park Ridge, which is where [Advocate] Lutheran General is, and . . . neither are they going to do that with Northwest Community Hospital." TR 541-43 (Mendonsa), *in camera*. Respondent's contention that the two hospitals were "vastly different" from a geographic perspective, RRB 14, also conflicts with Spaeth's testimony that Evanston was

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Highland Park's second overall closest competitor (after Lake Forest). TR 2163-64 (Spaeth).

We agree with respondent that not all of the MCO testimony is particularly precise and that it does not all support complaint counsel's case. We do not agree, however, that the MCO testimony undermines complaint counsel's case. Furthermore, while we likely would give less weight to customer testimony with such ambiguities in a challenge to an unconsummated merger, ambiguities are less concerning here, where our analysis is a retrospective inquiry based on empirical evidence and documents reflecting the parties' post-merger assessments of the deal. Antitrust analysis depends fundamentally on market facts. As the ALJ and we have found, the facts here – the merging parties' contemporaneous business assessment about the transaction's competitive effects, complaint counsel's and Respondent's econometric analyses of ENH's post-merger prices, and portions of the merging parties' and the MCOs' testimony – demonstrate on the whole that it is very likely that the merger enabled the combined firm to exercise market power.

The section of the *Merger Guidelines* and the cases upon which respondent relies set forth conditions that typically are necessary for a transaction to enable the unilateral exercise of market power. These authorities do not mandate the use of a particular type of proof to establish those conditions. In particular, they do not require a court to enumerate the customers who view the merging parties as their first and second choices. As respondent acknowledges, the *Merger Guidelines* provide that a plaintiff may draw upon different types of evidence to establish unilateral effects. *Merger Guidelines* § 2.211 n.22.

One type of evidence that can be used to identify unilateral effects is “natural experiments,” by which economists use natural variations in the economy or other social phenomena to perform an economic analysis. For example, in *Staples*, the FTC and the

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court relied, in part, on data that showed that “Staples and Office Depot both charge[d] higher prices where they face[d] no superstore competition [than when they did face competition from other superstores, which] demonstrate[d] that an office superstore can raise prices above competitive levels.” *See Staples*, 970 F. Supp. Supp. at 1082; *see generally* Joseph Larson *et al.*, *The Role of Economics and Economists in Antitrust Law*, 2004 Colum. Bus. L. Rev. 419, 453 (2004) (describing the use of natural experiments in merger analysis, including how “[c]omparisons of prices before and after competitor entry and exit are good candidates for natural experiments”).

Here, complaint counsel relied on economic analysis of Respondent’s post-merger prices (a form of natural experiment), as well as Evanston’s and Highland Park’s business documents, to establish the relevant product and geographic market and to show that the transaction enabled the merged firm unilaterally to exercise market power. The documents do not need to state affirmatively that a sufficient number of MCOs (or their members) viewed the merging parties as next best substitutes. Seldom do business documents use the language of the *Merger Guidelines* and economists to describe competition in markets. Further, economic analysis of actual market events, combined with review of other evidence, is a sound methodology to determine whether customers accounting for a significant share of ENH’s business viewed Evanston and Highland Park as next-best substitutes for particular needs, and support our making such a determination in this case.

e. Repositioning of Competitors

Respondent also maintains that complaint counsel has failed to show that repositioning by ENH’s competitors did not prevent or or eliminate any anticompetitive effects. RRB 20-22. We disagree. Following the *Merger Guidelines*, the courts generally hold that entry must be likely in a two-year period in order to conclude that it will offset a transaction’s anticompetitive effects. *See Cardinal*

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Health, 12 F. Supp. 2d at 55; *Merger Guidelines* § 3.2. As the ALJ found, new entry or repositioning did not reduce the market power power that ENH obtained from the merger during a two-year period. period. To the contrary, the econometric evidence, viewed in conjunction with the rest of the record, demonstrates that ENH was able to increase its prices by above-market rates for at least two two years after the merger occurred.

The weight of the evidence shows that it is unlikely that new entry or expansion reduced ENH's market power after the two-year period either. No new hospitals have been built in the relevant geographic market since the merger, which suggests that entry or expansion has not alleviated the market power created by the transaction. IDF ¶ 1021. Further, because it takes at least two and one-half years to build a new hospital, it is unlikely that new entry will occur in the geographic market in the near future. IDF ¶ 1024.

In addition, the documents, MCO testimony, and econometrics do not indicate that ENH could exercise market power due to capacity constraints at hospitals outside of the geographic market. Rather, the likely cause of the market power created by the merger was the elimination of competition between hospitals that were the most geographically convenient for a significant number of MCO members who lived within the triangle formed by the three ENH hospitals. Thus, we agree with the ALJ that new entry or repositioning did not alleviate the transaction's anticompetitive effects.

f. Elzinga-Hogarty Test

Finally, respondent argues that patient flow data undermine the the ALJ's conclusion that the triangle formed by the three ENH hospitals is a relevant geographic market and that the ALJ erred by by not considering such data. RB 32-33; ID 139. As the name suggests, patient flow data provide information about where patients

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travel to obtain hospital services. TR 2356, 2375 (Elzinga); TR 6203-04 (Noether). Respondent claims that in the context of “an 80% service area,” Evanston had more patient overlap with Northwestern Memorial, Rush North Shore, Advocate Lutheran General, St. Francis, and Weiss than with Highland Park. RB 32, *in camera*. In addition, respondent maintains that there was at least as great an overlap before the merger between Highland Park and Advocate Lutheran General or Lake Forest as between Evanston and Highland Park. *Id.*

A number of courts have considered patient flow data when they have defined the geographic market. In particular, they have applied the Elzinga-Hogarty (“E-H”) test to patient flow information as a proxy test to determine whether a firm could exercise market power in a potential geographic market. *See California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057, 1072 (N.D. Cal. 2002); *FTC v. Tenet Healthcare Corp.*, 17 F. Supp. 2d 937 (E.D. Mo. 1998), *rev’d on other grounds*, 186 F.3d 1045 (8th Cir. 1999); *FTC v. Freeman Hosp.*, 911 F. Supp. 1213, *aff’d*, 69 F.3d 260, 264-65 (8th Cir. 1995); *United States v. Mercy Health Servs.*, 902 F. Supp. 968, 978 (N.D. Iowa 1995), *vacated as moot*, 107 F.3d 632 (8th Cir. 1997).

The E-H test was devised by professors Kenneth G. Elzinga and Thomas F. Hogarty to help to delineate geographic markets, specifically in the coal and beer industries. TR 2374-76 (Elzinga); *see* Kenneth G. Elzinga & Thomas F. Hogarty, *The Problem of Geographic Market Delineation in Antimerger Suits*, 18 Antitrust Bull. 45 (1973); Kenneth G. Elzinga & Thomas F. Hogarty, *The Problem of Geographic Market Delineation Revisited: The Case of Coal*, 23 Antitrust Bull. 1 (1978). The objective of the E-H test is to “measure[] the accuracy of a [potential] market delineation by by determining the amount of either imports into or exports from a tentative market.” *United States v. Country Lake Foods, Inc.*, 754 F. Supp. 669, 672 n.2 (D. Minn. 1990). The test’s underlying assumption is that if an area has significant exports outside of the area or imports into the area, then that area is not a relevant

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geographic market because it is unlikely that a dominant firm within the area could exercise market power. *See id.*; TR 2372-73 (Elzinga).

At trial, Professor Elzinga testified that the E-H test was not an appropriate method to define geographic markets in the hospital sector because of two related problems, which he termed the “silent majority fallacy” and the “payor problem.” TR 2369 (Elzinga). The silent majority fallacy is the false assumption that patients who travel to a distant hospital to obtain care significantly constrain the prices that the closer hospital charges to patients who will not travel to other hospitals. TR 2356, 2384-87, 2391 (Elzinga). Elzinga testified that for the most part, patient decisions do not have such a constraining effect because their choices of hospitals largely are based not on price but on other factors, such as location and the preferences of their physician. TR 2387-88 (Elzinga); *see* TR 2463-65 (Haas-Wilson). He explained that:

[p]eople who travel outside their home turf for hospital services usually do so [because] . . . [t]here’s some particular service or amenity that they associate with that distant hospital that’s important to them, or they may have family who lives some distance away and they travel to that hospital. People who consume . . . hospital services close to home typically are there either because their doctor places them at that hospital or, for purposes of their own convenience or the convenience of their family, it is very important for them to be hospitalized close to home. So, unlike products like coal and beer that will move about in response to the market signals . . . prices change and beer gets shipped to a different location – here, the prices of hospital services do not drive most people to change the location of where they consume hospital services.

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TR 2387-88 (Elzinga).⁸⁹

Further reducing the effect of prices on patients' hospital choices is that patients rarely pay directly the full cost of hospital services. Insurance companies pay the large majority of hospital costs in most instances from revenues obtained through a broad base of employer and employee-paid premiums and deductibles. Consequently, when a hospital raises its prices, the increase often is spread out over a broad number of employers and members, many many of whom will never use the hospital. Even if an MCO tries to steer patients toward less costly hospitals through "tiering" of co-payments, the price effect often is diluted because the co-payments often do not cover the difference between the total costs of the expensive hospital and those of other, less costly hospitals.⁹⁰ Consequently, there is little reason to infer from some residents' choice of a more distant hospital that others would do likewise in response to a price increase from a closer hospital.⁹¹

Put more formally, the workings of the third-party payor system in the United States are such that rarely do patients fully internalize the benefits and costs of their decision to purchase a

⁸⁹ See also *Capps et al.*, *supra* note 76, at 739 ("Given the propensity of some patients to travel substantial distances for care, [the Elzinga-Hogarty] standard has led to large market boundaries and, consequently, permissive merger rulings. Our results indicate that this may be a serious error. . . . Many patients, especially those with conditions that are relatively straightforward to treat, have a strong preference to go to a convenient, nearby hospital. These preferences give hospitals with no nearby competitors a strong bargaining position.").

⁹⁰ Respondent maintains that MCOs can in fact force patients at least partially to internalize the price of hospital services through various steering techniques, such as hospital-specific co-payments and tiered networks. RB 33 n.6. The bulk of the evidence, however, is that, at least in the Chicago area, MCOs largely do not engage in such steering. *E.g.*, TR 594-95 (Neary); TR 1760-61 (Hillebrand).

⁹¹ See FED. TRADE COMM'N, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Ch. 4, at 8-10 (July 2004), *available at* <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf> (describing the silent majority fallacy).

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medical product or service. This lack of internalization is what Elzinga termed the “payor problem”:

[T]here’s a wedge between the consumption of the service and the person who decides where the service will be consumed and then some other party actually paying for the service, and consequently, the usual market analysis of goods and services . . . in response to price incentives really doesn’t fit. And so it follows in my view that looking at the flow of patients really doesn’t help you define the contours of a relevant geographic market area[] because the patients who are moving are not necessarily moving in response to price incentives.

TR 2395-96 (Elzinga).

Elzinga concluded that because “the ability of particular hospitals to raise prices is not disciplined or thwarted by the travel patterns” of patients, TR 2388 (Elzinga), using patient flow data is uninformative about whether it would be profitable for merging hospitals to raise prices, and that the application of the E-H test to patient flow data would identify overly broad geographic markets. TR 2393 (Elzinga).

We find Elzinga’s testimony to be persuasive. Respondent did not directly dispute Elzinga’s views about the general lack of validity of using the E-H test in hospital markets to define geographic markets, including the propensity of the test to define improperly large markets. Moreover, Noether agreed that “the use of of the [E-H] test is not appropriate for this case.” DX 7126 at 6. Nonetheless, there is some merit to Respondent’s argument that the the ALJ erred in holding that patient flow data are always irrelevant to determining the relevant geographic market. RB 32-33; ID 139. MCO demand for hospital services is partially a derived demand

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based on patient preferences, and the percentage of patients in a given area who use a hospital can, in certain circumstances, provide some rough indication of MCO preferences when they form a network. Ultimately, however, we believe that we should view patient flow data with a high degree of caution because of the silent majority fallacy and payor problem and, at best, we should use it as one potentially very rough benchmark in the context of evaluating other types of evidence. A robust application of the hypothetical monopolist methodology is almost certain to produce a more reliable determination of the geographic market than is analysis of patient flow data.

In this case, even assuming that Respondent's description of the patient flow information is correct, it provides no sound basis to alter our conclusion that the merger resulted in ENH's ability to exercise market power or that the triangle formed by the ENH hospitals is a relevant geographic market. For the reasons that Professor Elzinga explained, that Evanston and Highland Park may have had a greater patient flow overlap with certain other hospitals than they did with each other is not inconsistent with the conclusion that the combination of Evanston and Highland Park enabled the merged entity to exercise market power. To the contrary, here the record reflects that the merger did just that, and, consequently, that the relevant geographic market is narrower than the patient flow data might suggest.

4. Summary of Competitive Effects Analysis

In summary, we find that the merger enabled ENH to exercise market power, and that ENH used this market power to increase its average net prices to MCOs for acute inpatient hospital services by a substantial amount – at least the 9% or 10% calculated by Baker. No one type of evidence is dispositive. Instead, the econometric evidence, viewed in conjunction with Respondent's pre- and post-merger documents and the MCO and executive testimony, demonstrate that ENH's substantially higher-than-predicted merger-coincident price increases were due to

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to market power, rather than competitively-benign factors. Respondent's alternative explanations for these price increases are not supported by the weight of the record evidence. We also find that that because the merger enabled ENH to raise prices by a substantial substantial amount (at least equal to a SSNIP) through the unilateral exercise of market power, the geographic triangle in which the three ENH hospitals are located constitutes a well-defined well-defined antitrust geographic market under Section 7. *See* IV Areeda, Hovenkamp & Solow, *supra* note 69, ¶ 913b, at 64.

VI. EFFICIENCIES AND JUSTIFICATIONS

Having found that the transaction reduced competition substantially, we now address Respondent's efficiency claims and other justifications for the transaction. Respondent argues that the merger produced competitive benefits that outweigh the harm to competition alleged to have resulted from this merger. First, respondent argues that the merger increased the financial strength of Highland Park, transforming it from a weak to a strong competitor. Second, respondent argues that the merger produced significant quality improvements at Highland Park, enhancing that hospital's ability to compete with other hospitals in the Chicago area. RB at 62. Finally, respondent argues that its not-for-profit status reduces the merger's potential to cause competitive harm. We address these arguments in turn.

A. The "Weakened Company" Justification

ENH argues that, prior to the merger, Highland Park was on a financial "downward spiral" that limited its competitive viability in the future, and that the evidence of Highland Park's weakened financial condition rebuts or mitigates complaint counsel's showing regarding the merger's anticompetitive effects. ENH implicitly concedes that Highland Park's alleged financial difficulties fall short of the criteria required to establish a "failing

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firm” defense under the *Merger Guidelines*.⁹² Instead, it relies on *United States v. General Dynamics Corp.*, 415 U.S. 486 (1974), and cases that have followed it, for the proposition that, even if the the acquired firm is not “failing,” evidence that it has “severely limited” resources is relevant to the assessment of whether the challenged transaction is likely to cause competitive harm. RB at 63. 63.

In *General Dynamics*, the Supreme Court held that the market share statistics used by the government to challenge the merger of two coal companies were insufficient to sustain its case because, by failing to take into account the fact that the acquired firm’s coal coal reserves were depleted or committed under long-term contracts, those statistics overestimated the acquired firm’s ability to compete in the future. 415 U.S. at 500-04. Several courts have applied the *General Dynamics* rationale in ruling that evidence of the acquired firm’s weakened financial condition, among other factors, may rebut the government’s statistical showing of anticompetitive market concentration. See *Kaiser Aluminum & Chem. Corp. v. FTC*, 652 F.2d 1324, 1337-41 (7th Cir. 1981); *FTC v. FTC v. National Tea Co.*, 603 F.2d 694, 698-700 (8th Cir. 1979); *FTC v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 153-54 (D.D.C. 1998). These courts have generally cautioned, however, that

⁹² As the Merger Guidelines state:

A merger is not likely to create or enhance market power or facilitate its exercise if the following circumstances are met: 1) the allegedly failing firm would be unable to meet its financial obligations in the near future; 2) it would not be able to reorganize successfully under Chapter 11 of the Bankruptcy Act; 3) it has made unsuccessful good-faith efforts to elicit reasonable alternative offers of acquisition of the assets of the failing firm that would both keep its tangible and intangible assets in the relevant market and pose a less severe danger to competition than does the proposed merger; and 4) absent the acquisition, the assets of the failing firm would exit the relevant market.

Merger Guidelines § 5.1 (footnotes omitted).

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“[f]inancial weakness, while perhaps relevant in some cases, is probably the weakest ground of all for justifying a merger,” and “certainly cannot be the primary justification” for permitting one. *Kaiser Aluminum*, 652 F.2d at 1339, 1341; *accord Arch Coal*, 329 F. Supp. 2d at 154.⁹³ Notably, “while a merger is a relatively ‘permanent’ arrangement having long-lasting competitive effects, financial difficulties not raising a significant threat of failure are typically remedied in a moderate length of time.” IVA Areeda, Hovenkamp & Solow, *supra* note 69, ¶ 963, at 14. As the Eleventh Circuit held in *University Health*:

[W]e 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.

938 F.2d at 1221; *accord Tenet Healthcare*, 17 F. Supp. 2d at 947.⁹⁴

The precise standard for evaluating a weakened company justification is not material here because the record evidence does

⁹³ As the Seventh Circuit observed in rejecting a weakened company defense, even the acquisition of a weak company can have anticompetitive consequences. *Kaiser Aluminum*, 652 F.2d at 1339 (“The 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.”); *id.* at 1341 (“History records and common sense indicates that the creation of monopoly and the loss of competition involve the acquisition of the small and the weak by the big and the strong.”).

⁹⁴ See also *Rockford Mem’l*, 717 F. Supp. at 1289 (rejecting defendants’ argument that the merger should be allowed “on the basis of its prediction of future financial calamity,” finding that “this ‘failing market’ or ‘writing on the wall’ defense [is] too broad and ungainly to ward off a Section 7 violation”), *aff’d*, 898 F.2d 1278 (7th Cir. 1990).

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not substantiate ENH's contention that Highland Park's pre-merger financial condition prevented it from competing effectively. Instead, the evidence shows that Highland Park's financial condition was essentially sound. Highland Park had a strong balance sheet, with more than sufficient cash and assets to cover its long-term debt, continue operations, and – as Highland Park's strategic and financial plans indicated it intended to do – make substantial capital expenditures to improve its services and facilities. IDF ¶¶ 1028-51. Before the merger Highland Park had “historically achieved strong financial results compared to the median of not-for-profit hospitals.” CX 545 at 3. At the end of 1998, Highland Park and its affiliated corporations had cash and unrestricted investments of approximately \$218 million and long-term debt of \$120.5 million. By the end of 1999, cash and unrestricted investments had increased to approximately \$260 million, while long-term debt had diminished to \$116.7 million. CX 693 at 16-17. At the end of 1998, Highland Park had enough cash on hand to run a fully functional hospital for 444 days without any additional revenue (2.4 times the national average for “A” rated hospitals) – and this amount did not even include assets of the pre-merger Highland Park Foundation, whose funds went to support Highland Park and backed up its long-term debt. CX 1912 at 2; TR 5846, 5859-60 (Kaufman); IDF ¶¶ 1052-55. Indeed, Highland Park was sufficiently well-capitalized that, during the 1999 1999 merger negotiations with Evanston, it insisted on contributing contributing \$100 million to establish an independent community foundation. TR 5843 (Kaufman); CX 1912 at 3.

Although Highland Park experienced operating losses in 1999, 1999, its management believed that Highland Park would “remain financially strong over the foreseeable future.” CX 1055 at 3. The vast majority of the operating loss reported by Highland Park in 1999 was for merger-related costs. CX 1732 at 4; TR 412-13 (Newton). Highland Park's 1999-2003 financial plan – which assumed that Highland Park would not merge with another institution – set forth a long-range capital budget that included over over \$100 million for various strategic initiatives and capital investments. CX 545 at 3. Highland Park anticipated that, based on

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on growth through new clinical services and existing cash and investments, the hospital could “generate sufficient cash” to “restore the profitability” of the hospital and fund its numerous planned strategic initiatives and improvements. CX 1903 at 1; CX 545 at 3-4. Highland Park also had the support of a very wealthy community, which contributed millions of dollars to capital campaigns to fund various hospital projects. For example, one such campaign in the early or mid-1990s raised more than \$10 million for new surgical suites; another in 1998 raised money for Highland Park’s dialysis center. TR 319-21 (Newton); TR 4954, 4959-60 (Styer).

Even as Highland Park contemplated merging with Evanston or another hospital, its management believed that continuing operations as an independent hospital was a viable alternative. IDF ¶¶ 1056-57, 1060-61. Highland Park’s Chairman of the Board testified that, if the merger with Evanston had fallen through, “[t]here was no urgency to have an alternative immediately available” and that Highland Park had the “financial wherewithal to sustain [itself]” for at least ten more years. CX 6305 at 11 (Stearns); IDF ¶¶ 1058-59.

ENH argues that Highland Park’s financial health was far worse than its reporting of positive operational income for all years except 1999 would suggest, because Highland Park was “subsidizing” its operations with investment income. RB 64.⁹⁵ However, financial statements prepared by Highland Park’s transaction counsel show that, even excluding investment income, Highland Park had positive operating income in 1997 and 1998. RX RX 514 at 12. ENH’s due diligence report also indicates that Highland Park had positive operating income (not including the pre-merger Highland Park Foundation, investment income, or

⁹⁵ The record shows that ENH itself reported certain investment income as part of its operational income, in both the pre- and post-merger periods. RX 1194 at ENHLTH 1407; CX 2068 at 6.

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financing and interest payments) in 1996, 1997, and 1998. RX 609 at EY000256-57. Furthermore, the fact that Highland Park had additional sources of funds available to it, including income from its investments and funds from Highland Park's pre-merger foundation, supports a finding that Highland Park had the financial wherewithal to make necessary capital investments and enhance its facilities and services – investments to which Highland Park was committed, even without a merger, to improve the hospital's future performance.

In sum, the record does not support a conclusion that Highland Park's pre-merger financial health precluded Highland Park from being a meaningful competitive force, or that there was no economically reasonable strategy that Highland Park could follow, either as a standalone entity or in partnership with another, to improve its prospects. Whatever challenges Highland Park faced prior to the merger, it had considerably greater financial resources and competitive options available to it than anything courts have found to satisfy a weakened company justification.

B. ENH's Quality Improvements Justification

ENH also argues that any adverse competitive effects resulting from the merger are outweighed by significant quality improvements at Highland Park that the merger has produced. ENH presented evidence that it has spent over \$120 million post-merger to make improvements and expand services at Highland Park in 16 areas: (1) OB/GYN, (2) quality assurance, (3) quality improvements, (4) nursing, (5) physical plant, (6) oncology, (7) radiology and radiation medicine, (8) emergency care, (9) laboratory medicine, (10) pharmacy, (11) cardiac surgery, (12) interventional cardiology, (13) intensive care, (14) psychiatry, (15) electronic medical records, and (16) medical staff integration and academic affiliation.

ENH's improved quality argument raises interesting questions about how quality of care fits within a competitive effects analysis. Quality is one dimension on which firms compete, and differences in prices may reflect differences in quality. Improved

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quality also may factor into analysis of efficiencies. As the *Merger Guidelines* recognize, “mergers have the potential to generate significant efficiencies by permitting a better utilization of existing assets, enabling the combined firm to achieve lower costs in producing a given quantity and quality than either firm could have achieved without the proposed transaction,” and efficiencies “can enhance the merged firm’s ability and incentive to compete, which may result in lower prices, improved quality, enhanced service, or new products.” *Merger Guidelines* § 4. However, ENH does not argue that the claimed quality improvements at Highland Park have come about as a result of cost-saving efficiencies produced by the merger.⁹⁶ Instead, ENH characterizes quality improvements at Highland Park as benefits distinct from cost-savings that offset any adverse competitive effects produced by the merger.

The case law provides no clear answers regarding how, or whether, such claimed qualitative benefits ought to fit into a competitive effects analysis. ENH’s quality improvements argument here is similar to one made by the defendants, and rejected rejected by the court, in *Rockford Memorial Corp.* In that case, the defendants argued that, even if the merger had anticompetitive effects, any adverse effects for consumers were outweighed by qualitative benefits to consumers from expanded and improved services that the merging hospitals intended to undertake. 717 F. Supp. at 1287-88. Although the court acknowledged that “the improvement in services would have a positive effect for consumers consumers of healthcare in the relevant market,” it held that such improvements were “irrelevant for the present § 7 inquiry” because because “the court’s exclusive role is to evaluate the merger’s effect

⁹⁶ Although ENH asserts, in passing, that some of ENH’s improvements to Highland Park enhance cost efficiency, *e.g.*, RB 75, it has made no effort to quantify any such cost savings or otherwise substantiate this claim.

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effect on competition for the relevant market and no more.” *Id.* at 1288-89.⁹⁷ Other courts have been more receptive to quality-of-care arguments, but those decisions shed little light on how qualitative benefits are to be weighed against the competitive harm shown to result from a merger. *See, e.g., Tenet Healthcare*, 186 F.3d at 1053-54 (mentioning improved quality as a benefit of merger, but basing reversal of district court’s preliminary injunction on failure to prove relevant market).

But whatever uncertainties there may be, it is clear that claims of quality improvements must be subject to the same “rigorous analysis” that applies to all claims of procompetitive efficiencies to ensure that they “represent more than mere speculation and promises.” *Heinz*, 246 F.3d at 721. ENH must show that the claimed benefits are (1) verifiable; (2) merger-specific, *i.e.*, ones that could not practicably be achieved without the proposed merger; and (3) greater than the transaction’s substantial anticompetitive effects. *See Merger Guidelines* § 4; *see also Heinz*, 246 F.3d at 721-22 (finding that, among other things, asserted efficiencies must be “merger-specific”); *University Health*, 938 F.2d at 1223 (“speculative, self-serving assertions” will not suffice); *Staples*, 970 F. Supp. at 1089-90 (rejecting claimed efficiencies that were “unverified” and not supported by “credible evidence”).

ENH argues that the first of these requirements is satisfied here because – unlike the typical case in which the merger has not yet been consummated – the claimed improvements here already have been implemented and therefore can be “verified,” and the natural inference is that they resulted from the merger. RB 76. We disagree. The fact that we can verify that ENH actually made the claimed improvements at Highland Park following the merger tells

⁹⁷ In the court’s view, weighing the claimed quality improvements against the merger’s anticompetitive effects would require a “value choice . . . beyond the ordinary limits of judicial competence.” *Rockford Memorial*, 717 F. Supp. at 1288 (citing *Philadelphia Nat’l Bank*, 374 U.S. at 371) (internal quotation marks omitted).

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tells us little about whether these changes improved quality of care, or whether these improvements could have been achieved by Highland Park without the merger and “without the concomitant loss of a competitor.” *Heinz*, 246 F.3d at 722.

The ALJ found that there were several problems with ENH’s quality improvement claims. First, ENH did not present any quantifiable evidence that improvements at Highland Park enhanced competition. Second, ENH failed to show that quality improved across the combined ENH system (not just at Highland Park) and relative to other hospitals. Third, the ALJ found that the vast majority of the claimed improvements at Highland Park were not merger-specific. ID 177-78. As to the last point, the ALJ found that, before the merger, Highland Park had already committed (and had the financial ability) to invest over \$100 million to improve and expand its facilities and services, including in many of the same areas identified by ENH as merger-related improvements. ID 182. The ALJ also found that, even apart from Highland Park’s actual plans, the types of improvements claimed by ENH – improved facilities, staffing changes, and new procedures – did not require a merger. The ALJ did find that two of the claimed quality improvements – installation of the EPIC electronic medical records management system, and integration and affiliation with an academic teaching hospital – were merger-specific, but he concluded that these improvements did not outweigh the anticompetitive effects of the merger. ID 190-92.

Although our analysis differs in some respects from that of the ALJ, we agree that the evidence presented by ENH fails to rebut complaint counsel’s showing of anticompetitive effects.⁹⁸ As we

⁹⁸ For example, we do not agree with the ALJ that ENH must show, as part of its initial burden of production, that quality improved across the ENH system. If ENH showed that the merger improved quality at Highland Park, complaint counsel could certainly counter ENH’s evidence by showing a decline in quality elsewhere in the ENH system (and, indeed, it presented expert testimony to this

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explained in our findings of fact, we find that the quality improvements asserted by ENH are not properly credited as benefits of the merger because Highland Park could, and likely would, have made similar improvements without a merger. Our core findings that support these conclusions are the following: (1) Highland Park had plans in place to improve its quality and expand its services without a merger, including undertaking many of the same improvements that ENH credits to the merger, such as developing a cardiac surgery program in affiliation with Evanston or another hospital, IDF ¶¶ 952-58; (2) before the merger Highland Park already had begun to make a number of the improvements that ENH contends the merger produced; and (3) a number of the changes that ENH made at Highland Park after the merger reflect emerging trends in the industry, rather than benefits unique to the merger. IDF ¶ 895 (quality assurance program); IDF ¶¶ 901-02 (quality improvement program); IDF ¶ 950 (decentralized (decentralized dispensation of medication); IDF ¶ 973 (use of intensivists); IDF ¶ 983 (electronic medical records systems); TR 3840-41 (Silver) (in-house physician coverage in obstetrics departments).

ENH contends that Highland Park could not have achieved any of these improvements without the merger because they required ENH's superior leadership and "collaborative and multidisciplinary culture," which Highland Park supposedly lacked. RB 77-78. This argument is without merit. As Areeda, Hovenkamp, and Solow have observed:

Differences in management efficiency among competing firms are well-nigh universal. The usual

effect), but it should not be part of ENH's initial burden to show otherwise. We also think that the ALJ spoke too broadly in stating that ENH must show that quality at Highland Park improved relative to other hospitals. As we discuss below, whether a claimed improvement merely reflects a general trend in the industry (and thus might be deemed not merger-specific) is a relevant factor to be considered with regard to certain types of improvements (e.g., certain process changes), but it is not necessarily an appropriate inquiry across the board.

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cure for inefficient management is to replace it, as is frequently and easily done, sometimes by the board of directors, sometimes by disgruntled shareholders. As a result, management replacement is not a “merger-specific” economy. To be sure, a merger may be a quicker way of achieving this goal, particularly where the board is indecisive or the shareholders are divided. But most firms have relatively inefficient management from time to time. To permit all such firms to solve their problems problems by substantial horizontal merger could eviscerate § 7 of the Clayton Act.

IVA Areeda, Hovenkamp & Solow, *supra* note 69, ¶ 974, at 74 (footnote omitted). Moreover, the record shows that, when the need arose, Highland Park could readily institute new leadership to effect changes in its operations and improve its quality of care. TR 3746-49 (Krasner); TR 5479-80 (Chassin).

As noted above, the only claimed improvement that we think is properly deemed merger-specific is medical staff integration and affiliation with a teaching hospital. ENH’s health care quality expert testified that the integration of medical staff and academic affiliation provides Highland Park physicians with greater opportunities to upgrade their skills and keeps them “on their toes.” TR 5373-78 (Chassin). But this does not constitute verifiable evidence that ENH has improved quality at Highland Park, much less that any such improvement is of sufficient magnitude to offset the competitive harm that demonstrably has resulted from the merger.

In addition, in many instances, ENH produced little verifiable evidence that the changes it made at Highland Park improved quality quality of care. ENH’s quality claims are based to a large extent on on the testimony of its administrators, physicians, and nurse leaders, leaders, who offered their observations about the quality of care at

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Highland Park before and after ENH made changes. But, for the most part, ENH did not produce data to substantiate its assessments of quality at Highland Park, even though the record shows that ENH routinely tracks numerous quality indicators as part of its quality improvement program. CX 2052; CX 2436; RX 1326, *in camera*.⁹⁹ Although ENH's quality expert, Dr. Chassin, included some quantitative data in his analysis (*e.g.*, comparing Highland Park's pre- and post-merger rates of administration of aspirin and beta blockers to heart attack patients, TR 5281-83 (Chassin)), his analysis was principally qualitative, and was itself based in large part on anecdotal information provided by ENH's current administrative and medical leadership. TR 3011-12 (Romano); TR 5161-66 (Chassin).¹⁰⁰

We recognize that assessing the impact on quality of ENH's changes at Highland Park is not a simple matter and that, as Dr. Chassin testified, outcome measures are not always valid measures of quality. TR 5143-45, 5148 (Chassin).¹⁰¹ But, as is the case with claimed economic efficiencies, difficulties of proof do not not relieve ENH of its burden to produce verifiable evidence. Given the particular circumstances of this case – the fact that the merger has already been consummated, many of the claimed improvements were implemented years ago, and ENH routinely tracks numerous quality indicators – ENH could have produced

⁹⁹ For example, ENH's witnesses testified that changes implemented by ENH in radiology and emergency care improved turn-around times in those departments, but ENH did not produce data to substantiate these statements. TR 3632-34, 3643 (Victor); TR 4283-84, 4296 (Harris).

¹⁰⁰ Complaint counsel's quality expert, Dr. Romano, testified – and Dr. Chassin himself acknowledged, TR 5473 (Chassin) – that Dr. Chassin's methods for gathering information did not meet accepted standards of qualitative research. Among other things, Dr. Chassin made no effort to obtain the views of individuals who might have contradictory views or a perspective different from that of ENH's leadership. TR 3013-18 (Romano).

¹⁰¹ On the other hand, Dr. Romano testified that structural measures are insufficient by themselves, "because they tell us very little, if anything, about the care that's actually provided to patients." TR 2988 (Romano).

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more concrete evidence than it did to substantiate its claims that the changes it made at Highland Park improved the quality of care. As the court emphasized in *Heinz*, “a rigorous analysis” is required to ensure that defendant’s claims of offsetting procompetitive benefits “represent more than mere speculation.” *Heinz*, 246 F.3d at 721. The dearth of verifiable evidence here is all the more reason for us to find that ENH has failed to satisfy its burden to prove “extraordinary” procompetitive benefits, *id.*, offsetting complaint counsel’s showing of competitive harm.

C. ENH’s Not-For-Profit Status

ENH also contends that the ALJ erred in rejecting its argument that its status as a not-for-profit hospital system greatly reduces the potential for competitive harm. RB 83 n.27. ENH does not devote much time to this argument, and we need not either. As the Seventh Circuit has observed in rejecting this defense, “[t]he adoption of the nonprofit form does not change human nature . . . , as the courts have recognized in rejecting an implicit antitrust exemption for nonprofit enterprises.” *Hospital Corp. of Am. v. FTC*, 807 F.2d 1381, 1390 (7th Cir. 1986) (citation omitted); *see also Rockford Mem’l*, 898 F.2d at 1285. Neaman also testified that there was no relationship between ENH’s non-profit status and the prices that ENH set. TR 1032-33 (Neaman). More broadly, the totality of the record shows that ENH’s non-profit status did not affect its efforts to raise prices after the merger, and we readily agree with the ALJ that ENH’s status as a nonprofit entity does not suffice to rebut complaint counsel’s evidence of anticompetitive effects.

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VII. COUNT II

Complaint counsel has appealed the ALJ's decision not to issue an order against respondent under Count II. Complaint counsel alleges in Count II that the transaction violated Section 7 because the evidence shows that the transaction allowed ENH to exercise market power. Complaint Counsel did not allege a relevant product or geographic market in Count II, stating that it is not necessary to do so. CB 72-74.

Having found that the evidence is sufficient to define the product and geographic markets, and that complaint counsel has prevailed under Count I, we consider it unnecessary to decide whether the law permits establishing a violation of Section 7 without defining a relevant market. Several observations are warranted, however.

First, we are obviously aware that the Supreme Court has held repeatedly that "[d]etermination of the relevant market is a necessary predicate to a finding of a violation of the Clayton Act" and that the Court has linked this requirement to the language of Section 7, which states that the plaintiff must establish that "in any line of commerce . . . in any section of the country, the effect of such [transaction] may be substantially to lessen competition." *See Brown Shoe*, 370 U.S. at 324 (citations omitted); *see also Marine Bancorp.*, 418 U.S. at 618.

More recently, however, courts have focused on the integral link between market definition and the direct analysis of whether a transaction will produce market power. *See, e.g., Swedish Match, Match*, 131 F. Supp. 2d at 156 (finding that market definition is "the key to the ultimate resolution of this type of case because of the the relative implications of market power"); *Staples*, 970 F. Supp. at 1082 ("Much of the evidence already discussed with respect to defining the relevant product market also indicates that the merger would likely have an anti-competitive effect."). In addition, while the courts appropriately have continued to rely on structural

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presumptions derived from market definition, they also have placed much greater emphasis on the use of direct effects evidence. Thus, the D.C. Circuit noted in *Baker Hughes* that “[m]arket share is just a way of estimating market power, which is the ultimate consideration . . . [w]hen there are better ways to estimate market power, the court should use them.” 908 F.2d at 992 (quoting *Ball Mem’l Hosp., Inc. v. Mutual Hosp., Inc.*, 784 F.2d 1325, 1336 (7th Cir. 1986)).

Implicit in these decisions is the well-established principle that market definition is not an end in itself but rather an indirect means to assist in determining the presence or the likelihood of the exercise of market power. See *Baker Hughes*, 908 F.2d at 992; *Toys “R” Us, Inc. v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000). As Professor Hovenkamp has explained in his treatise, “[m]arket structure evidence is the surrogate for bad performance, not the other way around.” Herbert Hovenkamp, *Federal Antitrust Policy* § 12.8, at 550 (3d ed. 2005).

Plainly, the enforcement agencies and courts need predictive tools and other inferential mechanisms to analyze market power in many merger cases. Market definition is one such type of tool. See *Toys “R” Us*, 221 F.3d at 937; see also Hovenkamp, *supra*, § 12.4c, at 524 (“Both concentration measures and estimates of market share are generalized attempts to predict the likelihood of anticompetitive behavior in the market.”). The role of the market definition tool, however, is potentially much less important in merger cases in which the availability of natural experiments allows for direct observation of the effects of competition between the merging parties, as well as the absence of such competition.

A line of modern cases brought under Section 1 of the Sherman Act is instructive. These courts have analyzed whether it is appropriate to determine the lawfulness of ongoing or completed conduct through direct effects evidence, in lieu of market market definition. In *FTC v. Indiana Federation of Dentists*, 476

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U.S. 447 (1986) (“*IFD*”), the Supreme Court reviewed an FTC decision that a dental association violated the antitrust laws by promulgating and enforcing a rule to withhold x-rays requested by dental insurers for use in claims evaluations. The association argued on appeal to the Supreme Court that the FTC’s decision was wrong as a matter of law because the FTC had not specifically defined the relevant market. *Id.* at 460. The Supreme Court disagreed, holding that product market analysis “is but a surrogate for detrimental effects.” *Id.* The Court further stated that “proof of actual detrimental effects, such as a reduction of output, can obviate the need for an inquiry into market power” through product market analysis. *Id.* at 460-61 (quoting VII Phillip Areeda, Areeda, Antitrust Law ¶ 1511, at 429 (1st ed. 1986)).

A number of lower courts in Section 1 cases, relying on *IFD*, have held that it is appropriate to prove anticompetitive effects through direct evidence in place of market definition. In *Toys “R” Us*, the Seventh Circuit reviewed an FTC decision that held unlawful agreements between Toys “R” Us and a group of toy manufacturers in which each manufacturer promised to restrict distribution of its products to low-priced warehouse stores. Toys “R” Us argued that the Commission’s decision was deficient because the Commission had not established that the company had a large share of a relevant market. 221 F.3d at 937. The court of appeals rejected this claim, holding that the Commission’s direct evidence of anticompetitive effects was sufficient to establish an antitrust violation:

[Toys “R” Us] seems to think that anticompetitive effects in a market cannot be shown unless the plaintiff, or here the Commission, first proves that it has a large market share. This, however, has things backwards. As we have explained elsewhere, elsewhere, the share a firm has in a properly defined relevant market is only a way of estimating market power, which is the ultimate consideration. The Supreme Court has made it clear that there are

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two ways of proving market power. One is through direct evidence of anticompetitive effects. . . . The other, more conventional way, is by proving relevant product and geographic markets and by showing that the defendant's share exceeds whatever threshold is important for the practice in the case.

Id. (citations omitted).¹⁰²

While *IFD* and *Toys "R" Us* involved horizontal conduct that arguably was subject only to a "quick look," courts have held that it is equally appropriate to use direct effects evidence in lieu of formal market definition in cases subject to a full rule of reason analysis. *See, e.g., Todd v. Exxon Corp.*, 275 F.3d 191, 207 (2d Cir. 2001) ("[U]se of anticompetitive effects to demonstrate market power . . . is not limited to 'quick look' or 'truncated' rule of reason cases.").

We recognize that *IFD* and its progeny did not make a complete complete break from the market definition process. In each of these cases, the courts also found that there was sufficient evidence evidence to identify at least the "rough contours" of the relevant product and geographic markets. *See Republic Tobacco Co. v. North North Atlantic Trading Co.*, 381 F.3d 717, 736 (7th Cir. 2004). We also recognize that these cases did not involve Section 7. But this

¹⁰² *See also Tops Markets, Inc. v. Quality Markets, Inc.*, 142 F.3d 90, 98 (2d Cir. 1998)(finding that market power "may be proven directly by evidence of the control of prices or the exclusion of competition, or it may be inferred from one firm's large percentage share of the relevant market"); *K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co.*, 61 F.3d 123, 129 (2d Cir. 1995) ("If a plaintiff can show an actual adverse effect on competition, such as reduced output[,]. . . we do not require a further showing of market power.") (citation omitted); *Capital Imaging Assocs. v. Mohawk Valley Med. Assocs.*, 996 F.2d 537, 546 (2d Cir. 1993) (explaining that plaintiff may avoid a "detailed market analysis" by offering 'proof of actual detrimental effects, such as a reduction of output') (citation omitted).

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does not negate the conceptual force of these decisions. None of these courts held that market definition was a necessary supplement to the direct effects evidence. Rather, they endorsed the use of direct effects evidence to determine, even absent a market definition, whether ongoing conduct has facilitated the exercise of market power.

Antitrust doctrine is not static. *See, e.g., State Oil Co. v. Khan*, 522 U.S. 3 (1997) (overruling early decision that held that vertical maximum price fixing was *per se* violation of the Sherman Act). It is important that the antitrust laws be able to “adapt[] to changed circumstances and the lessons of accumulated experience.” *Id.* at 20. Consequently, we do not rule out the possibility that a future merger case may lead us to consider whether complaint counsel must always prove a relevant market.

VIII. REMEDY

Having found that Evanston’s acquisition of Highland Park violated Section 7 of the Clayton Act, we turn to fashioning the appropriate remedy. The ALJ determined that ENH should divest Highland Park. ID 202-06. The ALJ also proposed a variety of other requirements intended to ensure that Highland Park would remain a viable hospital after divestiture and retain certain improvements that were implemented after the merger. ID 206-08.

Complaint counsel argues that the Commission should affirm the ALJ’s order, but also cross-appeals and urges the Commission to add provisions that would require ENH to assist Highland Park in the continuation of its cardiac surgery program, provide incentives for ENH’s employees to accept job offers from Highland Park, and indemnify any monitor or trustee charged with overseeing the divestiture.

Respondent argues that, if we find liability, we should forgo ordering divestiture and instead should restore competition by requiring ENH to negotiate and maintain separate MCO contracts on

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on behalf of Evanston on the one hand and Highland Park on the other. In conjunction, or in the alternative, respondent also suggests suggests that we could require ENH to give the Commission advance notification of any future acquisition or joint venture that ENH proposes to undertake.

The goal of a remedy for a Section 7 violation is to impose relief that is “necessary and appropriate in the public interest to eliminate the effects of the acquisition offensive to the statute.” *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 607 (1957). Thus, we attempt to craft a remedy that will create a competitive environment that would have existed in the absence of the violations. *In re RSR Corp.*, 88 F.T.C. 800, 893 (1976), *aff’d*, *RSR Corp. v. FTC*, 602 F.2d 1317 (9th Cir. 1979). “The antitrust laws would deserve little respect if they permitted those who violated them to escape with the fruits of their misconduct on the grounds that imposition of an effective remedy would incidentally result in even a substantial monetary loss.” *RSR*, 88 F.T.C. at 895.

Structural remedies are preferred for Section 7 violations. *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 recently said, “[m]uch of the case law has . . . found divestiture the most appropriate means for restoring competition lost as a consequence of a merger or acquisition.” *In re Chicago Bridge & Iron Co.*, No. 9300, 2005 WL 120878, at 93 (FTC Jan. 6, 2005). Divestiture is desirable because, in general, a remedy is more likely to restore competition if the firms that engaged in pre-merger competition are not under common ownership. There are also usually greater long-term costs associated with monitoring the efficacy of a conduct remedy than with imposing a structural solution.

In this case, the transaction eliminated the pre-merger price competition between Evanston and Highland Park, as well as the

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MCOs' option of contracting with one hospital but not the other. We can seek to remedy this competitive harm by requiring ENH to divest Highland Park or through injunctive restraints. After careful review of the record, we have determined that this is the highly unusual case in which a conduct remedy, rather than divestiture, is more appropriate.

A long time has elapsed between the closing of the merger and the conclusion of the litigation. This does not preclude the Commission from ordering divestiture, but it would make a divestiture much more difficult, with a greater risk of unforeseen costs and failure. ENH has integrated the operations of Evanston, Glenbrook, and Highland Park Hospitals, and has made improvements at Highland Park since the merger. The large majority of these improvements could have occurred without the merger, and therefore do not bear on whether the transaction violated Section 7. Nonetheless, while the improvements do not vindicate the merger under the antitrust laws, they are relevant to determining whether divestiture is appropriate because divestiture may reduce or eliminate the resulting benefits for a material period of time.

Thus, we need to consider whether certain improvements would not survive the divestiture *and* would take Highland Park a significant time to implement on its own after a divestiture. Two significant improvements meet these conditions – the development and implementation of the cardiac surgery program and the implementation at Highland Park of EPIC, the state-of-the-art medical record computer system.

The record reflects that a divestiture may have a substantial negative effect on Highland Park's cardiac surgery programs. Complaint counsel's expert, Dr. Romano, testified that it was not clear whether, without Evanston, Highland Park would have the volume that it needed to maintain the cardiac surgery program. TR 3193 (Romano), *in camera*. If Highland Park lost its cardiac surgery program, or if the quality of its surgical program diminished, then

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the quality of patient care to the community would suffer. Highland Park would need to transport some or all of its patients needing emergency cardiac surgery to other hospitals, potentially creating life-threatening risks. TR 5612-13 (Chassin); TR 4457 (Rosengart). The possibility of a delay in reestablishing cardiac surgery services at Highland Park is a significant factor that we must weigh in considering a remedy.

A delay in reestablishing Highland Park's cardiac surgery program also could put at risk Highland Park's interventional cardiology services. An interventional cardiology program involves procedures that may be scheduled in advance. To provide interventional cardiology services, however, it is necessary to have a cardiac surgery program as a back-up for the interventional program if complications occur. TR 5306-07 (Chassin).

We are also concerned about the effect of divestiture on Highland Park's ability to use EPIC. Although the implementation of the EPIC system at Highland Park was not a merger-specific efficiency, it likely would take Highland Park significant time to install EPIC (or a comparable record keeping system) independently, at a cost of millions of dollars if we ordered divestiture. ENH spent approximately \$14 million on EPIC and took more than one year to deploy the system fully. TR 1984 (Hillebrand); TR 1251, 1355 (Neaman); TR 3523 (O'Brien); TR 3976, 3987-88 (Wagner). We could order ENH to continue to make EPIC available to Highland Park for some time, but we are concerned about the potential effects on patient care from the inevitable glitches involved in Highland Park's swapping out complex software systems.

Accordingly, we reject divestiture as a remedy and will impose an injunctive remedy that requires respondent to establish separate and independent negotiating teams – one for Evanston and Glenbrook Hospitals (“E&G”), and another for Highland Park. While not ideal, this remedy will allow MCOs to negotiate

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separately again for these competing hospitals, thus re-injecting competition between them for the business of MCOs. Further, ENH should be able to implement the required modifications to its contract negotiating procedures in a very short time. In contrast, contrast, divesting Highland Park after seven years of integration would be a complex, lengthy, and expensive process.

We note that our rationale for not requiring a divestiture in this case is likely to have little applicability to our consideration of the proper remedy in a future challenge to an unconsummated merger, including a hospital merger. For example, had we challenged this transaction prior to consummation, Evanston's intention to implement a cardiac surgery program and install EPIC at Highland Park likely would not have carried much weight in our analysis of the proper remedy because, at that time, Highland Park probably could have produced both improvements on its own in a comparable period, and thus neither improvement would have been merger-specific.

Nor will our reasoning here necessarily apply to consideration of the appropriate remedy in a future challenge to a consummated merger, including a consummated hospital merger. Divestiture is the preferred remedy for challenges to unlawful mergers, regardless of whether the challenge occurs before or after consummation. Thus, 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.

Although we have decided on the nature of the relief that is appropriate for this case, we lack sufficiently detailed information about the personnel involved in ENH's contract negotiation operations, or ENH's overall business operations, to craft the remedial order with the necessary precision. Accordingly, we order that, within thirty (30) calendar days, respondent must submit a detailed proposal to the Commission for implementing the type of injunctive relief that we have selected. Specifically, the proposal

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must identify and describe the mechanisms that respondent will use, and the steps that respondent will take, to implement the following requirements:

1. Respondent must allow all payors to negotiate separate contracts for E&G on the one hand and for Highland Park on the other hand;
2. Respondent must establish separate negotiating teams (and other relevant personnel) for E&G and Highland Park that will compete with each other, and other hospitals, for payors' business;
3. Respondent must establish a firewall-type mechanism that prevents the E&G and Highland Park contract negotiating teams (and other relevant personnel) from sharing any information that would inhibit them from competing with each other and with other hospitals;
4. Respondent may not make any contract for E&G or Highland Park contingent on entering into a contract for the other, and may not make the availability of any price or term for a contract for E&G contingent on entering into a contract for Highland Park, or *vice-versa*; and
5. Respondent shall promptly offer all payors with which it currently has contracts the option of reopening and renegotiating their contracts under the terms of this order.

Respondent's proposal should also describe, where appropriate, appropriate, mechanisms for the Commission to monitor the establishment of the organizational structure needed to implement the terms of the order, as well as Respondent's compliance with the the order throughout its term. Respondent's proposal shall also recommend mechanisms for resolving disputes between payors and and respondent with respect to Respondent's compliance with the

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terms of the order, including a discussion of the potential value of some form of dispute resolution mechanism.

Complaint counsel must submit any objections to or comments on Respondent's proposal within thirty (30) calendar days after respondent submits its proposal. Respondent may, if it chooses, respond to complaint counsel's filing within ten (10) calendar days.

Concurring Opinion of Commissioner J. Thomas Rosch

I concur with the Commission opinion's conclusion that Evanston Northwestern Healthcare Corp.'s acquisition of Highland Park Hospital violated Section 7 of the Clayton Act. There is much to be admired in the Commission opinion. However, particularly in light of Count II of the complaint, I believe the Commission opinion makes this case more difficult than necessary. I write separately to explain why that is so.

I depart from the Commission opinion in two fundamental respects. First, I believe 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 ("MCOs") over inclusion in MCO networks that is described by the Commission opinion. *See* Comm. Op. 62-63 (describing the "bargaining model" involved here). Reflecting those dynamics, complaint counsel's theory of anticompetitive effects is multi-dimensional.

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At one level, notwithstanding the physical and geographical differences between Evanston and Highland Park,¹ the two hospitals competed with each other in the sense that MCOs wanting to compete effectively for insureds located within the geographic triangle bounded by the three ENH hospitals viewed Evanston and Highland Park as each other's "next best substitute" in forming networks for that purpose. Complaint counsel's theory of anticompetitive effects was initially based on the merger's elimination of this dimension of competition, which enabled ENH to include Highland Park in its system and engage in system (all-or-nothing) supra-competitive pricing. *See* CPTB 4, 24; CB 14, 19-21.

At a second level, premerger, Evanston and Highland Park were also constrained in their pricing to MCOs by localized competition – *i.e.*, by the hospitals located closest to each of the two hospitals. Complaint counsel contends that the merger eliminated (or at least crippled) this localized competition because after the merger an MCO had to contract with all ENH hospitals in order to include one of them in its network, and that inhibited MCOs from playing Evanston and Highland Park off against their nearby competitors, as they could do pre-merger.

This multi-dimensional theory of liability, while unusual, is by no means unique. The Commission relied on similar theories when it challenged Rite-Aid's attempt to acquire Revco and Time Warner Inc.'s proposed acquisition of Turner Broadcasting System, Inc. *See* Jonathan B. Baker, *Unilateral Competitive Effects Theories in Merger Analysis*, 11 Antitrust 21, 24-25 (1997).

¹ Evanston Hospital and Highland Park are located 13.7 miles apart and each has other hospitals located closer to it than they are to each other (though there are no other hospitals located within the geographic triangle formed between the two Evanston hospitals and Highland Park), and Evanston is a teaching tertiary care hospital, while Highland Park is a non-teaching, community primary-secondary care hospital. However, as the Commission opinion notes, the two Evanston hospitals and Highland Park each provided primary-secondary care services. Comm. Op. 12, 26, 72-73

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Second, I believe the evidence that these unilateral anticompetitive effects have actually occurred has a significant impact on market definition. Specifically, the fact that this is a consummated merger means that ours is a retrospective analysis. We can look to see if there is any probative post-merger evidence that demonstrates whether or not the merger has been anticompetitive. We do not need to try to predict the future as would be necessary to analyze an unconsummated merger proposal. Where, as here, the post-transaction record establishes that the transaction has produced unilateral anticompetitive effects, it is not essential to define the relevant market upfront using the methodology described in the Horizontal Merger Guidelines. At least the “rough contours” of the relevant market can be identified on the basis of those effects, and that is sufficient as a matter of law.

I. Anticompetitive Effects

There is no dispute that immediately after the merger ENH increased prices for services at the ENH hospitals to a number of MCOs by many times the five percent increases described in the Horizontal Merger Guidelines as “significant” and that those price increases were “non transitory.” *See* U.S. Dep’t of Justice & Federal Trade Comm’n, *Horizontal Merger Guidelines* §1.11 (1992, revised 1997) (“Merger Guidelines”); Comm. Op. 16-17, 26-27, 64-65, 78. There is, however, a dispute over the cause of those price increases. Complaint counsel argued that this transaction created a hospital system that could and did obtain supra-competitive prices. *See* CPTB 2-4, 33-34; CB 14, 19-21. Respondent argued that its price increases at Evanston Hospital simply reflected its efforts to raise Evanston’s prices to a competitive level, and did not reflect supra-competitive pricing. RB 3. It also maintained that the post-merger price increases at Highland Park reflected an increase in the quality of services provided at the hospital. RB 3-5.

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I conclude that the merger materially changed the competitive dynamics that had theretofore existed in a fashion that violated Section 7.

A. The Law

Complaint counsel's theory of anticompetitive effects is viable as a matter of law. Respondent asserts that the Merger Guidelines description of unilateral anticompetitive effects in mergers involving differentiated products (Sections 2.21 and 2.211) does not squarely adopt that theory. RB 39-43; RRB 11, 22 (discussing Sections 2.21 and 2.211 and *In re R.R. Donnelly & Sons Co.*, 120 F.T.C. 36 (1995), embracing these provisions). I agree with respondent that the unilateral effects of a merger between producers of differentiated products (or services, like hospital services) cannot be considered illegal in all circumstances. I also agree that Sections 2.21 and 2.211 provide valuable guidance respecting the appropriate parameters. However, I disagree with respondent that complaint counsel's theory is outside those parameters.

The fundamental teaching of Sections 2.21 and 2.211 is that anticompetitive effects are likely when differentiated products of the merging parties are each other's next best substitute.² To be sure, those provisions might not apply if the merger eliminated only pre-merger localized competition, considered in isolation. In that dimension of competition, Evanston and Highland Park were arguably not each other's best alternative within the meaning of Sections 2.21 and 2.211 of the Merger Guidelines. Advocate Lutheran General was arguably Evanston's closest local competitor and Lake Forest was arguably the closest alternative to Highland Park.

² The provisions also establish a safe harbor when the merger could not result in substantial market power. But under complaint counsel's theory, after the merger the merging hospitals here enjoyed substantial market power.

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However, under complaint counsel's theory the merger's impact on localized competition cannot be considered in isolation. It was the *consequence* of the merger's primary effect, which was to eliminate competition between Evanston and Highland Park for inclusion in MCO hospital networks. To be specific, under complaint counsel's theory, before the merger MCOs who wanted to compete effectively for insureds located within the triangle considered Evanston and Highland Park to be each other's "next best substitute" in forming a network for that purpose, and the merger eliminated the competition between those next best substitutes. The lessening of the localized dimension of competition is an ancillary anticompetitive effect of the merger because the elimination of that dimension of competition resulted from the merger's elimination of competition between those next best substitutes. Thus, the unilateral effects provisions of the Merger Guidelines apply if the record sufficiently demonstrates that the transaction has had those anticompetitive effects.

This application of Sections 2.21 and 2.211 is not blunted by the language in Section 2.21 stating that "[t]he price rise will be greater the closer substitutes are the products of the merging firms." As the rest of that sentence makes clear, even products that are highly differentiated in terms of their physical and locational differences can be considered to be close substitutes with each other if "buyers of one product consider the other product to be their next choice." Thus, the elimination of the first dimension of competition – the competition between Evanston and Highland Park resulting from MCOs' desire to include one or the other of them in their networks – would represent an elimination of "close substitutes" within the meaning of Sections 2.21 and 2.211. And, since under complaint counsel's theory the injury to the second dimension of competition – the localized competition between each of the merging hospitals and its geographically more proximate rivals – was a consequence of the elimination of competition between those "close substitutes," those provisions of the Merger Guidelines would apply to that injury as well.

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Conceptually, the effect of the elimination of the competition between Evanston and Highland Park is the same as if Evanston and Highland Park had entered into an agreement with each other as to the prices they would charge MCOs (or to be more blunt if they had entered into a price-fixing agreement). To be sure, a marketing joint venture could produce a similar result. We tolerate a marketing joint venture when it is shown to produce a new product that would not otherwise exist, absent the collaboration, and if it is shown that the joint venture will produce efficiencies that outweigh any pricing effects. *See* Federal Trade Comm'n & U.S. Dep't of Justice, *Antitrust Guidelines for Collaborations Among Competitors* §§ 3.3, 3.36 (2000). However, under complaint counsel's theory, neither can be said about this transaction. Before the transaction, MCOs could, if they chose to do so, create a hospital network like the post-merger system of ENH hospitals by bargaining with Evanston and Highland Park individually (and playing each off against the hospitals proximate to each – for example, Lake Forest in the case of Highland Park). Thus, the merger was not necessary to produce that kind of hospital network. Moreover, according to complaint counsel (and the Commission opinion), respondent failed to prove that any claimed efficiencies outweighed the pricing effects of the merger.

Most significantly, complaint counsel's theory fits snugly within the language of Section 7 of the Clayton Act. That provision prohibits any merger that has the effect of substantially lessening competition. Under complaint counsel's theory, this merger had the effect of substantially lessening both dimensions of the pre-merger hospital competition that MCOs could take advantage of in fashioning a network that would be attractive to insureds located within the triangle.

B. The Facts

As a factual matter, complaint counsel's view of the anticompetitive effects in this case is supported by MCO testimony, testimony of Respondent's own principal economic expert, Professor

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Jonathan Baker, and the documents and testimony of the merging parties. MCO representatives described the pre-merger dynamics of competition among hospitals for inclusion in MCO networks. They testified that prior to the merger, MCOs wanting to compete effectively for insureds located within the geographic triangle formed by Evanston and Highland Park viewed those hospitals as “close substitutes” for each other when forming networks for that purpose. *See* Comm. Op. 18-25, 78.

For example, Jane Ballengee, PHCS’ Regional Vice President for Network Development, testified that before the merger PHCS “could have one or the other hospital in their network.” CB 21 (citing TR 166-67 (Ballengee)). Robert Mendonsa, a former general manager at Aetna, testified that before the merger Evanston was “extremely desirable” and that Aetna’s “walk-away point would have been pretty high . . . [but that Aetna] would have walked away because we still had Highland Park and we had Northwestern in the city and we had that coverage.” TR 530 (Mendonsa), *in camera*. United’s Jillian Foucre testified that Evanston and Highland Park would be the preferred choices of executives who lived in the triangle made up by the North Shore suburbs, and that executives who lived “within that area” made up by the triangle would not want to travel greater distances north or south to go to hospitals. TR 901-02 (Foucre). Foucre managed a team who negotiated with United’s network providers in the Chicago area. TR 879 (Foucre); CX 5174, *in camera*.³

Additionally, MCO representatives testified that prior to the merger there was another dimension of competition: Evanston and Highland Park were also constrained in their pricing to MCOs by localized competition – *i.e.*, the hospitals located close to each (and not each other). For example, Foucre also testified that, prior to the merger, she viewed Condell and Lake Forest as competitors to

³ Patrick Neary, who at the time of the merger was One Health’s Director of Network Development, also testified that he thought that ENH had purchased “their main competitor,” although he did not specify why this was the case. TR 600-01 (Neary).

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Highland Park, and that Evanston competed with Advocate Lutheran General, Rush North Shore, and St. Francis. TR 941-44 (Foucre). Lenore Holt-Darcy, Unicare's Regional Vice President at the time of the merger, testified that Highland Park competed with Lake Forest and Condell hospitals, and that Evanston competed with a significant number of tertiary hospitals in the Chicago area, including Rush North Shore and St. Francis. TR 1595-97 (Holt-Darcy), *in camera*.

The changes in these competitive dynamics are directly reflected in the post-merger pricing applicable to ENH's hospitals. It is undisputed that after the merger ENH negotiated a system contract for all three of its hospitals; MCOs were not given the option of entering into separate contracts for the hospitals, to decline to use one or more of the hospitals, or to pay different prices for the care at any one of them. *See* IDF ¶ 449; TR 1528 (Holt-Darcy), *in camera* (Post-merger, ENH offered an "all-or-nothing deal" to Unicare in which there would be one rate for all three hospitals, regardless of the level of service at each facility, like the "Three Musketeers, all for one and one for all."); *see also* Comm. Op. 16. Furthermore, as the Commission opinion says, economic evidence proffered by Professor Baker shows that immediately after the merger, the system prices that ENH charged a number of MCOs increased by many times more than the five percent described in the Merger Guidelines as "significant." Comm. Op. 17, 27, 64-65.

Beyond that, the record refutes Respondent's efforts to explain those price increases by factors divorced from the merger itself. First, while respondent claims that the pricing at Highland Park was attributable to the improvements that ENH made there, the record shows that price increases were imposed *before* these improvements were made. IDF ¶¶ 179, 457. Second, the econometric evidence presented by Professor Baker itself contradicted Respondent's claim that the price increases only brought Evanston's prices up to competitive levels: as the Commission opinion says, the "control group" of hospitals against whose price increases Professor Baker

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compared ENH's post-transaction price increases contained only high-end very expensive hospitals that were not comparable to Evanston or Highland Park, Comm. Op. 39, 43-44, 69; IDF ¶¶ 817-19, 821, 824, and indeed, for several MCOs ENH's price increases exceeded even that "control group's" price increases. Comm. Op. 44.

The evidence of post-merger supra-competitive pricing at Highland Park is especially compelling. The evidence is undisputed that tertiary care teaching hospitals command substantially higher prices than do primary-secondary care community hospitals like Highland Park. RB 17-18, RRB 36-37; TR 156-59 (Ballengee). Evanston was (and is) indisputably a tertiary care teaching hospital, but Highland Park was (and is) indisputably a community hospital, not a tertiary care teaching hospital. CB 54, n.57; ID 191.⁴ Indeed, respondent repeatedly emphasized how different Evanston and Highland Park were from each other, RB 2, 7, 9, 10; RRB 28 n.6, 36, and also admitted that tertiary care teaching hospitals like Evanston command higher prices than primary-secondary care community hospitals like Highland Park. RB 17-18, 51; RRB 36-37.

These admissions by respondent and its expert were not gratuitous. They were amply supported by MCO testimony. *See* TR 158-59 (Ballengee); TR 622 (Neary); TR 935, 1112 (Foucre), *in camera*; TR 565 (Mendonsa), *in camera*; TR 1289 (Neaman), *in camera*; TR 1590 (Holt-Darcy), *in camera*; *see also* RRB 36-37; RB 51; TR 6065 (Noether), *in camera*. Thus, to borrow an economics term, the demand curves for teaching and community hospitals are materially different from one another, and as a consequence teaching hospitals can and do charge more for their services.

⁴ While Evanston is not at the highest end of the teaching hospital spectrum (*see supra* p. 5), it is undeniably a teaching hospital. *See* Comm. Op. 43-44; CB 45. Evanston is affiliated with the Northwestern University School of Medicine, and this relationship was strengthened between 1992 and 1996. TR 1282 (Neaman); RX 584 at ENH JH 2951-52.

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Yet respondent has essentially admitted that, post-transaction, MCOs were charged the same prices for Highland Park's services that they were charged for Evanston's services, and Respondent's expert testified that Evanston's prices were "at the middle of the pack" of Chicago area academic hospitals. TR 6065-66 (Noether), *in camera*; RB 91-92. That ENH could and did charge teaching (and tertiary care) hospital prices at Highland Park is direct evidence that, as a result of the merger, it enjoyed and exercised market power sufficient to impose supra-competitive prices. *See* ID 171-72 ("[E]ven if the evidence demonstrates that Evanston deserved higher prices because of its teaching status, this does not provide any justification for charging the same higher rates for Highland Park, a non-teaching community hospital."); *see also* CB 47 n.49.

Finally, the record establishes that ENH did not suffer a "critical loss" – or indeed any loss – of sales to competing hospitals as a result of its price increases. Notwithstanding ENH's system-wide pricing at significantly increased prices, only one MCO (OneHealth) initially did not contract with ENH, and OneHealth ended up contracting with ENH after it concluded it could not afford to refrain from doing so. IDF ¶¶ 420-33. Thus, the record establishes that the price increases were the result of post-merger market power rather than of exogenous factors.

Indeed, respondent itself has said that ENH experienced no loss of business to competitors after the merger, citing the absence of any such output reduction as a reason why its price increases cannot be considered to be the product of an exercise of market power, as a matter of economics and law. RB 56; RRB 23-25. To borrow (respectfully) from Judge Diane Wood, this claim "has things backward." *Toys "R" Us, Inc. v. FTC*, 221 F.3d 928, 937 (7th Cir. 2000). Where, as here, there is evidence that the defendant has increased its prices significantly and the defendant's output does *not* decline, this in and of itself is evidence that the defendant enjoys market power. *See R.J. Reynolds Tobacco Company v. Cigarettes Cheaper!*, 462 F.3d 690, 695 (7th Cir. 2006) (Easterbrook, J.)

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(rejecting the district court's ruling on summary judgment that the defendant lacked market power because *inter alia*, the summary judgment record did not demonstrate that the defendant "lacks power to make significant price increases without substantial loss of sales"); *Olympia Equip. Leasing Co. v. Western Union Tel. Co.*, 797 F.2d 370, 373 (7th Cir. 1986) (Posner, J.) (market power is "the power to raise prices without losing so much business that the price increase is unprofitable"); *see also* William M. Landes & Richard A. Posner, *Market Power in Antitrust Cases*, 94 Harv. L. Rev. 937, 939 (1981).

The fact that ENH did not suffer any loss of business to other competitive hospitals in the face of its post-merger pricing also rebuts Respondent's assertion that MCOs could easily assemble a hospital network excluding the ENH hospitals by contracting with a system of hospitals like the Advocate Lutheran system to serve insureds located within the triangle and thus constrain the post-merger pricing of the ENH system. RB 46. Respondent has relied for this assertion on the ALJ's conclusion that Advocate Lutheran could constrain ENH's pricing. ID 144, 149. However, that conclusion is not inconsistent with the ALJ's ultimate conclusion that the merger violated Section 7. The hospitals in a network excluding the ENH hospitals would be more distant from the triangle than the ENH hospitals, and, as such, that network would be an imperfect substitute at best.

The existence of an imperfect substitute might constrain ENH's pricing somewhat. However, the case law recognizes that even firms enjoying monopoly power may be somewhat constrained in their pricing by other products; that constraint does not mean that the firm lacks monopoly power. *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 426 (2d Cir. 1945); *see also* IIA Phillip E. Areeda, Herbert Hovenkamp & John Solow, *Antitrust Law*, ¶ 506a, at 104-05 (2d ed. 2002) ("IIA Areeda, Hovenkamp & Solow"). Indeed, Professor Baker has written that the imperfect substitutes in the proposed RiteAid-Revco and TimeWarner-Turner Broadcasting mergers discussed above were not considered to constrain post-merger

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market power (and hence pricing) sufficiently to avoid Section 7 liability. *See Baker, supra*, at 24-25. Similarly here, the record establishes that the ability of MCOs to assemble a network of non-ENH hospital systems did not prevent ENH from pricing the hospitals in its system at supra-competitive levels.

Nor does the direct evidence of post-transaction supra-competitive pricing stand alone. It is supported by the evidence described by the Commission opinion that senior officials at Evanston and Highland Park anticipated that the merger would enable them to raise their prices, that the merged firm did in fact implement an extraordinary price increase immediately after completion of the transaction, and that the same senior officials then attributed their success at raising prices to increased bargaining leverage produced by the merger. Comm. Op. 14-18, 65-67.

II. Market Definition

The Commission opinion also makes the market definition question more difficult than it needs to be in this case. As the Commission opinion says, Count II of the complaint in this case raised the question whether it is always necessary to define the relevant market in a Section 7 challenge at the time and in the fashion described in the Merger Guidelines. Comm. Op. 86. In proceeding under Count II complaint counsel did not define a market upfront using the Merger Guidelines methodology. Rather, it relied instead primarily on the direct evidence of the transaction's anticompetitive effects, in accordance with Count II. CB 5. I agree with complaint counsel that especially when a merger has been consummated and the evidence shows it has had actual anticompetitive unilateral effects, the law allows liability to be established by direct evidence of those effects, without initially defining a relevant market using Merger Guidelines methodology, at least where, as here, the evidence of anticompetitive effects identifies the "rough contours" of the market.

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A. The Law

The Commission opinion articulately describes the trend in the courts towards greater reliance on direct evidence in defining markets. Comm. Op. 86-88. In cases brought under Section 1 of the Sherman Act, the courts have analyzed the analogous issue of whether it is appropriate to determine the lawfulness of completed or ongoing conduct through direct effects evidence, in lieu of market definition. *See id.* (discussing *FTC v. Indiana Fed’n of Dentists*, 476 U.S. 447 (1986) (“IFD”)); *Toys “R” Us*, 221 F.3d 928; *Todd v. Exxon Corp.*, 275 F.3d 191, 207 (2d Cir. 2001); *Ball Mem’l Hosp. v. Mutual Hosp. Ins.*, 784 F.2d 1325, 1336 (7th Cir. 1986)).

The purpose of market definition and the direct analysis of anticompetitive effects are consistent – both techniques seek to determine whether a planned agreement by competitors is likely to facilitate the exercise of market power, or whether a completed one has enabled the exercise of market power. *See Toys “R” Us*, 221 F.3d at 937. As the Commission opinion observes, for more than a decade the courts and scholars have recognized repeatedly that market definition is not an end in itself but rather an indirect means to assist in determining the presence or the likelihood of market power. Comm. Op. 86-88; *see also United States v. Baker Hughes, Inc.*, 908 F.2d 981, 992 (D.C. Cir. 1990); IIA Areeda, Hovenkamp & Solow, *supra*, ¶ 532a, at 190-91; Herbert Hovenkamp, *Federal Antitrust Policy* § 12.8, at 550 (3d ed. 2005) (“Hovenkamp”). Market definition is a tool for analyzing market power, but it is not the only tool, either as a matter of law or economics. *Toys “R” Us*, 221 F.3d at 937.

As the Commission opinion also says, enforcement agencies and courts often need predictive tools like market definition in order to analyze market power in unconsummated merger cases because the transaction has not yet occurred. *See Hovenkamp, supra*, § 12.4c, at 524-25. However, challenges to consummated mergers do not necessarily require predictive or inferential mechanisms because there may be a rich amount of empirical evidence that shows a

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transaction's actual anticompetitive effects. To the contrary, it would make no sense to adopt a rule providing that even when there is clear direct evidence that a consummated transaction has enabled the merged party to engage in supra-competitive pricing, the enforcement agency must nonetheless define with precision the relevant market upfront in order to establish liability under Section 7.

Like the Commission opinion, I recognize that *IFD* and its progeny did not “make a complete break from the market definition process.” Comm. Op. at 88. In each of those cases, the courts also found there was sufficient evidence to identify at least the “rough contours” of the relevant markets. *Id.* The Section 1 cases discussed by the Commission opinion permitted the use of direct effects evidence in order to determine whether ongoing conduct has facilitated the exercise of market power so long as the rough contours of the relevant market are identified.

There is no principled reason why the same analysis cannot be applied in Section 7 cases. Indeed, a decade and a half ago, Judge Posner observed that judicial interpretation of Section 1 of the Sherman Act and Section 7 of the Clayton Act had converged. *United States v. Rockford Memorial Corp.*, 898 F.2d 1278, 1281-83 (7th Cir. 1990); *see also* IV Phillip E. Areeda, Herbert Hovenkamp & John L. Solow, *Antitrust Law*, ¶ 913b, at 64 (2nd ed. 2006) (“In cases where a merger facilitates a significant ‘unilateral’ price increase for a grouping of sales that was not a distinctive-looking market prior to the merger, the appropriate conclusion is that the merger has facilitated the emergence of a new grouping of sales capable of being classified as a relevant market. This formulation meets the statutory requirement [in Section 7] that the ‘effect’ of a merger is anticompetitive in some ‘line of commerce’ in some ‘section of the country.’”); Comm. Op. 60-62 (citing authorities).

To be sure, a number of merger decisions – including several involving hospitals – have required that the relevant market be

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defined upfront and with precision. Indeed, several courts have rejected challenges to hospital mergers on the ground that the plaintiff failed to properly define the relevant market this way. *See, e.g., FTC v. Freeman Hospital*, 69 F.3d 260 (8th Cir. 1995); *California v. Sutter Health Sys.*, 84 F. Supp. 2d 1057 (N.D. Cal. 2000). However, the mergers in cases post-dating enactment of the Hart-Scott-Rodino (“HSR”) Act three decades ago have been unconsummated mergers. Consequently, the analysis had to be prospective. The agencies and the courts had to predict what the consequences of the transaction would be. That is a different task than the task in a consummated merger case like this one. As previously discussed, predictive tools, such as market definition, are less necessary in a consummated case when we can determine by direct evidence whether the merger enabled the combined firm to engage in anticompetitive conduct.

This is not to say that the post-transaction behavior in this case lacks significance in future unconsummated hospital merger cases. To the contrary, it may be that the experience in this case will be important in predicting the likely effects in certain of those cases. Moreover, evidence of likely post-transaction anticompetitive effects may sufficiently identify the contours of the relevant market in other unconsummated merger cases. *See* Comm. Op. at 61-62, discussing, *inter alia*, *FTC v. Staples, Inc.*, 970 F. Supp. 1066 (D. D.C. 1997), an unconsummated merger case in which the relevant product market was defined principally on the basis of the evidence of likely anticompetitive effects. At all events, the evidence of actual anticompetitive effects that exists in this case distinguishes it from all of the cases requiring upfront and precise market definition, including consummated merger cases pre-dating enactment of the HSR Act.⁵

⁵ Also, in most of the pre-HSR Act merger cases requiring upfront and precise market definition the theory of anticompetitive effects has been a “coordinated effects” theory – *i.e.*, that the merger threatened to facilitate coordination in a highly concentrated market. *See, e.g., United States v. Philadelphia Nat’l Bank & Trust Co.*, 374 U.S. 321 (1963); *see also FTC v. Elders Grain, Inc.*, 868 F.2d 901, 906 (7th Cir. 1989) (Posner, J.) (describing

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In short, I believe that as a matter of law, it was not necessary that anything more than the “rough contours” of the relevant market be defined in order to establish the existence of a Section 7 violation in this case, where complaint counsel’s theory of anticompetitive effects could be tested because the merger had been consummated. The evidence shows that this consummated merger enabled the merged firm unilaterally to engage in supra-competitive pricing, and that fact supports the propriety of relying on direct evidence in defining the rough contours of the relevant market.⁶

B. The Facts

In this case, Respondent’s documents and economic evidence described above, as well as the testimony of MCOs previously described, not only established the existence of anticompetitive effects resulting from the merger, but also identified at least the “rough contours” of the product and geographic markets alleged by complaint counsel. More specifically, complaint counsel asserted that the relevant product market is “general acute care hospital services, including primary, secondary, and tertiary services, sold to MCOs.” CB 37. Complaint counsel contended that the relevant geographic market was the triangle bounded by the three hospitals in the ENH system. CB 38; ID 137.

As Areeda and Hovenkamp explain, a relevant market is “a market relevant to the particular legal issue being litigated.” IIA Areeda, Hovenkamp & Solow, *supra*, ¶ 533c. Here the issue is

coordinated effects as the prevailing theory of anticompetitive effects in merger cases). As the Commission opinion points out, when that is the theory, it is important that all the competitors in the market be identified. Comm. Op. 59.

⁶ Of course, if anticompetitive effects have not yet occurred because the merged party is aware of the antitrust risks of engaging in post-transaction anticompetitive conduct, or for some other reason, the upfront market definition methodology described in the Merger Guidelines may be useful to predict whether or not they are likely to occur in the future.

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whether the merger enabled ENH to impose supra-competitive prices on MCOs who wished to compete effectively for insureds located within the geographic triangle bounded by the three ENH hospitals. I agree with the Commission opinion that the relevant product market in this case is acute inpatient services, which hospitals alone can provide. As the Commission opinion points out, the record in this respect is consistent with the long line of cases that have reached the same conclusion. Comm. Op. 56.

I also conclude that complaint counsel demonstrated that the relevant geographic market consisted of the triangle bounded by the three ENH hospitals. That conclusion is based on the evidence previously described that MCOs considered Evanston or Highland Park to be next best substitutes in forming networks in order to compete effectively for insureds located within that triangle. *See supra* p. 4. That conclusion is also based on the evidence previously described that after the merger, ENH gained the power to control the price of all three ENH hospitals, and ENH enjoyed and exercised this market power to impose extraordinarily high system prices on MCOs as the price for their effective competition in that geographic area. *See supra* pp. 5-7; CB 14, 19-21. And it is based on the evidence that, despite ENH's post-transaction system pricing and despite the extraordinarily high pricing that occurred at all three ENH system hospitals, none of the MCOs competing in that triangle ultimately declined to deal with ENH.

Again, respondent did not contest that the three ENH hospitals were uniquely located with respect to that triangle, or that ENH could and did engage in system pricing after the merger. Respondent instead argued that the triangle did not constitute the relevant geographic market because each of the ENH hospitals was located closer to other hospitals than to each other and that the pricing at these other hospitals would constrain the pricing at each. RB 2, 10. That is a *non sequitur*. It is correct that at one level of competition, prior to the transaction the pricing at Evanston and Highland Park was constrained by other hospitals that were located proximate to each. But that does not mean that same competitive constraint

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existed after the merger, when MCOs were forced to contract with all three ENH hospitals on ENH's terms, instead of confronting each constituent hospital with the local competition each faced, as MCOs could do before the merger. Indeed, Respondent's argument simply underscores that injury to that localized pre-merger competition is another consequence of the merger, which strengthens the conclusion that the competitive forces affecting pricing vis-à-vis the triangle were lessened as a result of the merger.

In short, what the record demonstrates is that, as complaint counsel has claimed, the merger had the effect of lessening competition in a relevant market consisting of primary, secondary, and/or tertiary inpatient hospital care services in the triangular area bounded by the ENH hospitals. ENH's control of all three hospitals in the triangle enabled it to impose supra-competitive prices for inpatient hospital care services that could not have been charged prior to the merger when the hospitals forming the triangle bargained separately.

I would affirm for these reasons, and I agree with the Commission opinion's relief order.

**CONCURRING OPINION OF COMMISSIONER JON
LEIBOWITZ**

I join the opinion of the Commission with respect to its findings of fact, its conclusion that the merger violated the Clayton Act as identified in Count 1 of the Complaint, and the remedy identified in that opinion. However, I believe that the weight of the evidence clearly supports a finding that the merger violated the Clayton Act in the manner identified in Count 2 of the Complaint as well.

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Consequently, I join in Section II of Commissioner Rosch's concurrence.

FINAL ORDER

This matter having been heard by the Commission upon the appeal of Respondents and the cross-appeal of Complaint Counsel, and upon the respective briefs and oral arguments in support of such positions, and the Commission having determined that Respondent Evanston Northwestern Healthcare Corporation (Respondent ENH) has violated Section 7 of the Clayton Act – for the reasons stated in the accompanying Opinion – the Commission has determined to require Respondent ENH to cease and desist from certain enumerated practices, and to require Respondent ENH to propose, for issuance by the Commission, a Final Order that conforms to the prescriptions of this Order. Accordingly,

IT IS ORDERED THAT the determination in the Initial Decision in this matter that the transaction at issue violated Section 7 of the Clayton Act is **AFFIRMED**;

IT IS FURTHER ORDERED THAT the Order issued as part of the Initial Decision in this matter, be, and it hereby is, **VACATED**;

IT IS FURTHER ORDERED THAT on or before September 10, 2007, Respondent ENH shall file with the Commission a detailed proposal for implementing the type of injunctive relief that the Commission has selected. Specifically, as prescribed in the Opinion of the Commission, the proposal shall identify and describe the mechanisms that Respondent ENH will use, and the steps that

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Respondent ENH will take, to implement the following requirements:

1. Respondent ENH must allow all payors to negotiate separate contracts for Evanston & Glenbrook Hospitals (E&G) on the one hand and for Highland Park on the other hand;
2. Respondent ENH must establish separate negotiating teams (and other relevant personnel) for E&G and Highland Park that will compete with each other, and other hospitals, for payors' business;
3. Respondent ENH must establish a firewall-type mechanism that prevents the E&G and Highland Park contract negotiating teams (and other relevant personnel) from sharing any information that would inhibit them from competing with each other and with other hospitals;
4. Respondent ENH may not make any contract for E&G or Highland Park contingent on entering into a contract for the other, and may not make the availability of any price or term for a contract for E&G contingent on entering into a contract for Highland Park, or *vice-versa*; and
5. Respondent ENH shall promptly offer all payors with which it currently has contracts the option of reopening and renegotiating their contracts under the terms of this order.;

IT IS FURTHER ORDERED THAT Respondent ENH's proposal shall also describe, where appropriate, mechanisms for the Commission to monitor the establishment of the organizational structure needed to implement the terms of the order, as well as Respondent ENH's compliance with the order throughout its term;

IT IS FURTHER ORDERED THAT Respondent ENH's proposal shall recommend mechanisms for resolving disputes

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between payors and Respondent ENH with respect to Respondent ENH's compliance with the terms of the order, including a discussion of the potential value of some form of dispute resolution mechanism;

IT IS FURTHER ORDERED THAT Complaint Counsel shall file with the Commission any objections to or comments on Respondent ENH's proposal within thirty (30) calendar days after Respondent ENH files its proposal; and

IT IS FURTHER ORDERED THAT Respondents shall file any response to Complaint Counsel's filing within ten (10) calendar days after Complaint Counsel file their objections or comments.

By the Commission.

Complaint

IN THE MATTER OF

**KMART CORPORATION,
KMART SERVICES CORPORATION,
AND
KMART PROMOTIONS, LLC**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

*Docket C-4197; File No. 062 3088
Complaint, August 14, 2007 – Decision, August 14, 2007*

This consent order addresses the failure of respondents Kmart Corporation et al. to disclose, or to disclose adequately, material terms and conditions of the Kmart Gift Card, as well as a deceptive claim regarding the gift card. The order prohibits respondents from advertising or selling Kmart Gift Cards without disclosing, clearly and prominently, both in advertising and at the point of sale, the existence of any expiration date or automatic fees. Kmart must also place this information on the front of the gift card. Respondents are prohibited from making any misrepresentation about any material term or condition associated with the Kmart Gift Card. The order prohibits respondents from collecting or attempting to collect any dormancy fee on any Kmart Gift Card activated prior to the date of issuance of the order, and requires them to create, maintain, and distribute a written policy to reimburse consumers whose gift cards were diminished by fees. Other provisions of the order include a document retention requirement to ensure compliance with the proposed order, a requirement to distribute copies of the order to applicable parties, and requirements relating to reports to the Commission.

Participants

For the Commission: *Julie G. Bush, Jonathan M. Kraden, Karen Leonard, Alice Saker Hrdy, Dianna Thaxton, and Peggy L. Twohig.*

For the Respondent: *Linda Goldstein, Manatt, Phelps & Phillips, LLP.*

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Kmart Corporation, Kmart Services Corporation, and Kmart Promotions, LLC (collectively, “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 Kmart Corporation is a Michigan corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.

2. Respondent Kmart Services Corporation is an Ohio corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.

3. Respondent Kmart Promotions LLC is a Virginia corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.

4. 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.

5. Since at least 2003, respondents have advertised, sold, and distributed the Kmart Gift Card and Kmart Cash Card (hereinafter, collectively referred to as the “Kmart Gift Card”) through their retail stores, the *Kmart.com* Web site, and through third parties.

6. The Kmart Gift Card is a plastic, stored-value card, similar in size and shape to a credit or debit card, that can be used to purchase goods or services from Kmart retail locations.

7. Respondents represent that a consumer can redeem the Kmart Gift Card for goods or services of an equal value to the monetary amount placed on the card. For example, respondents sell the Kmart Gift Card in stores and on the *Kmart.com* Web site in

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specific denominations for exact amounts (*e.g.*, a \$25 Kmart Gift Card costs \$25, etc.). Kmart Gift Cards are often branded with monetary amounts on the front of the cards. Additionally, respondents claim that the Kmart Gift Card is equivalent to cash, branding several as “Kmart Cash Cards.” In some instances, respondents sell the Kmart Gift Card affixed to cardstock that states that consumers can “use [the card] like cash at all Kmart locations.”

8. When a Kmart Gift Card was not used for 24 consecutive months, respondents deducted a fee of \$2.10 for *each* of the past 24 months, resulting in an immediate reduction of \$50.40 from the value of the Kmart Gift Card. Respondents describe the fee (hereinafter, “dormancy fee” or “fee”), on the back of the cards, using the following language: “after 24 months of non-use, a \$2.10 per month service fee will be deducted from your balance in arrears until the card is used or depleted.” In those instances where the balance of any Kmart Gift Card was less than \$50.40, the application of the dormancy fee reduced the card’s balance to zero.

9. In numerous instances, respondents failed to disclose or failed to disclose adequately the dormancy fee by, among other practices:

a. Disclosing the dormancy fee in small print (approximately five point font) on the back of the Kmart Gift Card, imbedded in a paragraph of “Terms and Conditions” (*See Attachment A*);

b. Affixing the Kmart Gift Card to cardstock that completely obscures the disclosure on the back of the card;

c. Failing to use understandable language and syntax to describe the dormancy fee; and/or

d. Selling Kmart Gift Cards on the *Kmart.com* Web site, without disclosing to consumers at the time of purchase that a dormancy fee may apply to the card.

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10. In numerous instances, consumers did not learn of the fee until they attempted to use their Kmart Gift Cards and found out that their cards had expired or held little or no remaining value. Some consumers have contacted respondents to request reimbursement for these fees, and respondents have provided some amount of reimbursement to consumers.

11. Since at least December 2005, respondents have stated on their Web site that Kmart Gift Cards “never expire.”

12. In the advertising and sale of Kmart Gift Cards, respondents have represented, expressly or by implication, that a consumer can redeem a Kmart Gift Card for goods or services of an equal value to the monetary amount placed on the card. Respondents have failed to disclose or failed to disclose adequately that, after 24 consecutive months of non-use, a \$2.10 fee is deducted, retroactively for each of the past 24 months, and again for each successive month of continued inactivity, from the value of the Kmart Gift Card. This fact would be material to consumers in their purchase or use of Kmart Gift Cards. The failure to disclose adequately this fact, in light of the representation made, was, and is, a deceptive practice.

13. In the advertising and sale of Kmart Gift Cards on the *Kmart.com* Web site, respondents have represented, expressly or by implication, that the Kmart Gift Card never expires. In truth and in fact, in numerous instances, after 24 consecutive months of non-use, a \$2.10 fee is deducted, retroactively for each of the past 24 months, from the value of the Kmart Gift Card, thereby causing any Kmart Gift Card valued at less than \$50.40 to expire. Therefore, the representation set forth in Paragraph 11 was, and is, false or misleading.

14. The acts and practices of respondents 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.

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THEREFORE, the Federal Trade Commission, on this fourteenth day of August, 2007, has issued this complaint against respondents.

By the Commission, with the five Commissioners voting in the affirmative, but with Commissioner Harbour and Commissioner Leibowitz concurring in part and dissenting in part from the Decision and Order.

Complaint

Attachment A



Example of Kmart Gift Card. (Actual Size)

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents 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 by the Commission, would charge respondents with violation of the Federal Trade Commission act; and

The respondents, their attorney, and counsel for the Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in the 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 the respondents have violated the said Act, and that 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, and having duly considered the comments filed thereafter by interested persons, 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.a. Respondent KMART CORPORATION is a Michigan corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.

Decision and Order

- 1.b. Respondent KMART SERVICES CORPORATION is an Ohio corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.
- 1.c. Respondent KMART PROMOTIONS, LLC is a Virginia corporation with its principal office or place of business at 3333 Beverly Road, Hoffman Estates, IL 60179.
2. 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 purposes of this Order, the following definitions shall apply:

1. “Clearly and prominently” shall mean as follows:
 - (A) In an advertisement communicated through an electronic medium (such as television, video, radio, and interactive media such as the Internet and online services), the disclosure shall be presented simultaneously in both the audio and video portions of the advertisement. *Provided, however,* that in any advertisement presented solely through video or audio means, the disclosure may be made through the same means in which the advertisement is presented. The audio disclosure shall be delivered in a volume and cadence sufficient for an ordinary consumer to hear and comprehend it. The video disclosure shall be of a size and shade, and shall appear on the screen for a duration, sufficient for an ordinary consumer to read and comprehend it. In addition to the foregoing, in interactive media the disclosure shall also be unavoidable and shall be presented prior to the consumer incurring any financial obligation.

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- (B) In a print advertisement, promotional material, or instructional manual, the disclosure shall be in a type size and location sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears. In multipage documents, the disclosure shall appear on each page where a gift card is advertised, promoted, mentioned, or depicted.
- (C) On a product label or gift card, the disclosure shall be in a type size and location on the principal display panel sufficiently noticeable for an ordinary consumer to read and comprehend it, in print that contrasts with the background against which it appears.
- (D) 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 on any label.
2. “Commerce” shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
 3. “Covered Fee” shall mean any fee or surcharge that is assessed automatically by respondents or their successors and assigns, following activation of any Kmart Gift Card, and that decreases the value of the gift card, including but not limited to any dormancy, maintenance, inactivity, monthly, balance inquiry, or other fees assessed automatically by respondents, their successors and assigns. *Provided, however,* this definition shall not apply to any replacement fee for any lost or stolen Kmart Gift Card.
 4. “Document” is synonymous in meaning and equal in scope to the usage of the term in Federal Rule of Civil Procedure 34(a), and includes writings, drawings, graphs, charts,

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photographs, audio and video recordings, computer records, and other data compilations from which information can be obtained and translated, if necessary, into reasonably usable form through detection devices. A draft or non-identical copy is a separate document within the meaning of the term.

5. “Eligible Consumer” shall mean any consumer who purchased or received a Kmart Gift Card prior to the date of issuance of this order, that was diminished in value by a Covered Fee for which no reimbursement previously has been issued.
6. “Kmart Gift Card” shall mean any payment device: (a) that is issued by, or on behalf of, respondents or their successors and assigns; and (b) that can be used to purchase goods or services at a Kmart retail location, or any other store or Web site operated by respondents or their successors and assigns; and (c) that is issued in a specified monetary amount; and (d) that may, or may not, be increased in value or reloaded; and (e) for which cash or other value or consideration was given.
7. Unless otherwise specified, “respondents” shall mean Kmart Corporation, Kmart Services Corporation, and Kmart Promotions LLC, corporations, their successors and assigns, and their officers, agents, representatives, and employees.

I.

IT IS ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution, in or affecting commerce, of any Kmart Gift Card, shall not fail to disclose clearly and prominently:

- A. the existence of any expiration date or Covered Fee associated with the Kmart Gift Card; *Provided, however,* that, at the point of sale, prior to purchase, respondents shall

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not fail to disclose clearly and prominently all of the material terms and conditions of any expiration date or Covered Fee associated with the Kmart Gift Card; and

- B. on the front of each Kmart Gift Card, the existence of any expiration date or Covered Fee associated with the Kmart Gift Card.

II.

IT IS FURTHER ORDERED that respondents, directly or through any corporation, subsidiary, division, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution, in or affecting commerce, of any Kmart Gift Card, shall not misrepresent, in any manner, expressly or by implication, any material term or condition of the Kmart Gift Card.

III.

IT IS FURTHER ORDERED that, upon issuance of this order, respondents, directly or through any corporation, subsidiary, division, or other device, shall:

- A. Not collect or attempt to collect any Covered Fee on any Kmart Gift Card activated prior to the date of issuance of this order; and
- B. Create, maintain, and distribute to all respondents' retail stores and customer care network centers, a written reimbursement policy that describes the methods by which Eligible Consumers may contact respondents to request reimbursement of the value of any Covered Fees that were deducted from their Kmart Gift Cards and the means by which respondents will reimburse the value of such Covered Fees. At a minimum, the reimbursement policy:

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1. Shall specify a toll free number, a valid email address, and a postal address consumers may use to request and obtain reimbursement of the value of such Covered Fees assessed against a Kmart Gift Card;
2. Shall specify that a consumer may complete a request for reimbursement of the value of any Covered Fees assessed against his or her Kmart Gift Card through the toll free number, email address, or postal address required by Part III.B.1. of this Order;
3. For two (2) years after the issuance of the order, shall be clearly and prominently disclosed, including, but not limited to, the toll free number, email address, and postal address required by Part III.B.1. of this Order, on respondents' primary web sites, including, but not limited to, *www.kmart.com* and *www.kmartcorp.com* web sites;
4. Shall be disclosed to any consumer who complains or inquires about the balance on a Kmart Gift Card; and
5. Shall require reimbursement of the value of any Covered Fee assessed on a Kmart Gift Card activated prior to the date of entry of this Order, in the form of a check or a Kmart Gift Card, to any Eligible Consumer who meets the following qualifications:
 - (a) contacts respondents using any of the methods specified in Part III.B.2 of this Order; and
 - (b) provides the Kmart Gift Card number and the consumer's mailing address and telephone number. The consumer may provide, but is not required to provide, the store where the card was purchased, the date the card was issued, and the physical Kmart Gift Card. Once a consumer provides the required

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information, respondents shall issue a reimbursement within ten (10) business days. *Provided however*, that for thirty (30) days after issuance of the order, respondents shall issue a reimbursement within fifteen (15) business days.

IV.

IT IS FURTHER ORDERED that respondents Kmart Corporation, Kmart Services Corporation, and Kmart Promotions LLC, and their successors and assigns, shall, for five (5) years after the date of issuance of this order, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution, in or affecting commerce, of any Kmart Gift Card, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

- A. Accounting records that reflect the cost of Kmart Gift Cards sold, revenues generated, and the disbursement of such revenues;
- B. Records documenting the sales figures and unit sales figures for the Kmart Gift Card; the total amount of any and all Covered Fees that have been deducted from Kmart Gift Cards; and the total number of Kmart Gift Cards from which a covered fee was deducted;
- C. Records maintained in the ordinary course of business reflecting during their employment: the name, physical address, and telephone number of each person employed by respondents, and their successors and assigns, including as an independent contractor, with responsibilities relating to compliance with this Order; that person's job title or position; the date upon which the person commenced work; and the date and reason for the person's termination, if applicable;

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- D. Complaints and refund requests relating to the Kmart Gift Card (whether received directly, indirectly or through any third party) and any responses to those complaints or requests;
- E. Copies of all advertisements or other marketing materials promoting, advertising, or referring to the Kmart Gift Card;
- F. Representative copies of all versions of the Kmart Gift Card; and
- G. All other records and documents reasonably necessary to demonstrate full compliance with each provision of this Order, including but not limited to, all documents obtained, created, generated or which in any way relate to the requirements, provisions or terms of this Order, and all reports submitted to the FTC pursuant to this Order.

V.

IT IS FURTHER ORDERED that respondents Kmart Corporation, Kmart Services Corporation, and Kmart Promotions LLC, and their successors and assigns, shall deliver a copy of this order to all current and future principals, officers, directors, and managers who engage in conduct related to the subject matter of the Order, and to the officers, directors, and managers of any third-party vendor who engages in conduct related to the subject matter of the Order, and shall secure from each such person, within thirty (30) days of delivery, a signed and dated statement acknowledging receipt of the Order. Respondents shall deliver this Order to current personnel within five (5) days after the date of service of this Order, and to future personnel within ten (10) days after their assuming their responsibilities.

VI.

Decision and Order

IT IS FURTHER ORDERED that respondents Kmart Corporation, Kmart Services Corporation, and Kmart Promotions LLC, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in any of the corporations 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. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that respondents Kmart Corporation, Kmart Services Corporation, and Kmart Promotions LLC, and their successors and assigns, shall, within sixty (60) days after service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied and are complying with this order.

VIII.

This order will terminate on August 14, 2027, 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

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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, with the five Commissioners voting in the affirmative, but with Commissioner Harbour and Commissioner Leibowitz concurring in part and dissenting in part from the Decision and Order.

Concurring and Dissenting Statement

**Statement of Commissioners Pamela Jones Harbour
and Jon Leibowitz
(Concurring in Part and Dissenting in Part)**

Today, the Commission approves a consent agreement with Kmart Corporation and two of its subsidiaries (collectively, “Kmart”) to settle charges that Kmart misrepresented material aspects of its gift cards and failed to disclose that, after two years of non-use, Kmart would deduct a \$50 fee from the gift card and a \$2.10 monthly fee thereafter. We concur in the Commission’s decision to bring an action and impose certain injunctive provisions upon Kmart, but dissent in part from the consent agreement because we believe the remedy should include disgorgement of ill-gotten profits. Otherwise, Kmart remains unjustly enriched by a substantial amount of buried “dormancy fees” while many consumers will have lost the chance for reimbursement because they long ago threw out their seemingly worthless gift cards in frustration.¹

Gift cards have become enormously popular with consumers and generated nearly \$28 billion in sales during the 2006 holiday season.² Gift card dormancy fees and expiration dates are material restrictions that affect the value of the cards. These restrictions must be clearly disclosed so that consumers can make informed decisions, whether they are purchasing the cards or receiving them as a gift.

The final order settles the Commission’s allegations that Kmart deceptively advertised its gift cards by, among other things,

¹ Kmart applied a dormancy fee of \$2.10 per month to the balance of every Kmart gift card that went unused for 24 months – both retroactively (\$50.40) and prospectively. Consequently, cards worth \$50 or less were rendered worthless if unused for two years. Imagine stashing a \$10, \$25, or \$50 gift card in a drawer and then pulling it out two years later for a trek to shop at Kmart, only to learn at the check-out counter that the card had no value. Kmart recently discontinued charging this dormancy fee after learning about the FTC’s investigation, but only on a prospective basis.

² Press Release, Nat’l Retail Fed’n Gift Card Spending Surpassed Expectations as Last-Minute Shoppers Looked for Quick, Easy Gifts; Most Consumers Have Spent Less Than Half of Card Values (Jan. 23 2007).

Concurring and Dissenting Statement

misrepresenting the existence of any expiration dates or fees associated with the cards. Not only did Kmart claim that the gift cards could be used “like cash at all Kmart locations,” but its website also affirmatively misled consumers by stating that the Kmart gift cards “never expire.” We agree that Kmart’s alleged conduct justifies the order injunctive provisions.

But we believe the order should go further. It should require Kmart to disgorge the profits of its unlawful behavior, provide more complete consumer redress, or a combination of both.³ More than three decades ago, in sponsoring the Magnuson-Moss Act extending the Commission’s authority under Section 19 to obtain monetary remedies, Senator Magnuson explained that the Commission cannot “rely merely upon a slap of the violator’s wrist to maintain fair play in the marketplace” and that “[a] mere cease-and-desist order has frequently let a wrongdoer keep his ill-gotten gains.”⁴ The same rationale holds true today.

In this case, Kmart deducted dormancy fees from consumers’ gift cards. It failed to give adequate notice. In many instances, Kmart’s actions rendered unused or partially used cards valueless, at significant monetary benefit to Kmart but considerable monetary detriment to consumers. Today’s final order, in our opinion, stops the deceptive practices but does not completely cure the consumer injury or fully excise Kmart’s ill-gotten gains. Pursuant to the order,

³ Commission consent orders have required advertisers to pay redress, offer refunds, or disgorge profits, and it is appropriate to do so here. See, e.g., *Hi-Health Supermart Corp.*, FTC Dkt. No. C-4136 (May 12, 2005) (requiring \$450,000 in redress); *ValueVision Int’l, Inc.*, FTC Dkt. No. C-4022 (Aug. 24, 2001) (requiring company to offer refunds to all purchasers of the challenged products); *Weider Nutrition Int’l, Inc.*, FTC Dkt. No. C-3983 (Nov. 17, 2000) (requiring \$400,000 in redress); *Dura Lube, Inc.*, FTC Dkt. No. D-9292 (May 5, 2000) (requiring \$2 million in redress); *Apple Computer, Inc.*, FTC Dkt. No. C-3890 (Aug. 6, 1999) (requiring company to honor representation that customers would receive free support for as long as they own the product); *Azrak-Hamway Int’l, Inc.*, 121 F.T.C. 507 (1996) (requiring toymaker to offer refunds); *L& S Research Corp.*, 118 F.T.C. 896 (1994) (requiring \$1.45 million in disgorgement).

⁴ 119 CONG. REC. 29480 (1973).

Analysis to Aid Public Comment

Kmart may not assess additional dormancy fees on previously activated gift cards and must reimburse previously assessed dormancy fees if consumers complain and can provide the gift card number. Many consumers no doubt already have thrown out their gift cards and will have no remedy under this settlement. Moreover, the order does not require Kmart automatically to restore previously deducted dormancy fees (absent consumer inquiries) or disgorge the windfall profits it made from these fees. Although Kmart's reimbursement practices have been improved by the Commission's efforts, in our opinion the refund policy, without additional monetary relief, is still too little, too late.

We commend staff for pursuing Kmart's failure to disclose its gift card dormancy fees and for challenging Kmart's affirmative misrepresentations that its gift cards do not expire. For the foregoing reasons, however, we respectfully dissent in part from the final order.

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

The Federal Trade Commission has accepted, subject to final approval, an agreement containing a consent order from Kmart Corporation, Kmart Services Corporation, and Kmart Promotions, LLC (collectively, "respondents").

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

Analysis to Aid Public Comment

should withdraw from the agreement or make final the agreement's proposed order.

Respondents advertise, sell, and distribute the Kmart Gift Card through their retail stores and Internet Website *www.Kmart.com*. The Kmart Gift Card is a plastic, stored-value card similar in size and shape to a credit or debit card, that can be used to purchase goods or services from Kmart retail locations. This matter concerns the respondents' alleged failure to disclose, or failure to disclose adequately, material terms and conditions of the Kmart Gift Card as well as a deceptive claim regarding the Kmart Gift Card.

The Commission's complaint alleges that, in the advertising and sale of Kmart Gift Cards, respondents have represented, expressly or by implication, that a consumer can redeem a Kmart Gift Card for goods or services of an equal value to the monetary amount placed on the card. Respondents have failed to disclose, or failed to disclose adequately, that, after 24 consecutive months of non-use, a \$2.10 fee is deducted, for each of the past 24 months, and again for each successive month of continued inactivity, from the value of the Kmart Gift Card. The proposed complaint alleges that the failure to disclose adequately this material fact is a deceptive practice.

The complaint also alleges that respondents have represented on the *Kmart.com* Web site that the Kmart Gift Card never expires. In truth and in fact, after 24 months of non-use, the application of the Kmart Gift Card dormancy fee causes any Kmart Gift Card valued at less than \$50.40 to expire. The complaint alleges that the representation that the Kmart Gift Card never expires is false and misleading.

The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I.A. of the proposed order prohibits respondents from advertising or selling Kmart Gift Cards without disclosing, clearly

Analysis to Aid Public Comment

and prominently: (a) the *existence* of any expiration date or automatic fees *in all advertising*, and (b) *all material terms and conditions* of any expiration date or automatic fee *at the point of sale and prior to purchase*. The effect of this provision is to require respondents to alert consumers to potential fees and expiration dates during advertising, and to fully disclose all relevant details at the point of sale, before consumers purchase the gift cards.

Part I.B. of the proposed order prohibits respondents from advertising or selling Kmart Gift Cards without disclosing, clearly and prominently the *existence* of any automatic fee or expiration date *on the front* of the gift card.

Part II of the proposed order prohibits respondents from making any misrepresentation about any material term or condition associated with the Kmart Gift Card.

Part III.A. of the proposed order prohibits respondents from collecting or attempting to collect any dormancy fee on any Kmart Gift Card activated prior to the date of issuance of the proposed order.

Part III.B. of the proposed order requires respondents to create, maintain, and distribute a written policy to reimburse consumers whose gift cards were diminished by fees. The policy: (1) must specify a toll free number, a valid email address and a postal address that consumers can use to complete a request for reimbursement of dormancy fees from Kmart; (2) must be clearly and prominently disclosed on Kmart's web site for two years from the issuance of the order; (3) must be disclosed to anyone who complains or inquires to Kmart about a gift card balance; and (4) requires reimbursement to any eligible consumer who (a) contacts Kmart by phone, email, or postal mail, and (b) provides a Kmart gift card number, a mailing address, and a phone number. Once a consumer provides the required information, Kmart must issue a reimbursement within 10 business days, provided however, that for thirty (30) days after

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issuance of the order respondents shall issue a reimbursement within fifteen (15) business days.

Part IV of the proposed order contains a document retention requirement, the purpose of which is to ensure compliance with the proposed order. It requires that respondents maintain accounting and sales records for the Kmart Gift Card, copies of ads and promotional material that contain representations covered by the proposed order, complaints and refund requests relating to the Kmart Gift Card, and other materials that were relied upon by respondents in complying with the proposed order.

Part V of the proposed order requires respondents to distribute copies of the order to various principals, officers, directors, and managers of respondents as well as to the officers directors, and managers of any third-party vendor who engages in conduct related to the proposed order.

Part VI of the proposed order requires respondents to notify the Commission of any changes in corporate structure that might affect compliance with the order.

Part VII of the proposed order requires respondents to file with the Commission one or more reports detailing compliance with the order.

Part VIII of the proposed order is a “sunset” provision, dictating the conditions under which the order will terminate twenty years from the date it is issued or twenty years after a complaint is filed in federal court, by either the United States or the, alleging any violation of the order.

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 in any way its terms.

Complaint

IN THE MATTER OF

AMERICAN PETROLEUM COMPANY, INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket C-4198; File No. 061 0229**Complaint, August 21, 2007 – Decision, August 21, 2007*

This consent order addresses actions by respondent American Petroleum, which agreed with several competing importers and sellers of lubricants to restrict the importation and sale of lubricants in Puerto Rico, in order to pressure the Puerto Rican Government to repeal a law requiring a refundable environmental deposit for lubricants purchased. The order enjoins American Petroleum from agreeing or attempting to agree with any other seller of lubricants (1) to restrain, restrict, limit, or reduce the import or sale of lubricants or (2) to deal with, refuse to deal with, threaten to refuse to deal with, boycott, or threaten to boycott any buyer or potential buyer of lubricants. The order does not interfere with the company's constitutional right to exercise rights under the First Amendment to petition any government body concerning legislation, rules, or procedures.

Participants

For the Commission: *Mark Frankena, Kenneth L. Glazer, Geoffrey M. Green, Peter D. Gulyn, Armando Irizarry, Geoffrey Oliver, and Louis Silvia.*

For the Respondents: *Rosalie Irizarry Silvestrini and Luis Oliver, Fiddler, Gonzalez & Rodriguez, P.S.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 American Petroleum Company, Inc., a corporation, hereinafter sometimes referred to as "respondent," has violated the provisions of said Act, 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 in that respect as follows:

1. Respondent American Petroleum Company, Inc. (“American Petroleum”) is a corporation organized, existing and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico, with its office and principal place of business located at Road 865 KM 0.2, Barrio Campanillas, Toa Baja, Puerto Rico 00951.
2. American Petroleum has for many years been engaged in the business of importing lubricating oil to, and selling lubricating oil in, the Commonwealth of Puerto Rico. The president and owner of American Petroleum is Nelson Soto.
3. Puerto Rico Law 278 of September 14, 2004 was intended to create incentives for the safe disposal of used lubricating oil. The law required all persons in the chain of distribution, from the importer to the end-user, to pay an environmental deposit of fifty cents for each quart of lubricating oil purchased. The deposit could be recovered after the used lubricating oil was delivered to an authorized collection center.
4. During 2005 and 2006, American Petroleum joined with numerous others in the Puerto Rico lubricating oil industry to lobby for the delay, modification, and/or repeal of Law 278. These efforts were partially successful. The Legislature postponed the starting date for the law until March 31, 2006.
5. In March 2006, with the effective date for Law 278 approaching, American Petroleum and several competing importers and sellers of lubricating oil adopted a new strategy to pressure the Legislature and the Governor to repeal Law 278. The companies agreed to cease importing lubricating oil, beginning on March 31, 2006, and continuing for so long as Law 278 remained in effect.

Complaint

6. On March 31, 2006, companies in the lubricating oil industry held a press conference in San Juan, with Nelson Soto of American Petroleum acting as the spokesman for the group. Soto announced that: (i) in order to pressure the government, numerous companies have agreed to suspend the importation of lubricating oil; (ii) this action will continue until Law 278 is repealed; and (iii) as existing inventories are depleted, the suspension of imports will result in shortages of lubricating oil throughout the island.

7. In December 2006, the Puerto Rico Legislature repealed Law 278.

8. The acts and practices of American Petroleum, including the acts and practices alleged herein, are in commerce or affect commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.

9. The agreement among American Petroleum and its competitors to cease importing lubricating oil, as alleged herein, had the purpose and effect, or the tendency and capacity, to restrain competition unreasonably, to increase prices, and to injure consumers.

Violations Alleged

10. As set forth in Paragraph 5 above, American Petroleum agreed with competitors to restrict the importation and sale of lubricating oil, in violation of Section 5 of the Federal Trade Commission Act, as amended.

11. The acts and practices of respondent, as alleged herein, 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.

Decision and Order

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twenty-first day of August, 2007, issues its complaint against respondent.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of American Petroleum Company, Inc. (hereinafter referred to as “Respondent”), 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 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 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 Act, and that a Complaint should issue stating its

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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 makes the following jurisdictional findings and issues the following Order:

1. Proposed Respondent American Petroleum Company, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico, with its office and principal place of business located at Road 865 KM 0.2, Barrio Campanillas, Toa Baja, Puerto Rico 00951.
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 ORDERED that, as used in this Decision and Order, the following definitions shall apply:

- A. “American Petroleum” or “Respondent” means American Petroleum Company, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its subsidiaries, divisions, groups, and affiliates controlled, directly or indirectly, by American Petroleum Company, Inc.; and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Commission” means the Federal Trade Commission.

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- C. “Lubricants” means motor oil, lubricating oil, and any other product used or intended to be used to reduce friction between rubbing surfaces.
- D. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, partnerships, and unincorporated entities.
- E. “Seller” means any person other than American Petroleum engaged in the business of importing or selling Lubricants.

II.

IT IS FURTHER ORDERED that in connection with the importation, distribution, offering for sale, or sale of any Lubricants in or affecting commerce, as “commerce” is defined by the Federal Trade Commission Act, Respondent shall cease and desist from, either directly or indirectly, or through any corporate or other device, soliciting, participating in, entering into, attempting to enter into, implementing, attempting to implement, continuing, attempting to continue, or otherwise facilitating or attempting to facilitate any combination, conspiracy, or agreement, either express or implied, with any Seller:

- A. To restrain, restrict, limit, or reduce the import or sale of Lubricants.
- B. To deal with, refuse to deal with, threaten to refuse to deal with, boycott, or threaten to boycott, any buyer or potential buyer of Lubricants.

Provided, however, that nothing in this Order shall prevent Respondent from exercising rights under the First Amendment to the United States Constitution to petition any government body concerning legislation, rules, or procedures.

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

- A. Within sixty (60) days after the date this Decision and Order becomes final, Respondent shall submit to the Commission a verified written report setting forth in detail the manner and form in which that Respondent has complied and is complying with this Order.
- B. One (1) year after the date this Decision and Order becomes final, annually for the next four (4) years on the anniversary of the date this Decision and Order becomes final, and at other times as the Commission may require, Respondent shall file with the Commission a verified written report setting forth in detail the manner and form in which it has complied and is complying with this Decision and Order.

IV.

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 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 Respondent.

V.

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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:

- 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 Decision and Order; and
- B. Upon five (5) days' notice to Respondent and without restraint or interference from it, to interview officers, directors, or employees of Respondent.

VI.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Decision and Order becomes final, send a copy of this Decision and Order by first class mail to each of its directors and officers.
- B. Mail a copy of this Decision and Order by first class mail to each person who becomes a director or officer, no later than (30) days after the commencement of such person's employment or affiliation with Respondent.
- C. Require each person to whom a copy of this Decision and Order is furnished pursuant to subparagraphs VI.A and VI.B of this Decision and Order to sign and submit to Respondent within thirty (30) days of the receipt thereof a statement that: (1) acknowledges receipt of the Decision and Order; (2) represents that the undersigned has read and understands the Decision and Order; and (3) acknowledges that the

Analysis to Aid Public Comment

undersigned had been advised and understands that non-compliance with the Decision and Order may subject American Petroleum to penalties for violation of the Decision and Order.

VII.

IT IS FURTHER ORDERED that this Decision and Order shall terminate on August 21, 2027.

By the Commission.

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 with American Petroleum Company, Inc. (“American Petroleum” or “Respondent”), an importer and seller of lubricants with its principal place of business located at Road 865 KM 0.2, Barrio Campanillas, Toa Baja, Puerto Rico 00951. The agreement settles charges that American Petroleum violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by agreeing with competitors to restrict the importation and sale of lubricants in Puerto Rico. The proposed consent order has been placed on the public record for 30 days to receive comments from interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

Analysis to Aid Public Comment

The purpose of this analysis is to facilitate comment on the proposed order. The analysis does not constitute an official interpretation of the agreement and proposed order, and does not modify their terms in any way. Further, the proposed consent order has been entered into for settlement purposes only, and does not constitute an admission by Respondent that it violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

I. The Complaint

The allegations of the complaint are summarized below:

American Petroleum has for many years been engaged in the business of importing lubricants into, and selling lubricants in, the Commonwealth of Puerto Rico.

Puerto Rico Law 278, enacted in 2004, was intended to create incentives for the safe disposal of used lubricants. The law required all persons in the chain of distribution, from the importer to the end-user, to pay an environmental deposit of fifty cents for each quart of lubricants purchased. The deposit could be recovered after the used lubricating oil was delivered to an authorized collection center. During 2005 and 2006, American Petroleum joined with numerous others in the Puerto Rico lubricants industry to lobby for the delay, modification, and/or repeal of Law 278. These efforts were partially successful. The Legislature postponed the starting date for the law until March 31, 2006.

In March 2006, with the effective date for Law 278 approaching, American Petroleum and several competing importers and sellers of lubricants adopted a new strategy to pressure the Government to repeal Law 278. The companies agreed to cease importing lubricants, beginning on March 31, 2006, and continuing for so long as Law 278 remained in effect. The conspirators issued a public warning that as a result of this joint action, shortages of lubricants

Analysis to Aid Public Comment

would arise throughout the island, and would continue until Law 278 was repealed.

In December 2006, the Puerto Rico Legislature repealed Law 278.

II. Legal Analysis

In several previous cases, the Commission has challenged under Section 5 of the FTC Act boycott activity where the victim was the government in its capacity as a consumer; that is, the conspiring sellers refused to deal in order to exact higher prices from the government.¹ Here, the lubricant importers are alleged to have used their economic might in order to pressure the government in its role as a regulator. As discussed below, the antitrust laws reach this conduct as well.

The conspiracy alleged in the complaint is per se unlawful. A horizontal agreement to restrict output is inherently likely to harm competition, and there is no legitimate efficiency justification for respondent's conduct. *SCTLA*, 493 U.S. 411; *NCAA v. Board of Regents*, 468 U.S. 85 (1984); *Sandy River Nursing Care v. Aetna Casualty*, 985 F.2d 1138 (1st Cir. 1993); *PolyGram Holding, Inc.*, 5 Trade Reg. Rep. (CCH) ¶ 15,453 (FTC 2003) (*available at* <http://ftc.gov/os/2003/07/polygramopinion.pdf>), *aff'd*, 416 F.3d 29 (D.C. Cir. 2005).

Ordinarily, members of a cartel reduce output across the market in order to force consumers to bid up prices. Here the strategy was to impose pain on consumers in order to coerce the Government of Puerto Rico to accede to the industry's demand that Law 278 be repealed. This raises the possibility of viewing the alleged conspiracy as a form of petitioning activity that arguably is immune from antitrust sanctions. As the Supreme Court has held, it is not the

¹ E.g., *Superior Court Trial Lawyers Ass'n*, 493 U.S. 411 (1990); *Peterson Drug Co.*, 115 F.T.C. 492 (1992); *Michigan State Medical Society*, 110 F.T.C. 191 (1983).

Analysis to Aid Public Comment

purpose of the antitrust laws to regulate traditional petitioning activity aimed at securing anticompetitive governmental action. *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961).

On the other hand, where competitors coordinate their commercial activity, conspiring in a manner that harms consumers directly, the fact that the conspirators intended thereby to motivate governmental action is not a defense to liability. *SCTLA*, 493 U.S. 411. An exception to this latter rule governs group boycotts that seek a purely political objective (that is, an objective that involves no special pecuniary benefit for the conspirators). A politically motivated boycott is protected by the First Amendment, and is not subject to antitrust liability. *NAACP v. Claiborne Hardware Co.*, 458 U.S. 886, 914 (1982) (The First Amendment protects “a nonviolent, politically motivated boycott designed to force governmental and economic change to effectuate rights guaranteed by the Constitution itself.”).²

The conduct alleged in the complaint would not be immune from antitrust sanctions under these precedents. In *Noerr*, the alleged restraint of trade (legislation favoring the conspirators) was the consequence of governmental action, and for this reason was exempt from antitrust review. In the present investigation, the alleged restraint of trade (a constriction in the supply of lubricants) was the means by which the conspirators sought to obtain favorable legislation. It follows that the *Noerr* defense is not applicable.³ The *Claiborne Hardware* defense is also inapplicable because the Puerto

² See also *Allied International, Inc. v. International Longshoremen’s Ass’n*, 640 F.2d 1368, 1380 (1st Cir. 1981), *aff’d*, 456 U.S. 212 (1982); *Missouri v. National Organization for Women, Inc.*, 620 F.2d 1301 (8th Cir. 1980).

³ See *In re Brand Name Prescription Drugs Antitrust Litig.*, 186 F.3d 781, 789 (7th Cir. 1999) (The *Noerr* doctrine “does not authorize anticompetitive action in advance of government’s adopting the industry’s anticompetitive proposal. The doctrine applies when such action is the consequence of legislation or other governmental action, not when it is the means for obtaining such action . . .”) (emphasis in original).

Analysis to Aid Public Comment

Rico conspiracy was an effort to escape regulation and advance the parochial economic interests of the importers. This was not a politically motivated boycott, as that term is used in the case law.

The present case is similar to *Sandy River Nursing Care v. Aetna Casualty*, 985 F.2d 1138. A group of insurance companies agreed to cease offering workers' compensation policies in Maine in order to coerce the legislature into authorizing higher rates. The Court of Appeals concluded that this concerted refusal to sell insurance was a per se violation of the Sherman Act, and that the legislative agenda of the insurance companies afforded them no defense to liability. The opinion explains: "[P]rivate actors who conduct an economic boycott violate the Sherman Act and may be held responsible for direct marketplace injury caused by the boycott, even if the boycotters' ultimate goal is to obtain favorable state action." 985 F.2d at 1142.

It is not a legitimate antitrust defense to claim that Law 278 is inefficient, and that the repeal thereof would enhance consumer welfare. The legality of an otherwise anticompetitive restraint cannot turn on the wisdom or efficiency of the governmental policy that is targeted by the conspirators.⁴

III. The Proposed Consent Order

⁴ An analogous defense was considered and rejected by the Commission in *Detroit Auto Dealers Ass'n*, 110 F.T.C. 417 (1989), *aff'd in part and rev'd in part*, 955 F.2d 457 (6th Cir. 1992). DADA involved an agreement among competing automobile dealers to limit the hours of operation of their dealerships. Respondents argued, inter alia, that the agreement to limit showroom hours was justified because it reduced the likelihood that their employees would join unions. Unionization would potentially lead to higher wages, and hence higher prices for automobiles. The Commission could find "no merit" in the proposed efficiency defense. "Given the national policy favoring the association of employees to bargain in good faith with employers over wages, hours and working conditions, we do not believe that preventing unionization can be a legitimate justification for an otherwise unlawful restraint." *Id.* at 498 n. 22.

Just as collective bargaining is part of national labor policy, Law 278 represents the environmental policy of the Commonwealth of Puerto Rico. And just as escaping national labor policy is not a cognizable antitrust defense, altering Puerto Rico environmental legislation is not a cognizable antitrust defense.

Analysis to Aid Public Comment

American Petroleum has signed a consent agreement containing the proposed consent order. The proposed consent order enjoins American Petroleum from conspiring with competitors to restrict output.

More specifically, American Petroleum would be enjoined from agreeing or attempting to agree with any other seller of lubricants: (i) to restrain, restrict, limit or reduce the import or sale of lubricants; or (ii) to deal with, refuse to deal with, threaten to refuse to deal with, boycott, or threaten to boycott any buyer or potential buyer of lubricants.

The proposed order would not interfere with the company's Constitutional right to engage in legitimate petitioning activity. The proposed order includes a safe harbor provision expressly permitting American Petroleum to exercise rights under the First Amendment to petition any government body concerning legislation, rules, or procedures.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

**COLEGIO DE OPTOMETRAS,
EDGAR DÁVILA GARCÍA, O.D.,
AND
CARLOS RIVERA ALONSO, O.D.**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4199; File No. 051 0044

Complaint, September 6, 2007 – Decision, September 6, 2007

This consent order addresses charges that respondent Colegio de Optometras de Puerto Rico, acting as a combination of competing optometrists, and in combination with individual optometrists including two of its officers, Edgar Dávila García, O.D., and Carlos Rivera Alonso, O.D., restrained competition among its member optometrists in its dealings with Ivision International Inc., a company that contracts with Puerto Rico health plans to administer vision plans and provide vision care services and products to covered patients. The order, among other things, prohibits the Colegio, Dr. Dávila, and Dr. Rivera from entering into or facilitating agreements among any optometrists with respect to their provision of optometry services, including (1) to negotiate on behalf of any optometrist with any payor; (2) to deal, refuse to deal, or threaten to refuse to deal with any payor; (3) regarding any term upon which any optometrist deals, or is willing to deal, with any payor, including, but not limited to, price terms; or (4) not to deal individually with any payor, or not to deal with any payor other than through the Colegio. Other provisions of the order include the requirement that respondents translate the Commission's order and complaint into Spanish and distribute them to Colegio members and other parties, as well as notification and compliance-related requirements.

Participants

For the Commission: Nancy F. Caban, Mark Frankena, Leonard L. Gordon, Thomas R. Iosso, Mazor Matzkevich, Carole A. Paynter, Susan E. Raitt, Louis Silvia, and David P. Wales, Jr.

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For the *Respondents: Fernando J. Fornaris, James W. McCartney and Sara E. Tolosa Ramirez, Cancio, Nadal, Rivera & Diaz, P.S.C.*

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, having reason to believe that Colegio de Optometras de Puerto Rico (“Respondent Colegio” or “the Colegio”), Edgar Dávila García (“Respondent Dávila”), and Carlos Rivera Alonso (“Respondent Rivera”) have 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 in that respect as follows:

NATURE OF THE CASE

1. This matter concerns Respondents’ price-fixing conspiracy and concerted refusal to deal with vision and health plans (collectively, “payors”) as part of a concerted effort among competing optometrists in Puerto Rico to force such plans to, among other things, raise the rates of vision care service reimbursement.

RESPONDENTS

2. Respondent Colegio is a not-for-profit incorporated professional association of optometrists in Puerto Rico, and is organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico, with its principal address at Eleanor Roosevelt Avenue, #118, Hato Rey, Puerto Rico, 00918.

3. Respondent Dávila is an optometrist licensed to practice optometry in Puerto Rico and is engaged in the business of

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providing vision care services to patients for a fee in Puerto Rico. Respondent Dávila served as the Treasurer of the Colegio from 2002 through 2004; he also served as the head of the Colegio's Health Plans Commission from 2001 through 2004. Respondent Dávila's principal address is Dr. Berrocal & Asociados, 150 De Diego Avenue, Suite 404, Santurce, Puerto Rico, 00907.

4. Respondent Rivera is an optometrist licensed to practice optometry in Puerto Rico and is engaged in the business of providing vision care services to patients for a fee in Puerto Rico. Beginning in 2004, Respondent Rivera served as President Elect of the Colegio; he officially became President in October of 2004. He ceased serving as President in September of 2006. Respondent Rivera's principal address is Centro Visual Juncos, 29 Martinez, Juncos, Puerto Rico, 00777.

JURISDICTION

5. At all times relevant to this complaint, Respondent Colegio existed and operated in substantial part for the pecuniary benefit of its members.

6. Respondents are "persons, partnerships, or corporations" within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

7. Respondents' general business practices, including the acts and practices herein alleged, are in or affecting "commerce" as defined in the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

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**OVERVIEW OF THE VISION CARE SERVICES MARKET
AND OPTOMETRIST COMPETITION**

8. Vision care services (including eye examinations) and products (contact lenses and eye glasses) often are offered as part of health benefits packages provided by health plans. These vision care services and products are provided to eligible members and their dependents (collectively, “patients”) by optometrists and ophthalmologists. Some health plans contract directly with such providers, while other health plans also (or alternatively) use vision plans to provide and manage these vision benefits.

9. Approximately 500 optometrists are members of Respondent Colegio, constituting all of the optometrists licensed to practice in Puerto Rico. Membership in the Colegio is required by statute in order to practice optometry in Puerto Rico; the failure to do so will result in the suspension of the optometrist’s license to practice.

10. Respondent Colegio has a Board of Directors, elected by the members of the Colegio. The Colegio also has a Health Plans Commission that is responsible for issues relating to payors. The Colegio’s enabling statute authorizes the Colegio to serve as a professional association; it does not authorize it to negotiate the reimbursement rates paid to its members by payors.

11. The officers and members of Respondent Colegio engage in the practice of providing optometry services to patients for a fee in Puerto Rico. Except to the extent that competition has been restrained as alleged herein, the members of the Colegio have competed and now are competing among themselves in Puerto Rico.

12. Absent agreements among competing optometrists on the terms, including price, on which they will provide services to patients in health and vision plans, competing optometrists decide individually whether to enter into or remain in contracts with payors,

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and on the terms and conditions under which they are willing to enter into or remain in such contracts.

ANTICOMPETITIVE CONDUCT

13. Respondent Colegio's member optometrists, including the members of its Board of Directors and Health Plans Commission, represent numerous discrete economic interests. The conduct of the Colegio constitutes combined or concerted action by its member optometrists.

14. As more fully described subsequently, Respondent Colegio, acting as a combination of competing optometrists, and in combination with individual optometrists including Respondents Dávila and Rivera, have restrained competition among its member optometrists by, among other things:

A. facilitating, negotiating, entering into, and implementing express or implied agreements among its member optometrists on price and other competitively significant terms;

B. negotiating fees and other competitively significant terms in payor contracts on behalf of the Colegio's members; and

C. refusing or threatening to refuse to deal with payors except on collectively agreed-upon terms.

15. Respondent Colegio has undertaken these acts and practices with the knowledge of its officers and other member optometrists.

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CONDUCT WITH IVISION

16. Since 1997, Ivision International Inc. (“Ivision”) has offered vision care services and products in Puerto Rico. Ivision contracts with Puerto Rico health plans to administer vision plans and provide vision care services and products to covered patients. The health plans pay Ivision on a capitated basis, per individual member. Ivision then contracts with Puerto Rico optometrists to provide these services. By August of 2004, Ivision had almost 130 optometrists – located all over Puerto Rico – in its network, making it very attractive to health plans.

17. Under a typical Ivision plan, specific benefits such as eye examinations, eye glasses and contact lenses are provided to the health plans’ patients. Ivision pays the optometrists in its network a set fee for the provision of different vision care services to each patient. The patient pays a corresponding co-payment for each covered service or product provided. As per Ivision’s agreements with optometrists, the optometrist remits to Ivision the co-payments it receives from the patients. As a result, the fees paid by Ivision to the optometrist are the total net compensation received by the optometrist for treating a patient.

18. Ivision, not the optometrist, also is the entity that “sells” the covered eye wear to the patient. Ivision sends sample frames and lenses on consignment to the optometrists and contracts with a laboratory to ship the finished products to the optometrists for dispensing to patients. Ivision pays the optometrist a fee for the dispensing of the eye wear.

19. The arrangements delineated in paragraphs 16 through 18 typically lead to optometrists, who contract through Ivision, earning less than those contracting directly with health plans; however, those optometrists also gain access to numerous patients through Ivision’s plan. Although patients remain free to decline the vision benefit provided by the health plans and to choose uncovered goods or

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services, because of the tremendous cost advantages, patients often decide to opt for the vision plan and choose covered goods and services.

20. In June and July 2004, Ivision sent out announcements to optometrists regarding its contracts with several new health plans (many of which previously had contracted only directly with optometrists). Ivision scheduled meetings with optometrists to be held that August to discuss the mechanics of implementing these new contracts.

21. Under these new contracts, Ivision paid optometrists the same fees as in its contracts with other health plans. But as a result of Ivision's new affiliations, the optometrists would lose much if not all of their more lucrative direct business with these plans.

22. In early August 2004, Ivision began receiving calls from optometrists, some of whom were Colegio representatives, complaining about the reimbursement structure and rates for the new health plan contracts and threatening that if Ivision did not pay more it would lose optometrists. In addition, as part of a collective effort to force Ivision to raise its reimbursement rates, Colegio representatives and other optometrists contacted additional optometrists and urged them to de-participate from Ivision's network.

23. On August 22, 2004, Ivision met with its providers in Hato Rey (a suburb of San Juan in the northern part of Puerto Rico). At the beginning of the meeting, only three or four optometrists were present. Twenty minutes later, approximately eighteen cars arrived at the same time. Although none of the late arrivals made explicit reference to an earlier meeting, it was apparent from the optometrists' coordinated attacks on Ivision's rates that communications had taken place among them. In fact, there had been a previous optometrists-only meeting at which a chart comparing Ivision's rates with those of health plans had been distributed.

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24. During the meeting with Ivision, the optometrists demanded that Ivision pay them higher reimbursement rates, in the form of one fee for an examination and another fee for refraction, instead of paying a flat fee for both services. The optometrists also complained that Ivision was taking over the role of health plans in Puerto Rico. Respondent Rivera, who was an Ivision provider, stated that he was the President-Elect of the Colegio and that he knew or was familiar with all the optometrists in Puerto Rico. He indicated that as President-Elect of the Colegio he had the authority to meet with Ivision and discuss rates on behalf of the Colegio's members. Respondent Rivera also indicated that if Ivision did not raise reimbursement rates, the Colegio would make sure that Ivision had no providers left in Puerto Rico. In response to Ivision's assertion that it could enlist other providers, Respondent Rivera maintained that he could get to those providers who had not yet joined Ivision and that Ivision would not have any optometrists in its network.

25. One day later, on August 23, 2004, Respondent Dávila circulated a letter on Colegio letterhead addressed to all of the members of the Colegio (all of the optometrists in Puerto Rico) concerning Ivision's new health plan contracts. Respondent Dávila, who was not an Ivision provider, wrote this letter in his capacity as President of the Colegio's Health Plans Commission. In the letter, Respondent Dávila pointed out that Ivision's reimbursement rates represent an exaggerated reduction in the revenues obtained before, and he urged optometrists not to participate in the Ivision network. Respondent Dávila informed the Colegio members that the Colegio was going to develop a policy to be followed with respect to the Ivision plan. He concluded the letter by stating that to continue onward, all of the providers were needed; that this was not a battle that the Colegio could confront alone.

26. Then, on August 25, 2004, two optometrists – a Colegio advisor and a former Colegio officer – met with Ivision representatives and told them that Ivision was going to lose all of its providers and that if it did not pay the providers what they deserved,

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they would quit. At a later meeting, the same former Colegio officer told Ivision's President that the providers were really angry and wanted to destroy Ivision. The President also was told that if Ivision agreed to pay \$51 (matching another plan's fee), the providers would forget Ivision's other problems and everything would go away.

27. On September 1, 2004, at Respondent Dávila's instigation, an officer of the Colegio announced an "extraordinary" meeting of the Board of Directors to be held on September 7, 2004. On that same day, Respondent Dávila sent to all Colegio members notice of a September 9, 2004 meeting in Guayanilla and a September 13, 2004 meeting in San Juan. In the notice, he informed the members that they would be meeting to discuss and create policies on how to work with different situations that affect the rendering of their services as health plan providers. He concluded by stressing the importance of attendance – that the members' ideas and collaboration were needed.

28. On September 7, 2004, the Colegio Board of Directors, including Respondents Dávila and Rivera, held a special meeting to discuss Ivision. That meeting was followed by the September 9, 2004 meeting, at which the Colegio members in attendance, including Respondents Dávila and Rivera, complained about Ivision's reimbursement structure and discussed the reimbursement chart that had been distributed earlier. As described by one of the attendees: "I was at the meeting in Guayanilla a few months ago. I remember exactly how the I-Vision monopoly was explained and how the optometrists who were present there (some 20) were advised to resign S.T.A.T. (immediately) from I-Vision to let them know that we were not pleased with the contract and that we had to sit down to negotiate, since the contract only benefits I-Vision."

29. At the September 13, 2004 meeting in San Juan, there were approximately sixty Colegio members in attendance, including Respondents Dávila and Rivera. Respondent Rivera asked for a show of hands as to who was going to remain in the Ivision network.

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No optometrist raised a hand. In addition, several optometrists voiced complaints about Ivision's reimbursement rates and discussed leaving Ivision. The chair of one of the Colegio's committees offered to distribute a sample letter terminating the Ivision contract and circulated a sign-up sheet for those who wanted to receive a copy.

30. At that same meeting, a former officer of the Colegio announced his resignation from Ivision. A few days later, on September 17, 2004, this same optometrist also sent letters to health plans PROgrama de Servicios de Salud de la Asociacion de Maestros ("PROSSAM"), Humana Insurance of Puerto Rico, Inc. ("Humana") and Preferred Medicare Choice, announcing that in light of Ivision's reimbursement structure and rates, the optometrists had decided to resign en masse from Ivision, which would cause a great uproar to the plan's subscribers.

31. On October 4, 2004, at the initiation of Respondent Dávila, he and Respondent Rivera, along with an officer and an advisor to the Colegio, met with officials from some of the health plans with which Ivision contracted, PROSSAM, Humana and First Medical. They discussed the Colegio's – and their own – unhappiness with Ivision's rates, as well as those rates being paid to those optometrists who still had direct contracts with the health plans. The Colegio representatives then requested that the health plans pay optometrists higher fees. They also asked the health plan officials to put pressure on Ivision, and informed them that providers were not going to remain in the Ivision network if the reimbursement rates did not increase.

32. By October 15, 2004, almost 40 Colegio members had left the Ivision network. These optometrists either quit outright by notifying Ivision that they were cancelling their optometrist agreements (some in similarly-worded letters), or by simply refusing service to those patients enrolled in Ivision plans so that Ivision was forced to terminate these doctors as optometrists.

Complaint

33. So as to maintain an effective network, retain its remaining optometrists and recruit new optometrists in the face of Respondents' efforts and success in organizing a boycott, Ivision was forced to raise substantially its reimbursement rates. In November 2004, Ivision increased its rate for an eye examination and the dispensing of eye glasses from \$30 to \$35; it made a similar increase for an examination and the dispensing of contact lenses. Ivision was also forced to waive monetary amounts that some optometrists owed it.

CONDUCT WITH OTHER PAYORS

34. In addition to the conduct described in paragraphs 22 through 33, Respondents orchestrated collective negotiations with at least two other payors.

35. Their efforts included several meetings with and letters to a certain health plan, all directed at having that plan amend its contracts with optometrists so that the optometrists could provide additional higher paying services for the plan. Indeed, to increase its negotiating leverage with this plan, Respondent Dávila sent a letter to all Colegio members urging them not to join the plan until these issues were resolved to the Colegio's satisfaction.

36. Further, officers of the Colegio on several occasions approached another health plan and attempted to negotiate higher reimbursement levels for its members who service that plan.

37. Thus far, these two health plans have been able to resist the collective action exerted by Respondent Colegio.

RESPONDENTS' PRICE FIXING AND CONCERTED REFUSAL TO DEAL IS NOT JUSTIFIED

38. Respondents' price fixing and concerted refusal to deal, and the agreements, acts, and practices described above, have not been,

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and are not, reasonably related to any efficiency-enhancing integration among the optometrist members of the Colegio. Respondent Colegio's member optometrists do not share substantial financial risk and are not otherwise integrated in ways that would increase the potential for increased quality and reduced cost of the care the optometrists provide to patients.

**RESPONDENTS' ACTIONS HAVE HAD SUBSTANTIAL
ANTICOMPETITIVE EFFECTS**

39. Respondents' acts and practices as described herein have had, or tend to have, the effect of restraining trade unreasonably and hindering competition in the provision of optometry services in Puerto Rico in the following ways, among others:

- A. price and other forms of competition among competing optometrists were unreasonably restrained;
- B. prices for vision care services were increased; and
- C. payors, employers, and individual consumers were deprived of the benefits of competition among optometrists.

**VIOLATION OF THE FEDERAL TRADE
COMMISSION ACT**

40. The combination, conspiracy, acts, and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission, on this sixth day of September, 2007, issues its Complaint against Respondents Colegio de Optometras, Edgar Dávila García, and Carlos Rivera Alonso.

Decision and Order

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of certain acts and practices of the Colegio de Optometras, Edgar Dávila García, O.D., and Carlos Rivera Alonso (hereinafter sometimes collectively referred to as “Respondents”), and Respondents having been furnished with a copy of the draft Complaint that Counsel for the Commission proposed to present to the Commission for its consideration and which, if issued, would charge Respondents with violations of 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 to Cease and Desist (“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 this matter and having determined that it had reason to believe that Respondents have 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

Decision and Order

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:

1. Respondent Colegio De Optometras (“the Colegio”) is a not-for-profit corporation, organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico, with its principal address located at Eleanor Roosevelt Avenue, #118, Hato Rey, Puerto Rico, 00918.
2. Respondent Edgar Dávila García , O.D., an individual, is an optometrist licensed to practice optometry in Puerto Rico. His principal address is Dr. Berrocal & Asociados, 150 De Diego Avenue, Suite 404, Santurce, Puerto Rico, 00907.
3. Respondent Carlos Rivera Alonso, O.D., an individual, is an optometrist licensed to practice optometry in Puerto Rico. His principal address is Centro Visual Juncos, 29 Martinez, Juncos, Puerto Rico, 00777.
4. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, 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. “Respondent Colegio” means the Colegio de Optometras, a professional association, its officers, directors, employees, agents, attorneys, representatives, predecessors, successors, and assigns; and the subsidiaries, divisions, groups, and affiliates controlled by it, and the respective officers, directors, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each.
- B. “Respondent Dávila” means Edgar Dávila García, O.D.
- C. “Respondent Rivera” means Carlos Rivera Alonso, O.D.
- D. “Optometrist” means a doctor of optometry (“O.D.”) and includes any optometrist who individually or through a business entity (*e.g.*, clinical group or corporation) provides services relating to a person’s vision, including eye examinations, refractions, dispensing of contact lenses and eye glasses, and fitting of same.
- E. “Optometrist group practice” means a bona fide, integrated firm in which optometrists practice optometry together as partners, shareholders, owners, or employees, or in which only one optometrist practices optometry.
- F. “Participate” in an entity or an arrangement means (1) to be a partner, shareholder, owner, member, or employee of such entity, or (2) to provide services, agree to provide services, or offer to provide services to a payor through such entity. This definition applies to all tenses and forms of the word

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“participate,” including, but not limited to, “participating,” “participated,” and “participation.”

- G. “Payor” means any person that pays, or arranges for payment, for all or any part of any optometrist services for itself or for any other person, as well as any person that develops, leases, or sells access to networks of optometrists.
- H. “Person” means both natural persons and artificial persons, including, but not limited to, corporations, unincorporated entities, and governments.
- I. “Principal address” means either (1) primary business address, if there is a business address, or (2) primary residential address, if there is no business address.
- J. “Qualified clinically-integrated joint arrangement” means an arrangement to provide optometry services in which:
 - 1. all optometrists who participate in the arrangement participate in active and ongoing programs of the arrangement to evaluate and modify the practice patterns of, and create a high degree of interdependence and cooperation among, the optometrists that participate in the arrangement, in order to control costs and ensure the quality of services provided through the arrangement; and
 - 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.
- K. “Qualified risk-sharing joint arrangement” means an arrangement to provide optometry services in which:

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1. all optometrists who participate in the arrangement share substantial financial risk through their participation in the arrangement and thereby create incentives for the optometrists who participate jointly to control costs and improve quality by managing the provision of optometry services, such as risk-sharing involving:
 - a. the provision of optometry services to payors at a capitated rate,
 - b. the provision of optometry services for a predetermined percentage of premium or revenue from payors,
 - c. the use of significant financial incentives (*e.g.*, substantial withholds) for optometrists who participate to achieve, as a group, specified cost-containment goals, or
 - d. the provision of a complex or extended course of treatment that requires the substantial coordination of care by optometrists in different specialties offering a complementary mix of services, for a fixed, predetermined price, where the costs of that course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors; and
 2. any agreement concerning price or other terms or conditions of dealing entered into by or within the arrangement is reasonably necessary to obtain significant efficiencies through the arrangement.
- L. "Qualified joint arrangement" means a qualified clinically-integrated joint arrangement or a qualified risk-sharing joint arrangement.

Decision and Order

II.

IT IS FURTHER ORDERED that Respondents, directly or indirectly, or through any corporate or other device, in connection with the provision of optometry services in or affecting commerce, as “commerce” is defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44, cease and desist from:

- A. Entering into, adhering to, participating in, maintaining, organizing, implementing, enforcing, or otherwise facilitating any combination, conspiracy, agreement, or understanding between or among any optometrists with respect to their provision of optometry services:
 - 1. to negotiate on behalf of any optometrist with any payor;
 - 2. to deal, refuse to deal, or threaten to refuse to deal with any payor;
 - 3. regarding any term, condition, or requirement upon which any optometrist deals, or is willing to deal, with any payor, including, but not limited to, price terms; or
 - 4. not to deal individually with any payor, or not to deal with any payor other than through Respondent Colegio;
- B. Exchanging or facilitating in any manner the exchange or transfer of information between or among optometrists concerning any optometrist’s willingness to deal with a payor, or the terms or conditions, including any price terms, on which the optometrist is willing to deal with a payor;
- C. Attempting to engage in any action prohibited by Paragraphs II.A. or II.B. above; and

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- D. Encouraging, suggesting, advising, pressuring, inducing, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A. through II.C. above.

Provided, however, that nothing in this Paragraph II. shall prohibit any agreement or conduct involving any Respondent: (a) that subject to the requirements of Paragraph III. of this Order, is reasonably necessary to form, participate in, or take any action in furtherance of, a qualified joint arrangement, so long as such qualified joint arrangement does not restrict the ability of, or facilitate the refusal of, optometrists who participate in it to deal with payors on an individual basis or through any other arrangement; or (b) where such agreement or conduct solely involves optometrists in the same optometrist group practice.

III.

IT IS FURTHER ORDERED that for three (3) years from the date this Order becomes final, pursuant to each qualified joint arrangement (referred to in this Paragraph III. as “Arrangement”) in which any Respondent is a participant, that Respondent participant shall notify the Secretary of the Commission in writing (“Paragraph III. Notification”) at least sixty (60) days prior to:

- A. Participating in, organizing, or facilitating any discussion or understanding with or among any optometrists in such Arrangement relating to price or other terms or conditions of dealing with any payor; or
- B. Contacting a payor, pursuant to an Arrangement to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any payor, on behalf of any optometrist or any optometrist group practice in such Arrangement.

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Provided further, Paragraph III. Notification shall include the following information regarding the Arrangement pursuant to which Respondent intends to engage in the above identified conduct:

- a. the total number of optometrists participating in the Arrangement;
- b. a description of the Arrangement, including its purpose and geographic area of operation;
- c. a description of the nature and extent of the integration and the efficiencies resulting from the Arrangement;
- d. an explanation of the relationship of any agreement on prices, or contract terms related to price, to furthering the integration and achieving the efficiencies of the Arrangement;
- e. a description of any procedures proposed to be implemented to limit possible anticompetitive effects resulting from the Arrangement or its activities; and
- f. all studies, analyses, and reports that were prepared for the purpose of evaluating or analyzing competition for optometry services in any relevant market, including, but not limited to, the market share of optometry services in any relevant market.

Provided, however, that if Respondent Dávila or any Respondent Rivera is Participating in an Arrangement solely as participant of an optometrist group practice, that Respondent, may, upon written affirmation, exclude from his Paragraph III. Notification any information that is not known by such Respondent.

Provided further that:

Decision and Order

- (a) if, within sixty (60) days from the Commission's receipt of the Paragraph III. Notification, a representative of the Commission makes a written request for additional information to the Respondent providing such Paragraph III. Notification, that Respondent shall not participate in any Arrangement described in Paragraph III.A. or Paragraph III.B. of this Order prior to the expiration of thirty (30) days after substantially complying with such request for additional information, or such shorter waiting period as may be granted in writing from the Bureau of Competition;
- (b) the expiration of any waiting period described herein without a request for additional information shall not be construed as a determination by the Commission, or its staff, that the proposed Arrangement does or does not violate this Order or any law enforced by the Commission;
- (c) the absence of notice that the Arrangement has been rejected, regardless of a request for additional information, shall not be construed as a determination by the Commission, or its staff, that the Arrangement has been approved;
- (d) receipt by the Commission of any Paragraph III. Notification regarding participation pursuant to an Arrangement is not to be construed as a determination by the Commission that any such Arrangement does or does not violate this Order or any law enforced by the Commission; and
- (e) Paragraph III. Notification shall not be required prior to participating in any Arrangement described at Paragraph III.A. or Paragraph III.B. of this Order pursuant to an Arrangement for which Paragraph III. Notification has previously been given.

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IV.

IT IS FURTHER ORDERED that Respondent Colegio shall:

- A. Translate the Order and the Complaint into Spanish (“translated Order and Complaint”), and within thirty (30) days after the date on which this Order becomes final, send a copy of this Order and the Complaint with a copy of the translated Order and Complaint by:
 1. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each optometrist that is a member of Respondent Colegio;
 2. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each present officer, director, manager, and employee of Respondent Colegio; and
 3. first-class mail, return receipt requested, to the chief executive officer of each payor with whom Respondent Colegio has a record of being in contact since January 1, 2001.
- B. For a period of three (3) years after the date this Order becomes final:
 1. Distribute a copy of this Order and the Complaint with a copy of the translated Order and Complaint by:
 - a. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each optometrist that joins Respondent Colegio, and who did not previously

Decision and Order

receive a copy of this Order and the Complaint from Respondent Colegio, within thirty (30) days of the day that such membership begins;

- b. first-class mail, with return receipt requested or delivery confirmation, or electronic mail, with return confirmation, to each person who becomes an officer, director, manager, or employee of Respondent Colegio, and who did not previously receive a copy of this Order and the Complaint from Respondent Colegio, within thirty (30) days of the day that he or she assumes such responsibility with Respondent Colegio;
 2. Annually publish a copy of this Order and the Complaint with a copy of the translated Order and Complaint, in an official annual report or newsletter sent to all members of Respondent Colegio, with such prominence as is given to regularly featured articles.
- C. File a verified written report within sixty (60) days after the date on which this Order becomes final, annually thereafter for three (3) 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 such report shall include:
1. A detailed description of the manner and form in which Respondent Colegio has complied and is complying with this Order;
 2. The name, address, and telephone number of each payor with which Respondent Colegio has had any contact; and
 3. Depending on the method of delivery used, copies of the delivery confirmations, electronic mail confirmations, or signed return receipts required by Paragraphs IV.A. and IV.B. of this Order.

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V.

IT IS FURTHER ORDERED that Respondents Dávila and Rivera shall each file a verified written report within ninety (90) days after the date on which this Order becomes final, annually thereafter for three (3) 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 such report shall include a detailed description of the manner and form in which Respondents Dávila and Rivera individually have complied and are complying with this Order.

VI.

IT IS FURTHER ORDERED that Respondent Colegio shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Respondent Colegio, (2) acquisition, merger, or consolidation of Respondent Colegio, or (3) other change in Respondent Colegio 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 Respondent Colegio.

VII.

IT IS FURTHER ORDERED that each Respondent shall notify the Commission of any change in its principal address within twenty (20) days of such change in address.

VIII.

IT IS FURTHER ORDERED that, for the purpose of determining or securing compliance with this Order, each Respondent shall permit any duly authorized representative of the Commission:

Decision and Order

- A. Access, during office hours and in the presence of counsel, to inspect and copy all books, ledgers, accounts, correspondence, memoranda, calendars, and other records and documents in its possession, or under its control, relating to any matter contained in this Order; and
- B. Upon five (5) days' notice, and in the presence of counsel, and without restraint or interference from it, to interview officers, directors, or employees of the Respondents.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on September 6, 2027.

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 proposed consent order with the Colegio de Optometras de Puerto Rico (“the Colegio”) and two of its officers, Edgar Dávila García, O.D., and Carlos Rivera Alonso, O.D. The agreement settles charges that the Colegio, acting as a combination of otherwise competing optometrists, and in combination with individual optometrists, including Drs. Dávila and Rivera, violated Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, by facilitating, negotiating, entering into, and implementing express or implied agreements on price and other competitively significant terms; negotiating fees and other competitively significant terms in vision and health plan contracts on behalf of the Colegio’s members; and refusing or threatening to refuse to deal with such entities except on collectively agreed-upon terms. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should make the proposed order final.

The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify its terms in any way. Further, the proposed consent order has been entered into for settlement purposes only and does not constitute an admission by the Colegio or Drs. Dávila and Rivera that any of them violated the law or that the facts alleged in the complaint (other than jurisdictional facts) are true.

The Complaint

The allegations of the complaint are summarized below.

Analysis to Aid Public Comment

The Colegio is a not-for-profit, incorporated professional association of optometrists that is organized, existing, and doing business under and by virtue of the laws of the Commonwealth of Puerto Rico (“Puerto Rico”), with its office and principal place of business in San Juan, Puerto Rico.

The Colegio has approximately 500 member optometrists, constituting all of the optometrists licensed to practice in Puerto Rico. Except to the extent that competition has been restrained, the member optometrists of Colegio have been, and are now, in competition with each other for the provision of optometry services in Puerto Rico.

Dr. Dávila is a licensed optometrist who provides vision care services to patients for a fee. Dr. Dávila served as the Treasurer of the Colegio from 2002 through 2004; he also served as the President of the Colegio’s Health Plans Commission from 2001 through 2004. Dr. Rivera is a licensed optometrist who provides vision care services to patients for a fee. Dr. Rivera served as President-Elect of the Colegio in 2004, and then as President from October 2004 through September 2006.

Since 1997, Ivision International Inc. (“Ivision”) has offered vision care services and products in Puerto Rico. Ivision contracts with Puerto Rico health plans to administer vision plans and provide vision care services and products to covered patients. The health plans pay Ivision on a capitated basis, per individual member. Ivision then contracts with Puerto Rico optometrists to provide these services. By August of 2004, Ivision had almost 130 optometrists – located all over Puerto Rico – in its network, making it very attractive to health plans.

In June and July 2004, Ivision sent out announcements to optometrists regarding contracts with several new health plans (many of which previously had contracted only directly with optometrists). Ivision scheduled meetings with optometrists to be held that August to discuss the mechanics of implementing these

Analysis to Aid Public Comment

new contracts. Under these new contracts, Ivision paid optometrists the same fees as in its contracts with other health plans. As a result of these new contracts, the optometrists would lose much if not all of their more lucrative direct business with these plans.

In early August, Ivision began receiving calls from optometrists, some of whom were Colegio representatives, complaining about the reimbursement structure and rates for the new health plan contracts, and threatening that if Ivision did not pay more, it would lose optometrists. In addition, as part of a collective effort to force Ivision to raise its rates, Colegio representatives and other optometrists contacted additional optometrists and urged them to stop participating in Ivision's network.

On August 22, Ivision met with its providers. Just prior to that meeting, the optometrists held their own meeting at which a chart comparing Ivision's rates with those of other health plans had been distributed. During their meeting with Ivision, the optometrists demanded that Ivision pay them higher reimbursement rates, in the form of one fee for an examination and another fee for refraction, instead of paying a flat fee for both services. Dr. Rivera, who was an Ivision provider, stated that he was the President-Elect of the Colegio and that he knew or was familiar with all the optometrists in Puerto Rico. He indicated that as President-Elect of the Colegio he had the authority to meet with Ivision and discuss rates on behalf of the Colegio's members. Dr. Rivera also indicated that if Ivision did not raise reimbursement rates, the Colegio would make sure that Ivision had no providers left in Puerto Rico. In response to Ivision's assertion that it could enlist other providers, Dr. Rivera maintained that he could get to those providers who had not yet joined Ivision and that Ivision would not have any optometrists in its network.

The next day, Dr. Dávila circulated a letter on Colegio letterhead addressed to all of the members of the Colegio concerning Ivision's new health plan contracts. Dr. Dávila, who was not an Ivision provider, wrote this letter in his capacity as President of the

Analysis to Aid Public Comment

Colegio's Health Plans Commission. In the letter, he urged optometrists not to participate in the Ivision network, and informed the Colegio members that the Colegio was going to develop a policy to be followed with respect to the Ivision plan. He concluded the letter by stating that to continue onward, all of the providers were needed, and that this was not a battle the Colegio could confront alone.

Two days later, a Colegio advisor and a former Colegio officer met with Ivision representatives and told them that Ivision was going to lose all of its providers and that if it did not pay the providers what they deserved, they would quit. At a later meeting, the same former Colegio officer told Ivision's President that the providers were really angry and wanted to destroy Ivision. The President also was told that if Ivision agreed to pay a certain amount (matching another plan's fee), the providers would forget Ivision's other problems and "everything would go away."

In September 2004, there were a number of meetings held by the Colegio Board of Directors and by Colegio members discussing how to deal with Ivision. At one meeting, the Colegio members present were advised to resign immediately from Ivision network to force Ivision to increase its reimbursement rates. At another meeting, attended by several Colegio members, Dr. Rivera asked for a show of hands as to who was going to remain in the Ivision network. No optometrist raised a hand. Several optometrists voiced complaints about Ivision's reimbursement rates and discussed leaving Ivision; an offer was made to circulate a sample letter terminating the Ivision contract. A former Colegio officer who announced his resignation from Ivision at that meeting followed this up a few days later by sending letters to certain health plans, stating that because of Ivision's reimbursement structure and rates, the optometrists had decided to resign en masse from Ivision, which would cause a great uproar among the plans' subscribers.

In early October 2004, some Colegio representatives, including Dr. Dávila and Dr. Rivera, met with officials from some of the

Analysis to Aid Public Comment

health plans with which Ivision contracted. The Colegio representatives requested that the health plans pay optometrists higher fees. They also asked the health plan officials to put pressure on Ivision, and informed them that providers were not going to remain in the Ivision network if the reimbursement rates did not increase.

The Colegio's and Drs. Dávila's and Rivera's efforts to obtain higher reimbursement rates from Ivision succeeded. By mid-October, almost 40 Colegio members had left the Ivision network. These optometrists either quit outright by notifying Ivision that they were cancelling their optometrist agreements (some in similarly-worded letters), or by simply refusing service to those patients enrolled in Ivision plans, so that Ivision was forced to terminate these doctors as optometrists. In order to maintain an effective network, retain its remaining optometrists and recruit new optometrists in the face of the Colegio's efforts and success in organizing a boycott, Ivision was forced to substantially raise its reimbursement rates. In November 2004, Ivision significantly increased its reimbursement rate for an eye examination and the dispensing of eye glasses; it made a similar increase for an examination and the dispensing of contact lenses. Ivision was also forced to waive monetary amounts that some optometrists owed it.

In addition to the conduct outlined above, the Colegio and Drs. Dávila and Rivera orchestrated collective negotiations with at least two other plans. Their efforts included several meetings with and letters to a certain health plan, all directed at having that plan amend its contracts with optometrists so that the optometrists could provide additional higher paying services for the plan. Indeed, to increase its negotiating leverage with this plan, Dr. Dávila sent a letter to all Colegio members urging them not to join the plan until these issues were resolved to the Colegio's satisfaction. Further, officers of the Colegio on several occasions approached another health plan and attempted to negotiate higher reimbursement levels for its members

Analysis to Aid Public Comment

who service that plan. Thus far, these two health plans have been able to resist the collective action exerted by the Colegio.

Respondents' price fixing and concerted refusal to deal, and the agreements, acts, and practices described above, have not been, and are not, reasonably related to any efficiency-enhancing integration among the optometrist members of the Colegio. By the acts set forth in the Complaint, the Colegio and Drs. Dávila and Rivera violated Section 5 of the FTC Act.

The Proposed Consent Order

The proposed consent order is designed to prevent a recurrence of the illegal concerted actions alleged in the complaint, while allowing the Colegio and its members, including Drs. Dávila and Rivera, to engage in legitimate joint conduct. The proposed order is similar to recent consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements refusing to deal with health plans.¹

The proposed order's specific provisions are as follows:

Paragraph II.A prohibits the Colegio, Dr. Dávila, and Dr. Rivera, from entering into or facilitating agreements among any optometrists with respect to their provision of optometry services, including: (1) negotiating on behalf of any optometrist with any payor; (2) dealing, refusing to deal, or threatening to refuse to deal with any payor; (3) regarding any term upon which any optometrist deals, or is willing to deal, with any payor, including, but not limited to, price terms; or (4) not to deal individually with any payor, or not to deal with any payor other than through the Colegio.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits the Colegio, Dr. Dávila, and Dr. Rivera

¹ New Century Health Quality Alliance, Inc., File No. 051-0137 (Oct. 6, 2006); Puerto Rico Association of Endodontists, Corp., File No 051-0170 (Aug. 29, 2006).

Analysis to Aid Public Comment

from exchanging or facilitating the transfer of information among optometrists concerning any optometrist's willingness to deal with a payor, or the terms or conditions, including any price terms, on which the optometrist is willing to deal. Paragraph II.C prohibits the Colegio, Dr. Dávila, and Dr. Rivera from attempting to engage in any action prohibited by Paragraphs II.A or II.B. Paragraph II.D prohibits the Colegio from encouraging, pressuring, or attempting to induce any person to engage in any action that would be prohibited by Paragraphs II.A through II.C.

Paragraph III requires that the Colegio, Dr. Dávila, and Dr. Rivera for three years from the date the Order becomes final, notify the Secretary of the Commission in writing at least sixty days prior to: (1) participating in, organizing, or facilitating any discussion or understanding with or among any optometrists in any qualified joint arrangement relating to price or other terms or conditions of dealing with any payor; or (2) contacting a payor to negotiate or enter into any agreement concerning price or other terms or conditions of dealing with any payor, on behalf of any optometrists or any optometrist group practice in such arrangement. The remaining provisions of Paragraph III contain other standard notification and compliance-related provisions.

Paragraph IV requires the Colegio to translate the Order and the Complaint into Spanish, distribute the translated Order and Complaint to Colegio members, as well as payors, and annually publish these documents in official annual reports or newsletters.

The proposed order will expire in 20 years.

Complaint

IN THE MATTER OF

**SOUTH CAROLINA STATE BOARD OF
DENTISTRY**CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 OF THE FEDERAL TRADE COMMISSION ACT*Docket 9311; File No. 021 0128**Complaint, September 12, 2003 – Decision, September 6, 2007*

This consent order relates to charges that the South Carolina State Board of Dentistry unlawfully restrained competition in the provision of preventive dental care services in the state by unreasonably restricting the delivery of dental cleanings, sealants, and topical fluoride treatments in school settings by licensed dental hygienists. The order requires the Board to affirm and publicize its support for the state legislative policy, embodied in the 2003 amendments to the Dental Practice Act that prevents the Board from requiring a dentist examination as a condition of the provision of preventive dental care in public health settings by dental hygienists. In addition, to prevent similar anticompetitive restraints in the future, the order requires the Board to give the Commission advance notice before adopting rules or taking other actions that relate to dental hygienists' provision of preventive dental services in a public health setting.

Participants

For the Commission: *Garry Gibbs, Elizabeth Hilder, Garth Huston, Markus H. Meier, Gary Schorr, and David P. Wales, Jr.*

For the Respondents: *William H. Davidson, II, Andrew Lindeman, and Kenneth P. Woodington, Davidson, Morrison & Lindeman; and Lynne W. Rogers, South Carolina Department of Labor, Licensing and Regulation.*

Complaint

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, having reason to believe that the South Carolina State Board of Dentistry 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 in that respect as follows:

STATEMENT OF THE CASE

1. Respondent South Carolina State Board of Dentistry (“the Board”), which consists almost entirely of practicing dentists, restrained competition in the provision of preventive dental care services by unreasonably restricting the delivery of dental cleanings, sealants, and topical fluoride treatments in school settings by licensed dental hygienists. Although the South Carolina General Assembly passed legislation in 2000 eliminating a statutory requirement that a dentist examine each child before a hygienist may perform cleanings or apply sealants in school settings, the Board in 2001 re-imposed the very examination requirement that the legislature had eliminated, and extended it to the application of topical fluoride in school settings as well. The effect of the Board’s action was to deprive thousands of school children – particularly economically disadvantaged children – of the benefits of preventive oral health care services. The Board’s anticompetitive action, undertaken by self-interested industry participants with economic interests at stake, was contrary to state policy and was not reasonably related to any countervailing efficiencies or other benefits sufficient to justify its harmful effects on competition and consumers.

Complaint

RESPONDENT

2. The Board is organized, exists, and transacts business under and by virtue of the laws of South Carolina, with its principal office at Synergy Business Park, Kingstree Building, 110 Centerview Dr., Columbia, South Carolina 29210.

3. The Board was created by the South Carolina legislature to supervise the practice of dentistry and dental hygiene.

4. By virtue of the Board's make-up, the licensed dentists of South Carolina regulate both themselves and dental hygienists.

5. The Board is composed of seven dentists, one dental hygienist, and one public member. The licensed dentists in South Carolina elect six of the dentist members for approval by the governor, and the dental-hygienist member is elected by licensed dental hygienists in South Carolina for approval by the governor. The governor of South Carolina appoints one of the dentist members and the public member.

6. While serving their membership terms, dentist members of the Board may, and do, continue to engage in the business of providing dental services for a fee. Except to the extent that competition has been restrained as alleged below, and depending on their geographic location, licensed dentists in South Carolina compete with each other and with dentist members of the Board.

7. The Board is the sole licensing authority for dentists and dental hygienists in South Carolina. It is generally unlawful for an individual to practice or to offer to practice dentistry or dental hygiene in South Carolina unless he or she holds a current license to practice.

8. The Board is authorized by South Carolina law to take disciplinary action against any licensee who violates any rule or regulation promulgated by the Board. Disciplinary action by the

Complaint

Board may include the suspension or revocation of a license, or other limitations or restrictions on a licensee.

JURISDICTION

9. The Board is a state regulatory body and is a “person” within the meaning of Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45.

10. Substantial sums of money flow into South Carolina from the federal government and other out-of-state payers for the purchase of preventive dental care services. The acts and practices of the Board, including the acts and practices alleged herein, have been or are in or affecting “commerce” within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

**PREVENTIVE DENTAL SERVICES
IN SOUTH CAROLINA**

11. Dental hygienists are licensed health care professionals who specialize in providing preventive oral health services. Such services include cleaning teeth, taking x-rays, providing nutrition and dietary counseling, providing fluoride treatments, and applying dental sealants. Dental hygienists are also trained to detect signs of oral disease and to educate patients on maintaining optimal oral health.

12. There are over 2,200 dental hygienists licensed to practice in South Carolina. Dental hygienists in South Carolina practice in collaboration with a supervising dentist or under the direction of the South Carolina Department of Health and Environmental Control’s public health dentist.

13. Firms owned by dental hygienists working in collaboration with a dentist (either supervised by a private dentist or working at

Complaint

the direction of South Carolina's public health dentist) can compete with dentists for the provision of preventive dental care services.

14. Many children in South Carolina suffer from oral health problems because they do not receive preventive dental care, particularly children in low-income families. Over 400,000 children – more than 40 percent of children in South Carolina – are Medicaid-eligible. In the early 1990s, only 12 percent of Medicaid-eligible children received preventive dental care services.

15. In 1988, the South Carolina General Assembly enacted a law specifically authorizing dental hygienists to provide preventive services in schools. That law, however, required that hygienists could provide cleanings and apply dental sealants only if a dentist had examined the child's teeth within the previous 45 days. The 1988 law did not significantly increase the delivery of dental hygienists' services in school settings.

16. In 2000, South Carolina substantially increased Medicaid reimbursement for dental services. With federal matching funds, about \$79 million became available annually for Medicaid-eligible dental services.

17. After Medicaid payment levels for dental care services increased, the number of South Carolina dentists participating in South Carolina's Medicaid-Dental program increased about one-third. More than 900 of the over 1,500 licensed dentists licensed in South Carolina now participate in the state's Medicaid-Dental program.

Complaint

**SOUTH CAROLINA GENERAL ASSEMBLY REMOVES A
BARRIER TO THE PROVISION OF PREVENTIVE
DENTAL CARE IN SCHOOLS**

18. In 2000, the South Carolina General Assembly amended its statutes to make it easier for dental hygienists to deliver preventive dental care services in school settings. Prior to the 2000 amendments, South Carolina statutes provided that a dental hygienist could provide cleanings and sealants in a school setting only if:

- a. a supervising dentist examined the patient no more than 45 days before the treatment;
- b. a supervising dentist provided written authorization for the procedures;
- c. the patient was not an active patient of another dentist; and
- d. the patient's parents provided written permission for the treatment.

19. The 2000 amendments removed these requirements, except the requirement for parental consent. The 2000 amendments provided instead that a dental hygienist could apply topical fluoride and perform the application of sealants and oral prophylaxis "under general supervision." S.C. Acts § 40-15-80(B) (2000). General supervision "means that a licensed dentist or the South Carolina Department of Health and Environmental Control's public health dentist has authorized the procedures to be performed but does not require that a dentist be present when the procedures are performed." S.C. Acts § 40-15-85 (2000). By virtue of the 2000 amendments, the Board could not require a dentist examination as a condition of a dental hygienist's providing preventive services in a school setting.

Complaint

20. Upon signing the 2000 amendments, South Carolina's governor announced: "This new law removes a regulation that hindered access to dental care."

21. The 2000 amendments embodied a policy to remove artificial barriers to the provision of oral preventive health care by dental hygienists to school children.

22. Health Promotion Specialists ("HPS") is a firm owned by a dental hygienist that provides preventive dental services to South Carolina children. HPS employs dental hygienists to provide those services and contracts with dentists to supervise the hygienists.

23. In January 2001, HPS began providing cleanings, sealants, topical fluoride treatments, and other preventive dental services on-site to children in South Carolina schools. By July 2001, HPS had screened over 19,000 children, and provided preventive services (cleanings, sealants, and topical fluoride treatments) to over 4,000 children, including nearly 3,000 Medicaid-eligible children. Because HPS's services were provided in schools, they were more convenient for the families of the children served. Dentists in traditional office practices risked losing patients to HPS.

24. Because a tremendous unmet need for preventive dental care remained, HPS expected to treat more than twice as many students in the fall semester of 2001 as it had in the spring semester. Relying on this forecast, HPS more than doubled the number of hygienists it employed.

BOARD CONDUCT

25. The Board has restrained competition in the provision of preventive dental care services by combining or conspiring with its members or others, or by acting as a combination of its members or others, to restrict unreasonably the ability of dental hygienists to deliver preventive services in school settings. In particular, on July 12, 2001, the Board adopted an emergency regulation

Complaint

governing dental hygienist practice in school settings that re-imposed the same examination requirement that the General Assembly removed in 2000: that a supervising dentist had to examine the patient no more than 45 days prior to treatment.

26. For the regulation to become effective, it required the approval only of the Board, a majority of which consists of practicing dentists elected by the licensed dentists of South Carolina. No financially disinterested state actor approved the regulation before or while it was in effect. Under state law, the regulation terminated after 180 days.

27. The emergency regulation conflicted directly with the policy articulated by the General Assembly, by re-imposing the precise barriers to dental hygienists' providing preventive services to school children that the legislature had just removed.

28. The effect of the emergency regulation was to reduce substantially the number of children (particularly economically disadvantaged children) who received preventive dental care. During the latter half of 2001, the period when the emergency regulation was in effect, HPS screened fewer than 6,000 children, about 13,000 fewer than it had screened during the first half of 2001. The emergency regulation also limited HPS's ability to provide preventive dental care; as a result, the regulation deprived thousands of South Carolina children of preventive dental care.

29. The Board's requirement that a dentist examine each child before a dental hygienist provides a cleaning, sealant, or fluoride treatment in school settings was not reasonably related to any efficiencies or other benefits sufficient to justify its harmful effect on competition and consumers.

Complaint

**STATE ADMINISTRATIVE REVIEW FINDS IMPOSITION
OF THE DENTIST PREEXAMINATION REQUIREMENT
IN SCHOOL SETTINGS CONTRARY TO THE 2000
AMENDMENTS**

30. In August 2001, the Board published a proposed permanent regulation substantially identical to the emergency regulation, which by law would lapse in January 2002.

31. Pursuant to South Carolina law, an administrative law judge was required, after a public hearing, to determine whether the proposed permanent regulation was a reasonable exercise of the Board's authority. The administrative law judge's report, along with the proposed regulation, had to be forwarded to the General Assembly for review in order for the permanent regulation to become effective.

32. In February 2002, the presiding administrative law judge issued a report that concluded that the Board's proposed permanent regulation was unreasonable and contravened state policy to the extent it reinstated the dentist pre-examination requirement that the legislature had eliminated in 2000.

33. The administrative law judge found that deletion of the statutory pre-examination requirement reflected a state policy adopted by the South Carolina legislature during its 2000 session to increase access to preventive oral health care for low-income children. The administrative law judge recommended that the Board delete the pre-examination requirement from its proposal before forwarding it to the legislature.

34. After issuance of the administrative law judge's report, the Board did not submit its proposed permanent regulation to the General Assembly for review. As a result, the proposed regulation did not take effect.

Complaint

**THE CURRENT THREAT TO THE DELIVERY OF
PREVENTIVE DENTAL SERVICES IN
SOUTH CAROLINA**

35. After the emergency regulation lapsed, at least three firms, including HPS, provided preventive dental care in schools pursuant to contracts with the Department of Health and Environmental Control. Under the contracts, these firms provided cleanings, fluoride treatments, and sealants, under standing orders, without a mandatory pre-examination by a dentist.

36. During the latter part of 2002, HPS provided preventive dental care treatments to nearly 10,700 school children, 6,000 more than during the same period in 2001, when the Board's emergency regulation was in effect.

37. In May 2003, the South Carolina General Assembly enacted legislation that expressly provides that dentist examination requirements applicable in some settings do not apply to dental hygienists' provision of preventive oral health care services, including cleanings, sealants and topical fluoride, when they are working in public health settings under the direction of the Department of Health and Environmental Control.

38. Nonetheless, when the Board in March 2003 considered the statutory revisions that the General Assembly later enacted, it maintained that in all settings where a dental hygienist provides treatment – whether public health or private practice – a licensed dentist has to see the patient and provide a treatment plan.

ANTICOMPETITIVE EFFECTS

39. The Board's acts and practices have had the effect of restraining competition unreasonably and injuring consumers in the following ways, among others:

Complaint

- a. hindering competition in the delivery of cleaning, sealant, topical fluoride, and other preventive dental services to school-aged children in South Carolina; and
- b. depriving thousands of school children – particularly economically disadvantaged school children – of the benefits of preventive oral health care.

VIOLATION

40. The combination, conspiracy, acts and practices described above constitute unfair methods of competition in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45. Such combination, conspiracy, acts, and practices, or the effects thereof, are continuing and will continue or recur in the absence of the relief herein requested.

NOTICE

Notice is hereby given to the Respondent that the fourteenth day of January, 2004, at 10:00 a.m., or such later date as determined by the Commission or by an Administrative Law Judge of the Commission, is hereby fixed as the time and Federal Trade Commission offices, 600 Pennsylvania Ave., N.W., Washington, D.C. 20580, as the place when and where a hearing will be had on the charges set forth in this Complaint, at which time and place you will have the right under the FTC 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.

Pending further order of the Commission, the Commission will retain adjudicative responsibility for this matter. *See* § 3.42(a) of the Commission's Rules of Practice for Adjudicative Proceedings. Pursuant to § 3.12 of those Rules, the Commission hereby allows you until 30 days from the date of service of this Complaint upon you to file either an answer or a dispositive motion. If you file a dispositive motion within that time, your time for filing an answer is

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extended until 10 days after service of the Commission's order on such motion. If you do not file a dispositive motion within that time, you must file an answer.

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 Administrative Law Judge shall file an initial decision containing appropriate findings and conclusions and an appropriate order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings and conclusions under § 3.46 of the Commission's Rules of Practice for Adjudicative Proceedings and the right to appeal the initial decision to the Commission under §3.52 of said Rules.

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 shall authorize the Administrative Law Judge, without further notice to you, to find the facts to be as alleged in the Complaint and to enter an initial decision containing such findings, appropriate conclusions, and order.

The Commission or the Administrative Law Judge will schedule an initial prehearing scheduling conference to be held not later than 14 days after an answer is filed by Respondent. Unless otherwise directed by the Commission or the Administrative Law Judge, the

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scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, NW, Room 532, Washington, D.C. 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 5 days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

NOTICE OF CONTEMPLATED RELIEF

Should the Commission conclude from the record developed in an adjudicative proceeding in this matter that the Board is in violation of Section 5 of the Federal Trade Commission Act, as alleged in the Complaint, the Commission may order such relief as is supported by the record and is necessary and appropriate, including, but not limited to, an order that requires the following:

1. The Board shall cease and desist from, either directly or indirectly, requiring that a dentist conduct an examination of a patient as a condition of a dental hygienist who is working in a public health setting pursuant to S.C. Code Ann. § 40-15-110(A)(10), or any recodification thereof, performing oral prophylaxis or applying sealants or topical fluoride to that patient, unless the examination requirement is adopted by the South Carolina General Assembly after the date that the order becomes final.

2. The Board shall mail a copy of the Complaint, order, and an explanatory notice to each Board member; each officer, director, representative, agent, and employee of the Board; each person licensed to practice dentistry or dental hygiene in South Carolina; and the superintendent of each school district in South Carolina.

3. The Board shall take such other measures that are appropriate to correct or remedy, or prevent the recurrence of, the anticompetitive practices in which it engaged.

Decision and Order

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this twelfth day of September, 2003, issues its Complaint against Respondent South Carolina State Board of Dentistry.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having heretofore issued its Complaint charging South Carolina State Board of Dentistry (“the Board”), hereinafter sometimes referred to as “Respondent,” with violating 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 Complaint, a statement that the signing of the 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 withdrawn this matter from adjudication in accordance with Section 3.25(f) of the Commission’s Rules, 16 C.F.R. § 3.25(f), and the Commission 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

Decision and Order

and consideration of public comments, and having duly considered the comments filed thereafter by interested persons pursuant to Section 3.25 of its Rules, now in further conformity with the procedure described in Section 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

1. Respondent is organized, exists, and transacts business under and by virtue of the laws of South Carolina, with its principal office at Synergy Business Park, Kingstree Building, 110 Centerview Dr., Columbia, South Carolina 29210.

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

- A. “South Carolina State Board of Dentistry” or “the Board” means South Carolina State Board of Dentistry, its members, officers, directors, committees, representatives, agents, employees, and successors, including, but not limited to, its executive director and investigators; and
- B. “Dental hygienist” means a person who practices dental hygiene, as defined in S.C. Code of Laws § 40-15-80.

Decision and Order

II.

IT IS FURTHER ORDERED that Respondent shall provide written notice to the Commission at least (30) thirty days prior to the promulgation of any proposed or final rule, regulation, policy, issuance of a formal complaint in a disciplinary action, or other action of the Board, relating to the provision by dental hygienists of preventive dental services in a public health setting pursuant to S.C. Code Ann. § 40-15-110(A)(10), or any recodification thereof, including, but not limited to, an action concerning a dentist who authorizes, supervises, or bills for, the provision by dental hygienists of preventive dental services in a public health setting.

Provided, however, that if protection of the public health prevents Respondent from notifying the Commission thirty days in advance of an action, then Respondent shall provide the notice required by this Paragraph as soon as is reasonably practicable.

III.

IT IS FURTHER ORDERED that Respondent shall:

- A. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail or electronic mail a notice in the form set forth in Appendix A of this Order, with a copy of the Order and Complaint attached, to:
 - 1. each Board member;
 - 2. each officer, director, representative, agent, and employee of the Board; and
 - 3. each person licensed to practice dentistry or dental hygiene in South Carolina.

Decision and Order

- B. Within thirty (30) days after the date on which this Order becomes final, distribute by first-class mail a notice in the form set forth in Appendix A of this Order, with a copy of the Order and Complaint attached, to the superintendent of each school district listed in Appendix B.
- C. Within thirty (30) days after the date on which this Order becomes final, publish a notice in the form set forth in Appendix A of this Order, along with a link to a copy of the Order and Complaint, on the South Carolina State Board of Dentistry website, and maintain these materials on the website for three (3) years from the date this Order becomes final.
- D. Publish a notice in the form set forth in Appendix A of this Order in the first South Carolina State Board of Dentistry newsletter to be published after the date this Order becomes final, and annually thereafter for three (3) years.
- E. For a period of three (3) years after the date this Order becomes final, distribute by first-class mail or electronic mail a notice in the form set forth in Appendix A of this Order, and attaching a copy of the Order and Complaint, to:
 - 1. any person who becomes a member of the Board, within thirty (30) days of the time his or her membership begins;
 - 2. any person who becomes an officer, director, representative, agent, or employee of the Board, within thirty (30) days of the time that he or she assumes such responsibility with the Board; and
 - 3. any person who becomes licensed to practice dentistry or dental hygiene in South Carolina, within thirty (30) days of the time he or she becomes licensed.

IV.

Decision and Order

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order becomes final, annually thereafter for three (3) years on the anniversary of the date this Order becomes final, and at such other times as the Commission may by written notice require, the Board shall submit to the Commission a verified written report detailing the manner and form in which the Board has complied and is complying with this Order.

V.

IT IS FURTHER ORDERED that, for purposes of determining or securing compliance with this Order, and upon written request with reasonable notice, 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 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; 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.

Decision and Order

VI.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change in the Board's authority to regulate the practice of dentistry and dental hygiene in South Carolina that may affect compliance obligations arising out of this Order, such as the complete or partial assumption of that authority by another governmental entity, or the dissolution of the Board.

VII.

IT IS FURTHER ORDERED that this Order shall terminate on September 6, 2017.

By the Commission.

Decision and Order

APPENDIX A

[date]

NOTICE

The South Carolina State Board of Dentistry has entered into a consent agreement with the Federal Trade Commission. In connection with the Commission's order issued pursuant to that agreement, which became final on [date], the Board is publishing this notice concerning the delivery of preventive dental services in public health settings:

The 2003 amendments to the Dental Practice Act (Act No. 45 of 2003) provide that the Board may not, directly or indirectly, require that a dentist conduct an examination of a patient as a condition of a dental hygienist who is working in a public health setting pursuant to S.C. Code Ann. § 40-15-110(A)(10), which pertains to licensed dental hygienists employed within or contracted through the public health system, or any recodification thereof, performing oral prophylaxis or applying sealants or topical fluoride to that patient.

The Board is in full agreement with the legislative policy set forth in the 2003 amendments as recited above.

resident

South Carolina State Board of Dentistry

Decision and Order

APPENDIX B

<u>Abbeville</u>	<u>Aiken</u>	<u>Allendale</u>	<u>Anderson 1</u>	<u>Anderson 2</u>	<u>Anderson 3</u>
<u>Anderson 4</u>	<u>Anderson 5</u>	<u>Bamberg 1</u>	<u>Bamberg 2</u>	<u>Barnwell 19</u>	<u>Barnwell 29</u>
<u>Barnwell 45</u>	<u>Beaufort</u>	<u>Berkeley</u>	<u>Calhoun</u>	<u>Charleston</u>	<u>Cherokee</u>
<u>Chester</u>	<u>Chesterfield</u>	<u>Clarendon 1</u>	<u>Clarendon 2</u>	<u>Clarendon 3</u>	<u>Colleton</u>
<u>Darlington</u>	<u>Dillon 1</u>	<u>Dillon 2</u>	<u>Dillon 3</u>	<u>Dorchester 2</u>	<u>Dorchester 4</u>
<u>Edgefield</u>	<u>Fairfield</u>	<u>Florence 1</u>	<u>Florence 2</u>	<u>Florence 3</u>	<u>Florence 4</u>
<u>Florence 5</u>	<u>Georgetown</u>	<u>Greenville</u>	<u>Greenwood 50</u>	<u>Greenwood 51</u>	<u>Greenwood 52</u>
<u>Hampton 1</u>	<u>Hampton 2</u>	<u>Horry</u>	<u>Jasper</u>	<u>Juvenile Justice</u>	<u>Kershaw</u>
<u>Lancaster</u>	<u>Laurens 55</u>	<u>Laurens 56</u>	<u>Lee</u>	<u>Lexington 1</u>	<u>Lexington 2</u>
<u>Lexington 3</u>	<u>Lexington 4</u>	<u>Lexington 5</u>	<u>Marion 1</u>	<u>Marion 2</u>	<u>Marion 7</u>
<u>Marlboro</u>	<u>McCormick</u>	<u>Newberry</u>	<u>Oconee</u>	<u>Orangeburg 3</u>	<u>Orangeburg 4</u>
<u>Orangeburg 5</u>	<u>Pickens</u>	<u>Richland 1</u>	<u>Richland 2</u>	<u>Saluda</u>	<u>Spartanburg 1</u>
<u>Spartanburg 2</u>	<u>Spartanburg 3</u>	<u>Spartanburg 4</u>	<u>Spartanburg 5</u>	<u>Spartanburg 6</u>	<u>Spartanburg 7</u>
<u>Sumter 17</u>	<u>Sumter 2</u>	<u>Union</u>	<u>Williamsburg</u>	<u>York 1</u>	<u>York 2</u>
<u>York 3</u>	<u>York 4</u>				

Analysis to Aid Public Comment

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

The Federal Trade Commission has accepted for public comment an agreement to a proposed consent order with the South Carolina State Board of Dentistry. The purpose of this analysis is to facilitate public comment on the proposed order. The analysis is not intended to constitute an official interpretation of the agreement and proposed order, or to modify their terms in any way. The proposed consent order has been placed on the public record for 30 days to receive comments by interested persons. Comments received during this period will become part of the public record. After 30 days, the Commission will review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed order final.

The proposed consent order has been entered into for settlement purposes only and does not constitute an admission by the Respondent that it violated the law or that the facts alleged in the complaint, other than the jurisdictional facts, are true.

The Challenged Conduct

The Commission's complaint, issued September 12, 2003, charges the South Carolina State Board of Dentistry with unlawfully restraining competition in the provision of preventive dental care services in South Carolina, in violation of Section 5 of the Federal Trade Commission Act. The Board is a state regulatory agency that licenses and regulates dentists and dental hygienists. The nine-member Board includes seven practicing dentists, six of whom are elected by the dentists in their local area.

The complaint alleges that the Board illegally restricted the ability of dental hygienists to provide preventive dental services (cleanings, topical fluoride treatments, and application of dental sealants) in school settings. The South Carolina legislature in 2000

Analysis to Aid Public Comment

eliminated a statutory requirement that a dentist examine each child before a hygienist may perform preventive care in schools, in order to address concerns that many schoolchildren, particularly those in low-income families, were receiving no preventive dental services. In July 2001, however, the Board adopted an emergency regulation that re-imposed the dentist examination requirement that the legislature had eliminated. As a result of the Board's action, a hygienist-owned company known as Health Promotion Services, which had begun sending hygienists to schools to provide preventive services under written protocols from a supervising dentist, had to change its business model and was able to serve far fewer patients.

By operation of South Carolina law, the emergency regulation expired after six months, in January 2002. By that time, the Board had published a proposal to adopt the dentist examination requirement as a permanent regulation. However, after a state administrative law judge concluded that the Board's proposed regulation was unreasonable and contravened state policy, the Board did not proceed with the permanent regulation.

The South Carolina legislature subsequently enacted legislation in May 2003 that expressly provides that dentist examination requirements applicable in some settings do not apply to dental hygienists' provision of preventive care services delivered in public health settings under the direction of the state health department. The new statute also added a provision stating that a dentist billing for services provided by a dental hygienist under such an arrangement was "clinically responsible" for the delivery of those services. Because in South Carolina dental hygienists cannot bill the state Medicaid program directly, this new provision would plainly apply to school-based preventive dental care programs. Aside from the general concern that the Board might once again defy a legislative change, there was evidence in Board minutes suggesting that the Board might interpret the "clinically responsible" language in the new statute to require that a licensed dentist examine a patient and provide a treatment plan in all settings, whether private dental offices or public health locations.

Post-Complaint Proceedings

Shortly after the complaint issued, the Board moved to dismiss the case, asserting that its actions were exempt from the antitrust laws by virtue of the state action doctrine. That doctrine, first articulated by the Supreme Court in *Parker v. Brown*, 317 U.S. 341 (1943), rests on the Court's holding that the Sherman Act was not intended to "restrain a state or its officers or agents from activities directed by its legislature." The Board also argued that the 2003 statute made it legally impossible for it to resume its challenged conduct and therefore rendered the case moot.

In a July 2004 opinion, the Commission rejected the Board's state action arguments.¹ As the Commission's opinion explains, the Board's claim to automatic state action protection by virtue of its status as a state agency is contrary to well-established Supreme Court precedent.² Furthermore, the Board failed to establish an essential element of the state action defense, because it was unable to show that its challenged conduct was undertaken pursuant to a clearly articulated policy of the legislature to displace competition with regard to the delivery of preventive dental care in schools. Neither the Board's general authority to regulate, nor its claims about the meaning of the state legislature's 2000 statutory revisions, demonstrated the requisite clear articulation to bring the challenged conduct within the protection afforded by the state action doctrine. On the contrary, the policy expressed by the legislature's elimination in 2000 of the statutory requirement for a dentist examination before dental hygienists could provide preventive services in schools was one favoring such competition, in order to increase access to

¹ In the Matter of South Carolina State Board of Dentistry, 138 F.T.C. 229, 230 (2004), available at <http://www.ftc.gov/os/adjpro/d9311/040728commissionopinion.pdf> and <http://www.ftc.gov/os/decisions/docs/Volume138.pdf>.

² See, e.g., *Southern Motor Carriers Rate Conf., Inc. v. United States*, 471 U.S. 48, at 57, 60-61 (1985).

Analysis to Aid Public Comment

critically important oral health care. Finally, because the Board failed to make a threshold showing of a legislative policy to displace the type of competition that it is charged with suppressing, its final argument, that any conflict with the 2000 statute was merely an error of state law and of no federal antitrust significance, failed as well.

The Board filed an appeal with the United States Court of Appeals for the Fourth Circuit seeking an interlocutory review of the Commission's state action ruling. The Commission moved to dismiss the appeal, arguing that the ruling did not fall within the narrow class of "collateral orders" that fall outside the general rule that interlocutory orders are not immediately appealable. The court of appeals agreed and dismissed the appeal for lack of jurisdiction. In its May 2006 decision in *South Carolina State Board of Dentistry v. F.T.C.*, 455 F.3d 436 (4th Cir. 2006), the court of appeals rejected the position of some other circuits, which have upheld interlocutory appeals from the denial of a claim of state action protection on the theory that the state action exemption is an immunity from suit:

[W]e cannot conclude that *Parker* creates an immunity from suit. The *Parker* doctrine did not arise from any concerns about special harms that would result from trial. Instead, *Parker* speaks only about the proper interpretation of the Sherman Act.

455 F.3d at 444.

With respect to the Board's arguments that the 2003 statute made it impossible for the Board to resume the challenged conduct, the Commission's July 2004 ruling rejected the Board's claim that the statute compelled dismissal of the complaint as a matter of law. Instead, it held the Board's motion to dismiss in abeyance pending discovery on factual issues relating to the risk of recurrence of the

Analysis to Aid Public Comment

challenged conduct.³ As noted in the Commission's decision, the very premise of the alleged violation in this case is that the Board flouted a statutory directive designed to promote competition and increase access to preventive dental services. Moreover, the complaint also alleges particular facts with regard to the Board's interpretation of language added by the 2003 statute that raise a significant risk of recurrence.

During the pendency of the Board's appeal on state action, the Commission stayed discovery in the case. The stay expired in January 2007, after the Supreme Court denied the Board's petition for certiorari seeking review of the appellate court's dismissal of the appeal, thereby clearing the way for discovery on the issues delegated to an FTC administrative law judge.

The Proposed Order

The proposed order has two central features:

- First, to eliminate the alleged anticompetitive effects of the challenged conduct, the proposed order requires the Board to affirm and publicize its support for the state legislative policy, now embodied in the 2003 amendments to the Dental Practice Act, that prevents the Board from requiring a dentist examination as a condition of dental hygienists providing preventive dental care in public health settings.
- Second, to prevent similar anticompetitive restraints in the future, the proposed order requires the Board to give the Commission advance notice before adopting rules or taking

³ Administrative agencies are not subject to the constitutional requirement of a "case or controversy" that limits the jurisdiction of Article III courts, but instead exercise discretion in deciding whether to hear cases that might be considered moot. See, e.g., *R.T. Communications, Inc. v. FCC*, 201 F.3d 1264, 1276 (10th Cir. 2001); *Tenn. Gas Pipeline Co. v. Fed. Power Comm'n*, 606 F.2d 1373, 1380 (D.C. Cir 1979).

Analysis to Aid Public Comment

other actions that relate to dental hygienists' provision of preventive dental services in a public health setting.

The Board announcement is set forth in Appendix A of the proposed order. That announcement: (1) expresses the Board's view that the 2003 statute prevents it from requiring a dentist examination when patients receive preventive services from dental hygienists working under arrangements with the state health department; and (2) states that the Board fully supports this legislative policy.

In addition to publication on the Board's website and in its newsletter, Paragraph III of the proposed order requires the Board to distribute this announcement, along with a copy of the Commission's complaint and order, to every dentist and dental hygienist holding a license to practice in South Carolina (and, for a period of three years, to new licensees), and to the superintendent of every school district in South Carolina. Widespread publication of this announcement is designed to remedy potentially significant chilling effects from the Board's past conduct on market participants who might otherwise be interested in participating in public health preventive dental care programs involving dental hygienists.

The proposed order's prior notice provision is contained in Paragraph II. It requires the Board to give the Commission written notice 30 days in advance of adopting proposed or final rules, policies, disciplinary and other actions, that relate to the provision by dental hygienists of preventive dental services in a public health setting pursuant to S.C. Code Ann. § 40-15-110(A)(10), a provision that governs dental hygienist practice in public health settings. The scope of the notice provision includes actions that concern dentists' authorizing, supervising, or billing for the provision by dental hygienists of preventive dental services in a public health setting. This prior notice requirement, which extends beyond the reinstitution of the restraint contained in the Board's 2001 emergency regulation, will enhance the Commission's ability to monitor the Board's future conduct and take prompt action where warranted.

Analysis to Aid Public Comment

The Commission has determined that it is not necessary to include a “cease and desist” provision that directly prohibits the Board from resuming the conduct challenged in the complaint. This conclusion rests on various factors particular to this case. A key factor is the experience in South Carolina since the 2003 changes to the South Carolina Dental Practice Act. The new statutory scheme has now been in place for nearly four years. Throughout this period, dental hygienists have been providing preventive services in schools under an agreement with the health department – without an initial examination by a dentist – and the Board has not reimposed its previous dentist examination requirement. Thus, although the 2003 amendments have not eliminated the need for relief in this case, they are a relevant consideration in determining the nature and scope of that relief.

Accordingly, the proposed order takes the statutory change into account. First, requiring the Board to distribute the announcement set forth in Appendix A to all dentists, dental hygienists, and school districts will ensure that interested parties know that the Board has formally acknowledged that it is legally barred from resuming the conduct challenged in the Commission’s complaint. Second, the notice requirement of Paragraph II addresses the possibility that the Board might attempt to restrain competition in the provision of dental hygienist services in public health settings in ways not addressed by the 2003 amendments. This notice provision will increase the Commission’s ability to monitor the Board’s future conduct and is likely to help deter the Board from imposing restraints on public health preventive dental care that are not grounded in the policies articulated by the South Carolina legislature.

As is standard in Commission orders, the proposed order contains certain reporting and other provisions that are designed to assist the Commission in monitoring compliance with the order.

Analysis to Aid Public Comment

The proposed order would expire in ten years.

Complaint

IN THE MATTER OF

JARDEN CORPORATION
AND
K2 INC.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket C-4196; File No. 071 0168**Complaint, August 8, 2007 – Decision, September 14, 2007*

This consent order addresses the \$1.2 billion acquisition by Jarden Corporation (“Jarden”) of K2 Incorporated (“K2”). The complaint alleged that the proposed 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. market for monofilament fishing line. The consent order requires the divestiture of Cajun Line[®], Omniflex[®], Outcast[®], and Supreme[™] monofilament fishing line products (the “Divested Assets”) to W. C. Bradley/Zebco (“Zebco”). Additionally, the order prohibits Jarden from using confidential information relating to the Divested Assets, and precludes certain key K2 employees from working at Jarden on competitive fishing line products for two years. The order further requires respondents to provide Zebco with the opportunity to enter into employment contracts with key individuals experienced in working with the Divested Assets.

Participants

For the *Commission*: Stephen Argeris, Sylvia M. Brooks, Mark Frankena, David Glasner, Tammy L. Imhoff, Brendan J. McNamara, Michael R. Moiseyev, and Louis Silvia.

For the *Respondents*: Christopher Dusseault, Gibson, Dunn & Crutcher; Mitchell D. Hollander, Kane Kessler; Raymond A. Jacobsen, Jr., McDermott, Will & Emery.

Complaint

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 Jarden Corporation (“Jarden”), a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets and voting securities of Respondent K2 Inc. (“K2”) (collectively “Respondents”), 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. RESPONDENT JARDEN

1. Respondent Jarden is a corporation organized, existing, and doing business under and by virtue the laws of the state of Delaware, with its office and principal place of business located at 555 Theodore Fremd Avenue, Suite B-302, Rye, NY 10580.

2. Respondent Jarden is engaged in, among other things, the research, development, manufacture, distribution, and sale of branded consumer and outdoor products, including fishing tackle sold through its subsidiary, Pure Fishing.

3. Respondent Jarden 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.

Complaint

II. RESPONDENT K2

4. Respondent K2 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 5818 El Camino Real, Carlsbad, CA 92008.

5. Respondent K2 is engaged in, among other things, the research, development, manufacture, distribution, and sale of branded sporting equipment, including fishing tackle sold through its subsidiary, Shakespeare.

6. Respondent K2 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 PROPOSED ACQUISITION

7. Pursuant to an Agreement and Plan of Merger dated as of April 24, 2007 (the “Agreement”), Jarden proposes to acquire 100% of the voting securities of K2 for approximately \$1.2 billion (the “Acquisition”).

IV. THE RELEVANT MARKET

8. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the acquisition is the research, development, manufacture, and sale of monofilament fishing line. Monofilament fishing line is the most widely-used and least expensive type of fishing line. It accounts for 60 to 75 percent of total sales for fishing line. While other specialized types of fishing line, including braided (or super line) and fluorocarbon, appear to be growing in popularity, especially among avid anglers,

Complaint

the vast majority of fishing line purchases in the United States are of monofilament line. The evidence indicates anglers, if faced with a five to ten percent increase in the price of monofilament line, would not switch to braided line or fluorocarbon line. Braided and fluorocarbon line are significantly more expensive than monofilament line and are used for particular fishing conditions.

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 line of commerce. Consistent with Commission findings in previous branded consumables cases, the need for distribution, infrastructure, and a U.S. sales force creates significant impediments to the ability of foreign firms to successfully and competitively import monofilament fishing line into the United States.

V. THE STRUCTURE OF THE MARKET

10. The relevant market for the manufacture, distribution, and sale of monofilament fishing line in the United States is highly concentrated as measured by the Herfindahl-Hirschman Index (“HHI”). Jarden dominates the monofilament fishing line market, and K2 is its most significant competitor. The proposed acquisition would entrench Jarden further as the dominant supplier of monofilament fishing line in the United States and increase concentration significantly.

VI. ENTRY CONDITIONS

11. Entry into the relevant line of commerce would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition set forth in Paragraph 12 below. Entry into the monofilament fishing line market would require the investment of high sunk costs to establish a brand name and provide promotional funding and advertising to support the product, which would be difficult to justify given the market structure and sales opportunities. As a result, new entry into any of these markets

Complaint

sufficient to achieve a significant market impact within two years is unlikely.

VII. 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 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 Respondents Jarden and K2 for the research, development, manufacture, and sale of monofilament fishing line in the United States;
- b. by increasing the ability of the merged entity to raise prices of monofilament fishing line unilaterally in the United States; and
- c. by reducing the merged entity's incentives to improve service or product quality for monofilament fishing line in the United States.

VIII. VIOLATIONS CHARGED

13. The Acquisition described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

14. The Acquisition described in Paragraph 7, 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 Maintain Assets

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this eighth day of August, 2007, 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 Jarden Corporation (“Jarden”) of Respondent K2 Inc. (“K2”), hereinafter referred to as “Respondents,” and Respondents 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 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 to accept the executed Consent Agreement and to

Order to Maintain Assets

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 Jarden 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 555 Theodore Fremd Avenue, Suite B-302, Rye, NY 10580.

2. Respondent K2 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 5818 El Camino Real, Carlsbad, CA 92008.

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 definitions used in the Consent Agreement and the proposed Decision and Order (and when made final, the Decision and Order), shall apply.

II.

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

A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and

Order to Maintain Assets

competitiveness of the assets and business associated with the Divestiture Assets, to minimize any risk of loss of competitive potential for the business associated with the Divestiture Assets, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the full economic viability, marketability or competitiveness of the Divestiture Assets.

- B. Respondents shall maintain the operations of the Divestiture Assets in the regular and ordinary course of business and in accordance with past practice (including regular repair and maintenance of the Divestiture Assets) and/or as may be necessary to preserve the marketability, viability, and competitiveness of each of the Divested Fishing Line Products associated with the Divestiture Assets and shall use their best efforts to preserve the existing relationships with the following: suppliers; vendors; distributors; customers; employees; and others having business relations with the Divestiture Assets. Respondents' responsibilities shall include, but are not limited to, the following:
1. providing the Divestiture Assets with sufficient working capital to operate the Divestiture Assets at least at current rates of operation, to meet all capital calls with respect to the Divestiture Assets and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Divestiture Assets;
 2. continuing, at least at their scheduled pace, any additional expenditures for the Divestiture Assets authorized prior to the date the Consent Agreement was signed by Respondents including, but not limited to, all research, development, and marketing expenditures;

Order to Maintain Assets

3. provide such resources as may be necessary to respond to competition against the Divested Fishing Line Products associated with the Divestiture Assets and/or to prevent any diminution in retail sales of such Products during and after the Acquisition and prior to divestiture;
 4. provide such resources as may be necessary to maintain the competitive strength and positioning of the Divested Fishing Line Products associated with the Divestiture Assets at all retail accounts;
 5. making available for use by the Divestiture Assets funds sufficient to perform all routine maintenance and all other maintenance as may be necessary to, and all replacements of, the Divestiture Assets;
 6. providing the Divestiture Assets with such funds as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Assets; and
 7. providing such support services to the Divestiture Assets as were being provided to these businesses by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. Respondents shall maintain a work force at least as equivalent in size, training, and expertise to what has been associated with the Divestiture Assets for the relevant Divested Fishing Line Product's most recent pre-Acquisition marketing plan.
- D. Respondents shall, until the Divestiture Date, provide all Divestiture Assets Core Employees with reasonable financial incentives to continue in their positions and to market and promote the Divestiture Assets consistent with past practices and/or as may be necessary to preserve the marketability,

Order to Maintain Assets

viability and competitiveness of the Divestiture Assets and to ensure successful execution of the pre-Acquisition marketing plans related to the Divestiture Assets. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Divestiture Date has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law). In addition to the foregoing, Respondents shall provide to each Divestiture Assets Key Employee who accepts employment with the Commission-approved Acquirer, an incentive equal to twenty-five (25) percent of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with the Commission-approved Acquirer;

provided, however, that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of Divestiture Assets Key Employees (other than those conditions contained in this Order) in connection with the Acquisition or prevents the Respondents from continuing the employment of the Divestiture Assets Key Employees in connection with the Acquisition.

- E. During the Employee Access Period, Respondents shall not interfere with the hiring or employing by the Commission-approved Acquirer of Divestiture Assets Key Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete or nondisclosure provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Assets Key Employee who

Order to Maintain Assets

receives a written offer of employment from the Commission-approved Acquirer;

provided, however, that this Paragraph E. shall not prohibit the Respondents from making offers of employment to or employing any Divestiture Assets Key Employee during the Employee Access Period where the Commission-approved Acquirer has notified the Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee;

provided further that if the Respondents notify the Commission-approved Acquirer in writing of their desire to make an offer of employment to a particular Divestiture Assets Key Employee and the Commission-approved Acquirer does not make an offer of employment to that employee within twenty (20) Days of the date the Commission-approved Acquirer receives such notice, the Respondents may make an offer of employment to that employee.

- F. Pending divestiture of the relevant Divestiture Assets, Respondents shall:
1. not use, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing, or sale of the Divestiture Assets other than as necessary to comply with the requirements of this Order or the Decision and Order;
 2. not disclose or convey any Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer; and
 3. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business

Order to Maintain Assets

Information related to the research, development, manufacturing, marketing or sale of the Divestiture Assets.

- G. Not later than five (5) days after the Acquisition Date, or the date on which this Order to Maintain Assets becomes final, whichever is earlier, Respondents shall provide written or electronic notification of the restrictions on the use of the Confidential Business Information by Respondents' personnel to all of Respondents' employees who:
1. are, or were, directly involved in the research, development, manufacturing, distribution, sale or marketing of the Divestiture Assets;
 2. are directly involved in the research, development, manufacturing, distribution, sale or marketing of Respondents' Fishing Line products; and
 3. may have Confidential Business Information.

Respondents shall provide such notification (in a form similar to that attached as Appendix B. to this Order to Maintain Assets) by e-mail with return receipt requested or by whatever manner or form of transmission as will assure receipt and acknowledgment by Respondents' employees, and keep a file of such receipts for one (1) year after the relevant Divestiture Date. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters, and 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 Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel relating to the Divestiture Assets.

Order to Maintain Assets

- H. Respondents shall adhere to and abide by the Divestiture Assets Supply Agreement, Transition Services Agreement and the Respondent Run-Off Licenses (“Agreements”). These Agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the related Decision and Order and this Order to Maintain Assets (“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.
- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the business associated with the Divestiture Assets, to minimize any risk of loss of competitive potential for the business associated with the Divestiture Assets, 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, within thirty (30) Days after the date this Order to Maintain Assets becomes final, and every thirty (30) Days thereafter until Respondents have fully complied with their obligations to divest the Divestiture Assets as required by Paragraphs II. and III. 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, the reports due under this Order to Maintain Assets may be consolidated with, and submitted to the Commission at the

Order to Maintain Assets

same time as, the reports required to be submitted by Respondents pursuant to Paragraph V. of the Decision and Order.

IV.

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 the order, including, but not limited to, assignment, the creation or dissolution of subsidiaries, or any other change in Respondents.

V.

IT IS FURTHER ORDERED that, for the purposes of determining or securing compliance with this Order to Maintain Assets, and subject to any legally recognized privilege, and upon written request with reasonable notice to Respondents made to their principal United States offices, Respondents shall permit any duly authorized representatives of the Commission:

- A. Access, during 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 Respondents relating to compliance with this Order to Maintain Assets; and
- B. Upon five (5) Days notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

VI.

Order to Maintain Assets

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 day after the divestiture of the Divestiture Assets, as required by and described in the Decision and Order, has been completed and Respondents notify the Commission that all related assignments, conveyances, deliveries, grants, licenses, transactions, transfers and other transitions are complete, or the Commission otherwise directs that this Order to Maintain Assets is terminated.

By the Commission.

Order to Maintain Assets

**PUBLIC
APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS
AGREEMENT CONTAINING CONSENT ORDERS
AND
PROPOSED DECISION AND ORDER**

Order to Maintain Assets

**PUBLIC
APPENDIX B
TO THE ORDER TO MAINTAIN ASSETS****NOTICE OF FTC ORDERS AND REQUIREMENT TO
MAINTAIN CONFIDENTIALITY**

Jarden Corporation (“Jarden”) and K2 Inc. (“K2”), hereinafter referred to as “Respondents,” have entered into an Agreement Containing Consent Orders (“Consent Agreement”) with the Federal Trade Commission (“FTC”) providing for divestiture of certain assets and other relief, in connection with the acquisition of K2 by Jarden. That Consent Agreement includes two orders: the Decision and Order and the Order to Maintain Assets.

The Decision and Order requires the divestiture of assets relating to Cajun Line®, Omniflex®, Outcast®, and Supreme™ monofilament fishing line products. These assets are hereinafter referred to as the “Divestiture Assets.” Both the Decision and Order and the Order to Maintain Assets require Respondents to commit that no Confidential Business Information relating to the Divestiture Assets will be disclosed to or used by any employee of the combined entity formed by the acquisition of a controlling interest in K2 by Jarden (“Combined Entity”). In particular, this is to protect such information from being used in any way for the research, development, sale or manufacture of any product that competes or may compete with any product that is marketed by the Respondents after the proposed acquisition. The Decision and Order also requires the complete divestiture of ALL documents (including electronically stored material) that contain Confidential Business Information related to the Divestiture Assets. Accordingly, no employee of the Combined Entity may maintain copies of documents containing such information, except as otherwise required by law.

Under the Decision and Order, the Respondents are required to divest the Divestiture Assets to W.C. Bradley/Zebco (“Zebco”). Until a complete divestiture of all of the Divestiture Assets occurs, the requirements of the second order – the Order to Maintain Assets – are in place to ensure the continued marketability, viability and

Order to Maintain Assets

competitive vigor of the Divestiture Assets and to ensure that no confidential business information related to the Divestiture Assets is communicated to the employees of Jarden.

You are receiving this notice because you are one or more of the following: (i) an employee with work responsibilities related to the Divestiture Assets; (ii) an employee for Jarden, or the Combined Entity, who has work responsibilities in some way related to products that compete or may compete with the Divestiture Assets; or (iii) an employee, former employee, contractor, or former contractor of K2 who might have Confidential Business Information in your possession related to Divestiture Assets.

All Confidential Business Information related to the Divestiture Assets must be retained and maintained by the persons involved in the operation of that business on a confidential basis, and such persons must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment involves responsibilities unrelated to the Divestiture Assets (such as persons with job responsibilities related to Jarden or K2 products that compete or may compete with the Divestiture Assets). In addition, any person who possesses such Confidential Business Information related to the Divestiture Assets and who becomes involved in the Combined Entity's business related to any product that competes or may compete with the Divestiture Assets must not provide, discuss, exchange, circulate, or otherwise disclose any such information to or with any other person whose employment relates to such businesses. Finally, any K2 employee, former employee, contractor, or former contractor, with documents that contain information that he or she believes might be considered Confidential Business Information related to Divestiture Assets and who has not received specific instructions as to how the documents in his or her possession should be disposed of should contact the contact person identified at the end of this notice.

Furthermore, the Decision and Order places restrictions upon the functions that certain employees of K2 can perform for the Combined Entity until two years (2) from the date of the divestiture of all of the Divestiture Assets.

Order to Maintain Assets

Any violation of the Decision and Order or the Order to Maintain Assets may subject Jarden, K2, or the Combined Entity to civil penalties and other relief as provided by law. If you have any questions regarding the contents of this notice, the confidentiality of information, the Decision and Order or the Order to Maintain Assets, you should contact [insert name and title].

ACKNOWLEDGMENT

I, _____ (print name), hereby acknowledge that I have read the above notification and agree to abide by its provisions.

Decision and Order

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Jarden Corporation (“Jarden”) of Respondent K2 Inc. (“K2”), hereinafter referred to as “Respondents,” and Respondents 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 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 (attached to this Order as Appendix II.), 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”):

Decision and Order

1. Respondent Jarden 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 555 Theodore Fremd Avenue, Suite B-302, Rye, NY 10580.

2. Respondent K2 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 5818 El Camino Real, Carlsbad, CA 92008.

3. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

I.

- A. “Jarden” means Jarden Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Jarden, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each. After the Acquisition, Jarden shall include K2.
- B. “K2” means K2 Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by K2, including, without limitation, Shakespeare Company, LLC, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.
- C. “Respondents” means Jarden and K2, individually and collectively.

Decision and Order

- D. “Zebco” means W.C. Bradley/Zebco Holdings Group, Inc., a corporation organized, existing and doing business under and by virtue of the laws of the state of Georgia, with its offices and principal place of business located at 6101 E. Apache, Tulsa, OK 74115.
- E. “Commission” means the Federal Trade Commission.
- F. “Acquisition” means the acquisition contemplated by the Merger Agreement and Plan of Merger by and among Jarden and K2, dated as of April 24, 2007.
- G. “Acquisition Date” means the date the Respondents close on the Acquisition pursuant to the Acquisition Agreement.
- H. “Acquirer Run-off License” means a transitional, non-exclusive, non-transferable, fully-paid, royalty-free limited license entered into by and among Respondents and the Commission-approved Acquirer to allow the Commission-approved Acquirer to use the Shakespeare Name and Marks for a period not to exceed eighteen (18) months after the Divestiture Date in connection with the sale of inventory of Divested Fishing Line Products that are labeled with the Shakespeare Name and Marks and that are acquired as part of the Divestiture Assets.
- I. “Acquired Assets Finished Inventory” means the finished inventory consisting of products incorporating Divested Fishing Line Products on which the Divested Fishing Line Products Names and Marks appear (including on packaging) that will be acquired by Respondent Jarden in connection with the Acquisition, including such finished inventory that exists within one hundred five days (105) after the Divestiture Date.

Decision and Order

- J. “Asset Purchase Agreement” means the July 31, 2007, Asset Purchase Agreement by and between Zebco and Shakespeare Company, LLC, a subsidiary of K2.
- K. “Commission-approved Acquirer” means the following: (1) Zebco; or (2) an entity approved by the Commission to acquire the Divestiture Assets that the Respondents are required divest pursuant to this Order.
- L. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondents that is not in the public domain and that is related to the research, development, manufacture, marketing, commercialization, importation, exportation, cost, pricing, supply, sales, sales support or use of the Divested Fishing Line Products or Divestiture Assets, respectively;

provided however, that Confidential Business Information shall not include 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 Respondents;
2. information related to the Divested Fishing Line Products or Divestiture Assets that Respondent Jarden can demonstrate it obtained without the assistance of Respondent K2 prior to the Acquisition;
3. information that is required by law to be publicly disclosed; or
4. information that does not relate to the Divested Fishing Line Products or Divestiture Assets.

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- M. “Divested Fishing Line Products” means any and all Fishing Line sold under or incorporating the commercial, trade or brand names “Cajun” (including, without limitation, “Cajun Line,” “Cajun Red,” and “Cajun Braid”), “Omniflex,” “Outcast,” and “Supreme.”
- N. “Divested Fishing Line Products Names and Marks” means the commercial, trade or brand names “Cajun” (including, without limitation, “Cajun Line,” “Cajun Red,” and “Cajun Braid”), “Omniflex,” “Outcast,” and “Supreme,” and any similar name(s) or derivatives or variations thereof, in every jurisdiction throughout the world, and all associated trademarks and trade dress.
- O. “Divestiture Assets” means all of the Respondents’ rights, title and interest in and to all assets related to the Respondents’ business of designing, manufacturing, marketing, selling, sourcing and distributing Fishing Line under the brand names Cajun (including, without limitation, Cajun Line, Cajun Red, and Cajun Braid), Omniflex; Outcast, and Supreme, including, without limitation (except for the Excluded Assets) the following:
1. all finished inventory, on hand or in transit, relating to the Divestiture Assets except as listed in the Excluded Assets;
 2. to the extent they relate to the Divestiture Assets, (i) all purchase or customer orders (to the extent not already filled by the Respondents in the ordinary course of business), (ii) the contracts, agreements and leases and all outstanding offers or solicitations made by or to the Respondents to enter into any contract set forth in Schedule 1.1(b) of the Asset Purchase Agreement, and (iii) all of the Respondents’ transferable licenses, quotas, consents, permits and approvals as set forth in Schedule 1.1(b) of the Asset Purchase Agreement;

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3. Divestiture Assets Intellectual Property;
4. all of the Respondents' books, records, books of account, sales and purchase records, lists of customers and prospects, lists of suppliers, marketing and promotional materials and other product information, UPC codes, pricing information, operations information, sales programs and any deviations and all other documents, files, records and other data and information of the Respondents (whether stored on hard or floppy disks or other media), relating to the operation of the Divestiture Assets; *provided, however*, that in cases in which documents or other materials included in the Divestiture Assets contain information: (1) that relates both to the Divested Fishing Line Products and to other products or businesses of Respondent K2 and cannot be segregated in a manner that preserves the usefulness of the information as it relates to the Divested Fishing Line Products; or (2) for which Respondent K2 has a legal obligation to retain the original copies, Respondent K2 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 Commission-approved Acquirer, Respondent K2 shall provide the Commission-approved 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 Respondent K2 provides the Commission-approved Acquirer with the above described information without requiring Respondent K2 completely to divest itself of information that, in content, also relates to products and businesses other than the Divested Fishing Line Products;

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5. all goodwill that relates to, or otherwise arises out of the Divestiture Assets business, including, without limitation, all goodwill associated with trademarks, service marks, and other Divestiture Assets Intellectual Property, together with the right to represent to third parties that the Commission-approved Acquirer is the successor to the Respondents' Divestiture Assets business; and
 6. any and all other assets of Respondent K2 relating to or otherwise used or held for use in the Divestiture Assets business, tangible or intangible, wherever located, belonging to or licensed to Respondent K2 as of the Divestiture Date, including any trade show materials used only for Respondent K2's fishing line business, but excluding the Excluded Assets.
- P. "Divestiture Assets Intellectual Property" means: all patents and applications therefor, trademarks and service marks (registered or unregistered) and applications therefor, commercial, trade or brand names, business and product names, logos, internet web sites, internet domain names, trade dress, copyrights, copyright registrations and applications therefor, owned, possessed, used or held by or licensed to the Respondents related to the operation of the Divestiture Assets and as set forth in Schedule 1.1(c) of the Asset Purchase Agreement, together with, to the extent applicable, intellectual designs, formulas, know-how, trade secrets, technical and manufacturing processes and information, testing and operating techniques and procedures, engineering data and plans including mold and manufacturing drawings, assembly and installation drawings, blueprints, procurement specifications and engineering and performance specifications, scientific experiments demonstrating that the color red is the first to be filtered out underwater and any other research data relating to the red Fishing Line product, as well as any marketing materials and

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information including marketing plans, surveys and strategies, promotional concepts, artwork, photographs, brochures, catalogs, print, television, radio and internet advertising, product packaging and packaging design and other proprietary information or materials owned or used by the Respondents in relation to the operation of the Divestiture Assets.

- Q. “Divestiture Assets Core Employees” means “Divestiture Assets Key Employee(s),” “Divestiture Assets Marketing Employee(s),” and “Divestiture Assets Research and Development Employee(s).”
- R. “Divestiture Assets Key Employee(s)” means those employees of Respondents that, within two years prior to the Divestiture Date, have dedicated at least ten (10) percent of working time to the Divestiture Assets, including, without limitation, those employees specifically identified in Appendix III. of this Order.
- S. “Divestiture Assets Marketing Employee(s)” means all salaried management level employees of Respondent K2 who directly have participated (irrespective of portion of working time involved, unless such participation was a part of a broad executive management portfolio, or of oversight of legal, accounting, tax or financial compliance) in the formulation of brand marketing or sales strategies, including pricing, discount, allowance, promotion, and advertising strategies relating to the Divested Fishing Line Products or Divestiture Assets in the United States within the eighteen (18) month period immediately prior to the Divestiture Date. These employees include, without limitation, employees involved in brand management, sales training, and market research, and the Divestiture Assets Key Employees.
- T. “Divestiture Assets Research and Development Employee(s)” means all salaried employees of Respondent

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K2 who directly have participated (irrespective of the portion of working time involved, unless such participation was a part of a broad executive management portfolio, or of oversight of legal, accounting, tax or financial compliance) in the research, development, or quality control approval process for the Divested Fishing Line Products or Divestiture Assets within the eighteen (18) month period immediately prior to the Divestiture Date.

- U. “Divestiture Assets Supply Agreement” means the July 31, 2007 Non-Exclusive Supply Agreement entered into by and between Zebco and Shakespeare Company, LLC, a subsidiary of K2, appended to the Asset Purchase Agreement as Exhibit A, and all amendments, exhibits, attachments, and schedules thereto, or, if Zebco is not the Commission-approved Acquirer, any other supply agreement entered into by and among Respondents and a Commission-approved Acquirer, provided such agreement will not be entered into without the consent of the Commission.
- V. “Divestiture Date” means the date on which Respondents (or a Divestiture Trustee) divests to a Commission-approved Acquirer the Divestiture Assets completely as required by Paragraph II. (or Paragraph III.) of this Order.
- W. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to Paragraph III. of this Order.
- X. “Excluded Assets” means:
 - 1. all cash, cash equivalents, and short term investments of Respondents;
 - 2. all real property of Respondents;
 - 3. all accounts receivable of Respondents, including all accounts owned or acquired by Respondents including, without limitation, accounts receivable, notes and notes

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receivable, other receivables, book debts, and other forms of obligations to Respondents that relate to, or otherwise arise out of, the Divestiture Assets prior to the Divestiture Date;

4. all minute books, charter documents, stock records, tax returns, books of account, and other constituent records relating to the company organization of Respondents;
5. all rights of Respondents relating to deposits and prepaid expenses and claims for refunds and rights of offset, except as expressly pursuant to the contracts and other agreements listed in Schedule 1.1(b) of the Asset Purchase Agreement;
6. all rights of Respondents relating to claims for refunds of taxes or other governmental charges of any nature;
7. all leases, licenses, contracts, agreements, consensual obligations, promises, consents, permits, approvals or undertakings or legally binding arrangements or commitments to which Respondents are a party or are legally bound by, or the rights thereunder, except as included in the contracts and agreements listed in Schedule 1.1(b) of the Asset Purchase Agreement;
8. all fixed assets of Respondents, wherever located, consisting of machinery and equipment, wherever located, including processing equipment, conveyors, machine tools, tools, tooling, data processing and computer equipment and systems, including all software, embedded or otherwise, and peripheral equipment and all engineering, processing and manufacturing equipment, office machinery, furniture, materials handling equipment, attachments, accessories, automotive equipment, trailers, trucks, forklifts, molds,

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dies, stamps, motor vehicles, rolling stock and other equipment of every kind and nature, trade fixtures and fixtures not forming a part of real property, together with all additions and accessions thereto, replacements therefor, all parts therefor or thereof, all substitutes for any of the foregoing, fuel therefor, and all manuals, drawings, instructions, warranties and rights with respect thereto, and all products and proceeds thereof and condemnation awards with respect thereto;

9. all insurance policies of Respondents and all rights, benefits and proceeds thereunder;
10. all subsidiaries of Respondents or any Person or entity under common control with Respondents or any equity thereof and all rights, title and interests owned by Respondents in any Person or entity, including any joint ventures or other business associations;
11. all rights of Respondents under express or implied warranties from suppliers and all other guarantees, warranties, indemnities, and similar rights in favor of Respondents, except as expressly pursuant to the contracts and other agreements listed in Schedule 1.1(b) of the Asset Purchase Agreement;
12. all of Respondents' claims and causes of action, except to the extent specifically and exclusively related to the Divestiture Assets;
13. any trademark licensed to or used by the Commission-approved Acquirer pursuant to or in connection with the Acquirer Run-off License;
14. all rights of Respondents under the Asset Purchase Agreement or the Respondent Run-off License;

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15. all current employees, officers, consultants or directors of Respondents; *provided, however*, that the foregoing shall not affect obligations of Respondents under Paragraph II. of this Order;
16. all rights, title, and interest in and to the Shakespeare Name and Marks, the worldwide applications and registrations for the Shakespeare trademark provided in, and the common law rights to the Shakespeare trademark, and in each case, any similar name or derivations thereof, including, without limitation, the trademark “Shakespeare Supreme”; *provided, however*, that the foregoing shall not affect the obligations of the Respondents under Paragraph IV.D. of this Order;
17. any Cajun Red inventory in excess of net book value in the aggregate of \$450,000 which excess inventory is intended to be sold to the Commission-approved Acquirer pursuant to the Divestiture Assets Supply Agreement;
18. any finished inventory related to Fishing Line under the brand name Omniflex, which inventory is intended to be sold to the Commission-approved Acquirer pursuant to the Divestiture Assets Supply Agreement;
19. any unfinished inventory relating to the Divestiture Assets, which unfinished inventory is intended to be used to manufacture finished inventory sold to the Commission-approved Acquirer pursuant to the Divestiture Assets Supply Agreement;
20. all assets and rights of Respondents not used in relation to the Divestiture Assets;

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21. all trade show materials which are used by Respondents for any business other than their Fishing Line businesses;
22. all right, title and interest in any and all patents and applications therefor and invention disclosures for or in relation to fishing reels, fishing rods, fishing tackle (other than Fishing Line), fishing tools, fishing kits and combos and fishing accessories;
23. all right, title and interest in any and all patents and applications therefor and invention disclosures for or in relation to Respondent K2's monofilament business for any function or application other than fishing line, including, without limitation, any industrial applications, weed trimmer line, cutting line, woven mats, carpeting, fabrics, paper production and any monofilament of a tensile strength and softness not used or usable for fishing line;
24. all right, title and interest in and to the Penn, Ugly Stik, Pflueger, Xtools, JRC and All-Star trademarks, the worldwide applications and registrations for the Penn, Ugly Stik, Pflueger, Xtools, JRC and All-Star trademarks provided in, and the common law rights to the Penn, Ugly Stik, Pflueger, Xtools, JRC and All-Star trademarks, and in each case, any similar name(s) or derivations thereof;
25. all right, title and interest in and to the patents and applications therefor and invention disclosures and all trademarks and applications therefor identified in Appendix IV. of this Order, the worldwide applications and registrations for such trademarks, and the common law rights to such trademarks, and in each case, any similar name(s) or derivations thereof;

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26. any asset or right used exclusively in relation to the Penn Fishing Tackle Mfg. Co. business of designing, manufacturing, selling, sourcing and distributing of fishing line;
 27. any asset or right used exclusively in relation to the business of designing, manufacturing, selling, sourcing and distributing of fishing line under the “Ugly Braid” brand name;
 28. all fishing kits and combos inventory to be sold off by Respondents pursuant to the Respondent Run-off License; and
 29. any and all rights and obligations of Respondents under or in connection with customer purchase orders to the extent such orders correspond to any products other than the Divested Fishing Line Products.
- Y. “Fishing Line” means any type, grade, or quality of monofilament, braided or super line, or fluorocarbon fishing line.
- Z. “Fishing Tackle Products” means any Fishing Line, fishing rods, fishing reels, or combination fishing rod and reel combination (or kits).
- AA. “Person” means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or governmental entity, and any subsidiaries, divisions, groups or affiliates thereof.
- BB. “Order to Maintain Assets” means the Order to Maintain Assets incorporated into and made a part of the Agreement

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Containing Consent Orders. The Order to Maintain Assets is attached to this Order and contained in Appendix II.

- CC. “Respondent Run-off License” means a transitional, non-exclusive, non-transferable, fully-paid, royalty-free limited license entered into by and among Respondents and the Commission-approved Acquirer to allow Respondents to use the Divested Fishing Line Product Names and Marks for a period of time not to exceed eighteen (18) months after the Acquisition Date in connection with the sale of the Acquired Assets Finished Inventory.
- DD. “Shakespeare Name and Marks” means the commercial, trade or brand name “Shakespeare,” and any variation of this name, and all associated trademarks and trade dress.
- EE. “Transition Services Agreement” means the July 31, 2007 Transition Services Agreement by and between Zebco and Shakespeare Company, LLC, a subsidiary of K2, appended to the Asset Purchase Agreement as Exhibit B.

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

- A. Not later than fifteen (15) days after the Acquisition Date, Respondents shall divest the Divestiture Assets, absolutely and in good faith, to Zebco pursuant to and in accordance with the Asset Purchase Agreement. The Asset Purchase Agreement is incorporated by reference into this Order and made a part hereof as Non-Public Appendix I. Any failure by Respondents to comply with the Asset Purchase Agreement shall constitute a failure to comply with this Order. The Asset Purchase 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 Zebco, or any obligations of Respondents, under the Asset Purchase Agreement. If any term of the Asset Purchase 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. Notwithstanding any paragraph, section, or other provision of the Asset Purchase Agreement, any failure to meet any condition precedent to closing (whether waived or not) or any modification of the Asset Purchase Agreement, without the prior approval of the Commission, shall constitute a failure to comply with this Order.

Provided, however, that if Respondents have divested the Divestiture Assets to Zebco 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 Zebco is not an acceptable purchaser of the Divestiture Assets, then Respondents shall immediately rescind the transaction with Zebco and shall divest the

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Divestiture Assets within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-approved Acquirer and only in a manner that receives the prior approval of the Commission;

provided further, however, that if the Respondents have divested the Divestiture Assets to Zebco prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies the Respondents that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondents, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture of the Divestiture Assets to Zebco (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;

provided further, however, that Respondents may not modify or amend the Divestiture Agreement without receiving the prior approval of the Commission.

B. As related to the Divestiture Assets, Respondents shall:

1. submit and deliver to the Commission-approved Acquirer, at Respondents' expense, in good faith and as soon as practicable, in a manner that ensures its completeness and accuracy, all Confidential Business Information;
2. provide the Commission-approved Acquirer with access to all Confidential Business Information and to employees who possess or are able to locate or identify the books, records, and files that contain Confidential Business Information pending complete delivery of all the Confidential Business Information;

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3. not use, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing, or sale of the Divestiture Assets other than as necessary to comply with the requirements of this Order;
 4. not disclose or convey any Confidential Business Information, directly or indirectly, to any person except the Commission-approved Acquirer; and
 5. not provide, disclose or otherwise make available, directly or indirectly, any Confidential Business Information related to the research, development, manufacturing, marketing or sale of the Divestiture Assets.
- C. Not later than five (5) days after the Acquisition Date, or the date on which the Order to Maintain Assets becomes final, whichever is earlier, Respondents shall provide written or electronic notification of the restrictions on the use of the Confidential Business Information by Respondents' personnel to all of Respondents' employees who:
1. are, or were, directly involved in the research, development, manufacturing, distribution, sale or marketing of the Divestiture Assets;
 2. are directly involved in the research, development, manufacturing, distribution, sale or marketing of Respondents' Fishing Line products; and
 3. may have Confidential Business Information.

Respondents shall provide such notification (in a form similar to that attached as Appendix B. to the Order to

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Maintain Assets) by email with return receipt requested or by whatever manner or form of transmission as will assure receipt and acknowledgment by Respondents' employees, and keep a file of such receipts for one (1) year after the relevant Divestiture Date. Respondents shall maintain complete records of all such agreements at Respondents' corporate headquarters, and 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 Commission-approved Acquirer with copies of all certifications, notifications and reminders sent to Respondents' personnel relating to the Divestiture Assets.

- D. Respondents shall prohibit any Divestiture Asset Marketing Employees and Divestiture Asset Research and Development Employees, with the exception of James Therrell, Advanced Product Engineer and Quality Control Manager for Shakespeare, from participating in the sales, marketing, or research and development of Respondents' Fishing Line products for a period of two (2) years after the Divestiture Date.
- E. Respondents shall require, to the extent lawful, as a condition of continued employment post-divestiture of the Divestiture Assets, that each Divestiture Assets Marketing Employee or Divestiture Assets Research and Development Employee retained by Respondents, and the direct supervisor(s) of any such employee, sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Assets strictly confidential, including the nondisclosure of such information to all other employees, executives, or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

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F. Respondents shall:

1. for a period of up to one (1) year from the Divestiture Date, provide the Commission-approved Acquirer with the opportunity to enter into employment contracts with the Divestiture Assets Employees. This period is hereinafter referred to as the “Employee Access Period”; and
2. not later than ten (10) days after the Divestiture Date, Respondents shall, subject to compliance with all laws: (1) provide the Commission-approved Acquirer with a list of all the Divestiture Assets Key Employees; (2) allow the Commission-approved Acquirer to interview any of the Divestiture Assets Key Employees; and (3) allow the Commission-approved Acquirer access to the personnel files and other documentation (“Employee Information”) relating to such Divestiture Assets Key Employees. Failure by Respondents to provide the Employee Information for any relevant employee within the time provided herein shall extend the Employee Access Period with respect to that employee in an amount equal to the delay.
3. provide an opportunity for the Commission-approved Acquirer to: (1) meet personally, and outside of the presence or hearing of any employee or agent of Respondents, with any one or more of the Divestiture Assets Key Employees; and (2) make offers of employment to any one or more of the Divestiture Assets Key Employees.

G. Respondents shall:

1. during the Employee Access Period, not interfere with the hiring or employing by the Commission-approved

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Acquirer of Divestiture Assets Key Employees, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the Commission-approved Acquirer, including, but not limited to, any non-compete or nondisclosure provisions of employment or other contracts with Respondents that would affect the ability or incentive of those individuals to be employed by the Commission-approved Acquirer. In addition, Respondents shall not make any counteroffer to a Divestiture Assets Key Employee who receives a written offer of employment from the Commission-approved Acquirer;

provided, however, that this Paragraph II.G.1 shall not prohibit the Respondents from making offers of employment to or employing any Divestiture Assets Key Employee during the Employee Access Period where the Commission-approved Acquirer has notified the Respondents in writing that the Commission-approved Acquirer does not intend to make an offer of employment to that employee;

provided further that if the Respondents notify the Commission-approved Acquirer in writing of their desire to make an offer of employment to a particular Divestiture Assets Key Employee and the Commission-approved Acquirer does not make an offer of employment to that employee within twenty (20) Days of the date the Commission-approved Acquirer receives such notice, the Respondents may make an offer of employment to that employee;

2. until the Divestiture Date, provide all Divestiture Assets Core Employees with reasonable financial incentives to continue in their positions and to market and promote the Divestiture Assets consistent with past practices and/or

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as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Assets and to ensure successful execution of the pre-Acquisition marketing plans related to the Divestiture Assets. Such incentives shall include a continuation of all employee compensation and benefits offered by Respondents until the Divestiture Date has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law). In addition to the foregoing, Respondents shall provide to each Divestiture Assets Key Employee who accepts employment with the Commission-approved Acquirer, an incentive equal to twenty-five (25) percent of such employee's base annual salary to be paid upon the employee's completion of one (1) year of employment with the Commission-approved Acquirer;

provided, however, that nothing in this Order requires or shall be construed to require the Respondents to terminate the employment of any employee or prevent Respondents from continuing the employment of Divestiture Assets Key Employees (other than those conditions contained in this Order) in connection with the Acquisition or prevents the Respondents from continuing the employment of the Divestiture Assets Key Employees in connection with the Acquisition; and

3. for a period of one (1) year from the Divestiture Date, not:
 - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Commission-approved Acquirer with any amount of responsibility related to the Divestiture Assets ("Divestiture Employee") to terminate his or her

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employment relationship with the Commission-approved Acquirer; or

- b. hire any Divestiture Employee;

provided, however, Respondents may hire any former Divestiture Employee whose employment has been terminated by the Commission-approved Acquirer or who independently applies for employment with the Respondents, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

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

- H. Upon reasonable notice and request by the Commission-approved Acquirer, and for a period not to exceed eighteen (18) months, Respondents shall make available to the Commission-approved Acquirer, such personnel, assistance and training as the Commission-approved Acquirer might reasonably need to transfer the Divestiture Assets, and shall continue providing such personnel, assistance and training, at the request of the Commission-approved Acquirer until the Divestiture Assets are completely transferred to the Commission-approved Acquirer in a manner that fully preserves their usefulness. This assistance may include, at the Commission-approved Acquirer's sole discretion, but is not limited to, the assistance contemplated in the Transition Services Agreement, attached to this Order as Exhibit B of the Asset Purchase Agreement.

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- I. Upon reasonable notice and request by the Commission-approved Acquirer, and subject to appropriate safeguards against the transmittal of confidential or competitively-sensitive information, Respondents shall provide, in a timely manner, assistance of knowledgeable employees of the Respondents to assist the Commission-approved Acquirer to prosecute any pending patent or trademark applications included in the Divestiture Assets Intellectual Property, and defend against, respond to, or otherwise participate in any litigation related to the Divestiture Assets Intellectual Property.
- J. Not later than fifteen (15) days after the Acquisition Date, Respondents shall enter into a Divestiture Assets Supply Agreement with the Commission-approved Acquirer for the supply of the Divested Fishing Line Products for a period not to exceed eighteen (18) months to ensure a steady supply of the Divested Fishing Line Products until such time as the Commission-approved Acquirer is able to obtain an independent supply, and shall supply the Commission-approved Acquirer with Divested Fishing Line Products with the Shakespeare Name and Marks for a period not to exceed eighteen (18) months after the Divestiture Date in order to exhaust current inventory of Divested Fishing Line Products labeled with the Shakespeare Name and Marks;

provided, however, Respondents may not modify or amend the Divestiture Assets Supply Agreement without receiving the prior approval of the Commission.
- K. In the event that Respondents divest the Divestiture Assets to a Commission-approved Acquirer other than Zebco, the Divestiture Assets Supply Agreement shall require Respondents to:

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1. deliver, in a timely manner and under reasonable terms and conditions, a supply of Divested Fishing Line Products;
 2. represent and warrant to the Commission-approved Acquirer that Respondents shall hold harmless and indemnify the Commission-approved Acquirer for any liabilities or loss of profits resulting from the failure by Respondents to deliver the Divested Fishing Line Products in a timely manner as required by the Divestiture Assets Supply Agreement unless Respondents can demonstrate that their failure was entirely beyond the reasonable control of Respondents and was in no part the result of negligence or willful misconduct by Respondents;
 3. make available to the Commission-approved Acquirer all records that relate to the manufacture of the Divested Fishing Line Products that are generated or created after the Divestiture Date; and
 4. not seek, pursuant to any dispute resolution mechanism incorporated in the Divestiture Assets Supply Agreement, a result that would be inconsistent with the terms or the remedial purposes of this Order.
- L. The purpose of this Paragraph II. of this Order is to ensure the continuation of the Divestiture Assets as part of an ongoing viable enterprise engaged in the same business in which such assets were engaged at the time of the announcement of the proposed Acquisition and to remedy the lessening of competition alleged in the Commission's complaint.

III.

IT IS FURTHER ORDERED that:

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- A. If Respondents have not divested all of the Divestiture Assets and fully complied with all of the obligations as required by Paragraph II. of this Order, the Commission may appoint a trustee to divest (“Divestiture Trustee”) the Divestiture Assets in a manner that satisfies the requirements of Paragraph II. 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 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 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. Within ten (10) days after appointment of a Divestiture Trustee, Respondents shall execute a trust agreement that, subject to the prior approval of the Commission, transfers to

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the Divestiture Trustee all rights and powers necessary to permit the Divestiture Trustee to effect the relevant divestiture or transfer required by the Order.

D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, 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 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;

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

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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 III. 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 Respondents' absolute and unconditional obligation to divest expeditiously and at no minimum price. The divestiture shall be made in the manner and to a Commission-approved 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, however, that Respondents shall select such Person 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 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,

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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 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 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 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 misfeasance, 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.

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9. 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.
 10. 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 III.
- 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.

IV.

IT IS FURTHER ORDERED that the Divestiture Agreement shall include the following provisions:

- A. Respondents shall covenant to the Commission-approved Acquirer that Respondents shall not join, file, prosecute, or maintain any suit, in law or in equity, against the Commission-approved Acquirer under any Divestiture Assets Intellectual Property that are owned or licensed by Respondents as of the Divestiture Date, as such suit would

Decision and Order

have the potential to interfere with the Commission-approved Acquirer's freedom to practice in the research, development, manufacture, use, import, export, distribution, marketing or sale of the Divestiture Assets.

- B. Respondents shall covenant to the Commission-approved Acquirer that Respondents shall not, in any jurisdiction throughout the world, (1) use any of the commercial, trade or brand names, trademarks, or trade dress included in the Divestiture Assets Intellectual Property, including the Divested Fishing Line Products Names and Marks, or any names, marks, or trade dress that are confusingly similar thereto, as a trademark, trade name, service mark, or trade dress for its own use; (2) attempt to register any such names, marks, or trade dress that are confusingly similar thereto; (3) challenge or interfere with the Commission-approved Acquirer's efforts to enforce its registrations for and rights in such names, marks, or trade dress against third parties.

Provided, however, that Respondents may enter into a transitional, non-exclusive, non-transferable, fully-paid, royalty-free limited license back ("Respondent Run-off License") with the Commission-approved Acquirer to allow Respondents to use the Divested Fishing Line Products Names and Marks included in the Divestiture Assets Intellectual Property in conjunction with Respondents' sale of the Acquired Assets Finished Inventory.

Provided further, however, that the duration of such a license may not exceed eighteen (18) months after the Divestiture Date.

- C. Respondents shall, upon reasonable request by the Commission-approved Acquirer and without further consideration, execute, acknowledge and deliver any further assignments, conveyances, and other instruments or transfers and other assurances and documents and shall take any other

Decision and Order

such action consistent with the terms of this Order as may be reasonably necessary to assign or transfer to the Commission-approved Acquirer the Divestiture Assets as contemplated by this Order.

- D. Respondents shall terminate their use of all names included in the Divestiture Assets, including, without limitation, the Divested Fishing Line Products Name and Marks.

Provided, however, that Respondents may continue to use the Divested Fishing Line Products Name and Marks in the manner contemplated by the Respondent Run Off License, for a period not to exceed eighteen (18) months after the Divestiture Date.

Provided further, that Respondents may continue to use the name Supreme in connection or combination with “Shakespeare” and any other name or mark owned by Respondents in connection with any of Respondents’ products other than Fishing Line. Notwithstanding the foregoing, Respondents agree that until such time as the Commission-approved Acquirer has abandoned the use of the term “Supreme” in connection with the sale of Fishing Tackle Products, Respondents will not emphasize the term “Supreme” in connection with the sale of any Fishing Tackle Product over any mark to which it is combined (*e.g.*, in “Shakespeare Synergy Supreme” the term “Supreme” will not be presented in a type size or style significantly larger than the marks “Shakespeare” or “Synergy”).

V.

IT IS FURTHER ORDERED that for a period of ten (10) years from the date this Order becomes final, Respondents shall not, without providing advance written notification to the Commission in a manner described in this paragraph, directly or indirectly:

Decision and Order

- A. Acquire any assets of or financial interest in any Person who develops, manufactures, or sells Fishing Line; or
- B. Enter into any contract to participate in the management of any Person who develops, manufactures, or sells Fishing Line.

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, 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 Respondents and not of any other party to the transaction. Respondents shall provide the notification to 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), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. 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.

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 Respondents

Decision and Order

have fully complied with the provisions of Paragraphs II., III. and IV. of this Order, each Respondent 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 and with the Order to Maintain Assets. Each 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 with the Order to Maintain Assets, including a description of all substantive contacts or negotiations for the divestiture and the identity of all parties contacted. Each Respondent shall include in its compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning divestiture.

- B. Beginning one (1) year 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, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they are complying and have complied with this Order, the Order to Maintain Assets, and the Divestiture Agreements.

VII.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any proposed (1) dissolution of Respondents, (2) acquisition, merger or consolidation of Respondents, or (3) any other change in 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.

VIII.

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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 Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during 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 Respondents relating to any matters contained in this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from it, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on September 14, 2017.

By the Commission.

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NON-PUBLIC APPENDIX I.

ZEBCO ASSET PURCHASE AGREEMENT

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

APPENDIX II.

ORDER TO MAINTAIN ASSETS

APPENDIX III.

DIVESTITURE ASSETS KEY EMPLOYEES

Bill Smith, Sales Manager

Jim McIntosh, Product Manager

James Therrell, Advanced Product Engineer and Quality Control
Manager

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APPENDIX IV.**Excluded Intellectual Property****Patents and Patent Applications and Invention Disclosures**

Registration No.	Status	Jurisdiction	Description
4610916	Issued	United States	MONOFILAMENTS, AND FABRICS THEREOF
0221691	Issued	European Patent Office	MONOFILAMENTS, AND FABRICS THEREOF
4801492	Issued	United States	NOVEL MONOFILAMENTS AND FABRICS THEREOF
4748077	Issued	United States	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS
5591525	Issued	United States	POLYMERIC CABLE
5597646	Issued	United States	POLYMERIC CABLE AND FABRIC MADE THEREFROM
5489467	Issued	United States	PAPER MAKING FABRIC WOVEN FROM POLYESTER MONOFILAMENTS HAVING HYDROLYTIC STABILITY AND IMPROVED RESISTANCE TO ABRASION
1330673	Issued	Canada	MONOFILAMENTS, AND FABRICS THEREOF
5667890	Issued	United States	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS THEREOF
D364079	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
924763	Issued	France	CUTTING LINE FOR A ROTATING LINE TRIMMER
2024777	Issued	United Kingdom	CUTTING LINE FOR A ROTATING LINE TRIMMER
M92058701	Issued	Germany	CUTTING LINE FOR A ROTATING LINE TRIMMER
63707	Issued	Italy	CUTTING LINE FOR A ROTATING LINE TRIMMER
D349634	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER

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Registration No.	Status	Jurisdiction	Description
2024776	Issued	United Kingdom	CUTTING LINE FOR A ROTATING LINE TRIMMER
63706	Issued	Italy	CUTTING LINE FOR A ROTATING LINE TRIMMER
D358535	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
931674	Issued	France	CUTTING LINE FOR A ROTATING LINE TRIMMER
2030070	Issued	United Kingdom	CUTTING LINE FOR A ROTATING LINE TRIMMER
D370395	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D36573	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37607	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37607	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37651	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D376739	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37905	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37941	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
D37941	Issued	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
5534333	Issued	United States	SPIRAL FABRIC
6171446	Issued	United States	PRESS FELT WITH GROOVED FIBERS HAVING IMPROVED DEWATERING CHARACTERISTICS
0221691	Issued	Belgium	MONOFILAMENTS, AND FABRICS THEREOF
0221691	Issued	Germany	MONOFILAMENTS, AND FABRICS THEREOF
0221691	Issued	France	MONOFILAMENTS, AND FABRICS THEREOF
0221691	Issued	United Kingdom	MONOFILAMENTS, AND FABRICS THEREOF
6560878	Issued	United States	MULTI-COMPONENT, EXTRUDED VEGETATION CUTTING LINE

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Registration No.	Status	Jurisdiction	Description
1249920	Issued	Canada	METHOD OF FORMING SUPPORTED ANTISTATIC YARN
5308563	Issued	United States	PROCESS FOR PRODUCING ANTISTATIC YARNS
182356	Issued	Mexico	PROCESS FOR PRODUCING ANTISTATIC YARNS
6245694	Issued	United States	STATIC DISSIPATIVE AUTOMOTIVE BEDLINERS
0294504	Issued	European Patent Office	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
1736031	Issued	Japan	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
5840425	Issued	United States	MULTICOMPONENT SUFFUSED ANTISTATIC FIBERS AND PROCESSES FOR MAKING THEM
5820805	Issued	United States	PROCESS FOR MAKING ANTISTATIC FIBER
0294504	Issued	Austria	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	Belgium	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	France	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	Germany	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	United Kingdom	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	Italy	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	Sweden	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Issued	Switzerland	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
6670034	Issued	United States	SINGLE INGREDIENT, MULTI-STRUCTURAL FILAMENTS

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Registration No.	Status	Jurisdiction	Description
6589392	Issued	United States	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
6668462	Issued	United States	MULTI-COMPONENT, EXTRUDED VEGETATION CUTTING LINE
6912789	Issued	United States	MULTIPURPOSE ROTARY CUTTING TOOL HAVING INTERCHANGEABLE HEADS
[tbd]	Pending	Japan	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS
Application 2456885	Pending	Canada	MULTIPURPOSE ROTARY CUTTING TOOL HAVING INTERCHANGEABLE HEADS
Application PA/A/2004001298	Pending	Mexico	MULTIPURPOSE ROTARY CUTTING TOOL HAVING INTERCHANGEABLE HEADS
Application 2460969	Pending	Canada	SINGLE INGREDIENT MULTI-STRUCTURAL FILAMENTS
Application 02819297.4	Pending	China (Peoples Republic)	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
Application PA/2004003316	Pending	Mexico	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
Application PA/A/2004/003315	Pending	Mexico	SINGLE INGREDIENT MULTISTRUCTURAL FILAMENTS
Application 02773736.0	Pending	European Patent Office	SINGLE INGREDIENT MULTISTRUCTURAL FILAMENTS
Application 10/850846	Pending	United States	CONTAINER WITH CLIP FOR STORING AND CARRYING TRIMMER LINE STRIPS
Application 02819296.6	Pending	China (Peoples Republic)	SINGLE INGREDIENT, MULTI-STRUCTURAL FILAMENTS
Application 05101429.4	Pending	Hong Kong	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
Application 05101427.6	Pending	Hong Kong	SINGLE INGREDIENT, MULTI-STRUCTURAL FILAMENTS
Application 11/371509	Pending	United States	ENCLOSED SPOOL
Application 11/683063	Pending	United States	CUTTING TOOL ATTACHED TO PACKAGE FOR WOUND LINE

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Registration No.	Status	Jurisdiction	Description
Application PCT/US2007/05742	Pending	Patent Cooperation Treaty	PACKAGE FOR WOUND LINE AND CUTTING TOOL ATTACHED THERE TO
[tbd]	Unfiled	[tbd]	ALCOHOL SOLUBLE COPOLYAMIDE FOR BONDING POLYESTER AND POLYAMIDE THREAD
[tbd]	Unfiled	[tbd]	EXTRUDED NYLON PRODUCTS WITH IMPROVED MOISTURE STABILITY
[tbd]	Unfiled	[tbd]	Soft Nylon 6/10 Monofilaments - Roger Evans- inventor - Disclosure provided to RK circa April 2002
[tbd]	Unfiled	[tbd]	Abrasive Fiber Made by Suffusion Process for Car Finishes
[tbd]	Unfiled	[tbd]	PET/Nylon Bicomponent Monofilament with Conductive Carbon Coating
Application PCT/US97/05815	Closed	Patent Cooperation Treaty	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS
4,992,515	Closed	United States	NYLON TERPOLYMER CROSSLINKED WITH MELAMINE FORMALDEHYDE FOR COATING SEWING THREADS
5,283,110	Closed	United States	HIGH TEMPERATURE COPOLYESTER MONOFILAMENTS WITH ENHANCED KNOT TENACITY FOR DRYER FABRICS
0292186	Closed	European Patent Office	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS
5,407,736	Closed	United States	POLYESTER MONOFILAMENT AND PAPER MAKING FABRICS HAVING IMPROVED ABRASION RESISTANCE
Application 1995- 507077	Closed	Japan	POLYESTER MONOFILAMENT AND PAPER MAKING FABRICS HAVING IMPROVED ABRASION RESISTANCE
5,424,125	Closed	United States	MONOFILAMENTS FROM POLYMER BLENDS AND FABRICS THEREOF
5,429,073	Closed	United States	BEDDING MATERIALS FOR ANIMALS
Application 1994- 262044	Closed	Japan	BEDDING MATERIALS FOR ANIMALS

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Registration No.	Status	Jurisdiction	Description
5,759,925	Closed	United States	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS THEREOF
5,464,890	Closed	United States	POLYESTER MONOFILAMENTS EXTRUDED FROM A HIGH TEMPERATURE POLYESTER RESIN BLEND WITH INCREASED RESISTANCE TO HYDROLYTIC AND THERMAL DEGRADATION AND FABRICS THEREOF
Application 1787/95	Closed	Czech Republic	POLYESTER MONOFILAMENTS EXTRUDED FROM A HIGH TEMPERATURE POLYESTER RESIN BLEND WITH INCREASED RESISTANCE TO HYDROLYTIC AND THERMAL DEGRADATION AND FABRICS THEREOF
Application 7(1995)513798	Closed	Japan	POLYESTER MONOFILAMENTS EXTRUDED FROM A HIGH TEMPERATURE POLYESTER RESIN BLEND WITH INCREASED RESISTANCE TO HYDROLYTIC AND THERMAL DEGRADATION AND FABRICS THEREOF
5,460,869	Closed	United States	POLYESTER MONOFILAMENT AND PAPER MAKING FABRICS HAVING IMPROVED ABRASION RESISTANCE
5,456,973	Closed	United States	MONOFILAMENTS FROM POLYMER BLENDS AND FABRICS THEREOF
Application 565507	Closed	Canada	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS
Application 08/445,406	Closed	United States	THERMOPLASTIC ELASTOMER RIBBON HAVING PARALLEL FILAMENTS
5,648,152	Closed	United States	POLYESTER MONOFILAMENTS EXTRUDED FROM A HIGH TEMPERATURE POLYESTER RESIN BLEND WITH INCREASED RESISTANCE TO HYDROLYTIC AND THERMAL DEGRADATION AND FABRICS THEREOF
Application M9302674.9	Closed	Germany	CUTTING LINE FOR A ROTATING LINE TRIMMER
Application MI93O000176	Closed	Italy	CUTTING LINE FOR A ROTATING LINE TRIMMER

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Registration No.	Status	Jurisdiction	Description
Application 29/076,591	Closed	United States	CUTTING LINE FOR A ROTATING LINE TRIMMER
Application 2,250,916	Closed	Canada	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS
Application 97918534.5	Closed	European Patent Office	MONOFILAMENTS EXTRUDED FROM COMPATIBILIZED POLYMER BLENDS CONTAINING POLYPHENYLENE SULFIDE, AND FABRICS
5985450	Closed	United States	STRIATED MONOFILAMENTS USEFUL IN THE FORMATION OF PAPERMAKING BELTS
Application 2285130	Closed	Canada	FIBERS HAVING IMPROVED DEWATERING CHARACTERISTICS FOR PRESS FELTS
Application 99308223.9	Closed	European Patent Office	FIBERS HAVING IMPROVED DEWATERING CHARACTERISTICS FOR PRESS FELTS
Application 88304257.4	Closed	Austria	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS.
Application 88304257.4	Closed	Belgium	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS.
Application 88304257.4	Closed	Germany	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS.
Application 88304257.4	Closed	France	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS.
Application 88304257.4	Closed	United Kingdom	NOVEL MONOFILAMENTS, FABRICS THEREOF AND RELATED PROCESS.
Application 86307818.4	Closed	Austria	MONOFILAMENTS, AND FABRICS THEREOF
Application 86307818.4	Closed	Sweden	MONOFILAMENTS, AND FABRICS THEREOF
Application 09/608,421	Closed	United States	BICOMPONENT SOLVENT PROCESS FOR THE MANUFACTURE OF NON-WATER SOLUBLE NYLONS AND USES OF THE PRODUCTS THEREOF
4545835	Closed	United States	METHOD OF FORMING SUPPORTED ANTISTATIC YARN
Application 09/712,153	Closed	United States	STATIC DISSIPATIVE AUTOMOTIVE BEDLINERS

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Registration No.	Status	Jurisdiction	Description
4704311	Closed	United States	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
0294504	Closed	Netherlands	PROCESS FOR MAKING ELECTRICALLY CONDUCTIVE TEXTILE FILAMENTS
5457968	Closed	United States	SEATING SUPPORT
6352772	Closed	United States	PAPERMAKING BELTS COMPRISING STRIATED MONOFILAMENTS
Application 60/530,053	Closed	United States	BLOWING DEVICE AND METHOD FOR USE WITH PORTABLE LAWN TRIMMER
Application PCT/US02/32351	Closed	Patent Cooperation Treaty	SINGLE INGREDIENT, MULTI-STRUCTURAL FILAMENTS
Application PCT/US02/32436	Closed	Patent Cooperation Treaty	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
[tbd]	Closed	United States	NON-CARBON CONDUCTIVE FILAMENT
10/696223	Closed	United States	SINGLE INGREDIENT MULTI-STRUCTURAL FILAMENTS
Application PCT/US02/025416	Closed	Patent Cooperation Treaty	MULTIPURPOSE ROTARY CUTTING TOOL HAVING INTERCHANGEABLE HEADS
[unfiled]	Closed	United States	TEXTURED FILAMENT VIOLIN HORSE HAIR REPLACEMENT
Application 2002355436	Closed	Australia	MULTIPURPOSE ROTARY CUTTING TOOL HAVING INTERCHANGEABLE HEADS
Application 2460797	Closed	Canada	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
Application 02773739.4	Closed	European Patent Office	MULTICOMPONENT MONOFILAMENT FOR PAPERMAKING FORMING FABRIC
Application 60/666,497	Closed	United States	FLAME RETARDANT MULTI-STRUCTURAL FILAMENTS (Provisional)
Application 11/254054	Closed	United States	MECHANISM FOR ATTACHING TRIMMER LINE STRIPS TO A HEAD OF A TRIMMING APPARATUS

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Trademarks and Trademark Applications

Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
3170131	European Community	16-May-2003/ 16-Jun-2004	ALBANY	28 Int.: Fishing rods, fishing reels, fishing line, and fishing tackle accessories.
1,432,693	United Kingdom	19-Jul-1990/ 30-Jun-1994	ALPHA	28 Int.: Fishing tackle, fishing rods, fishing reels, and fishing lines.
75/377,798/ 2,187,855	United States	23-Oct-1997/ 08-Sep-1998	ALPHA	28 Int.: Fishing line
15388/28WZ/ 966 432	Germany	23-Apr-1977/ 09-Jan-1978	AMBIDEX	28 Int.: Sporting apparatus, landing nets for anglers, landing net- sticks for anglers, fishing equipment; namely fishing rods, fishing lines, fishing hooks, fishing reels, artificial baits, floats, quills and plummets, ground- finders.
1,504,213/	United Kingdom	18-Jun-1992/ 03-Dec-1993	BETA	28 Int.: Fishing tackle, fishing rods, fishing reels, and fishing lines.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
2332267	United Kingdom	16-May-2003/ 17-Oct-2003	BORAK	28 Int.: Fishing rods, fishing reels, fishing line, and fishing tackle accessories.
777226	Australia	30-Oct-1998/ 18-Jun-1999	CONDEX	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
2358467	United Kingdom	16-Mar-2004/ 27-Aug-2004	CONTENDER	28 Int.: Fishing rods, fishing reels, fishing line, and fishing tackle.
3888138	European Community	16-Jun-2004/ 06-Jun-2005	DEVILS OWN	28 Int.: Fishing rods, fishing reels, fishing line, and fishing tackle accessories.
75/564,248/ 2,378,119	United States	02-Oct-1998? 15-Aug-2000	EXCURSION	28 Int.: Fishing rods, reels, and line sold individually and as a unit with a carrying case.
0963730/ 0665600	Benelux	02-May-2000/ 02-Oct-2000	FLY TECH	IC 28: Fishing tackle, fishing rods, fishing line and reels; accessories for the aforesaid goods.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
001622687	European Community	20-Apr-2000/ 03-Jul-2001		IC 28: Fishing tackle, fishing rods, fishing line and reels; accessories for the aforesaid goods.
2231178	United Kingdom	02-May-2000/ 20-Oct-2000	FLY TECH	IC 28: Fishing tackle, fishing rods, fishing line and reels; accessories for the aforesaid goods.
1,432,681	United Kingdom	19-Jul-1990/	GRAFLITE	28 Int.: Fishing tackle, fishing rods, fishing reels, and fishing lines.
777227	Australia	30-Oct-1998/ 18-Jun-1999	INTREPID	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
700425	Australia	11-Jan-1996/ 21-Mar-1997	INVICTA	28 Int.: Fishing tackle, including rods, reels and line.
868966/ 598310	Benelux	10-Apr-1996	INVICTA	28 Int.: Fishing tackle, including rods, reels and line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
2,067,653/	United Kingdom	03-Apr-1996/ 28-Feb-1997	INVICTA	28 Int.: Fishing tackle, rods for fishing, reels for fishing, lines for fishing.
72/268,067/ 845,835	United States	31-Mar-1967/ 12-Mar-1968	MEDALIST & DESIGN	28 Int.: Reels, parts for reels, rods, and fishing lines.
777224	Australia	30-Oct-1998/ 18-Jun-1999	MEDALIST (STYLIZED)	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
74/340,199/ 1,842,437	United States	15-Dec-1992/ 28-Jun-1994	MICROCAST	28 Int.: Fishing rods, reels, and line.
74/340,198/ 1,843,768	United States	15-Dec-1992/ 05-Jul-1994	MICROSPIN	28 Int.: Fishing rods, reels and line.
285 669	Int'l Registration - Madrid	29-Jun-1964/	NORIS SHAKESPEARE & DESIGN	28 Int.: IC 28: Wound lines for fishing, fish hooks, reels, artificial lures for fishing, leaders; lines for fishing, landing nets, hoop nets, fishing rods, handles for landing nets.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
455 225	Int'l Registration - Madrid	07-Aug-1980	OMNI	28 Int.: Fishing rods, fishing-lines, fishing-reels.
2235196	United Kingdom	07-Jun-2000/ 10-Nov-2000	ORACLE	Fishing tackle, fishing rods, fishing reels, fishing lines; accessories for the aforesaid goods.
777225	Australia	30-Oct-1998/ 18-Jun-1999	PFLUEGER	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
4636985 Pending	China (Peoples Republic)	30-Apr-2005	PFLUEGER	28 Int.: Fishing rods; fishing reels; fishing line; fishing lures; fishing hooks; fishing bait; fishing jigs; fishing sinkers; fishing spinners; fishing leaders; fishing tackle boxes; soft sided fishing tackle gear bags.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
40-2006-56540	Korea, Republic of	08-Nov-2006/ 25-Apr-2007	PFLUEGER	28 Int.: Fishing rods; fishing reels; fishing line; fish hooks; fish lures; fish flies; jigs; sinkers; fishing tackle boxes; fishing nets; fishing rod supports; artificial fishing bait; fishing chairs; floats for fishing; fishing creels; bite indicators (fishing tackle).
4633392	European Community	14-Sep-2005/ 03-Apr-2006	POLESTAR	28 Int.: Fishing poles, fishing reels, fishing line, fishing tackle.
2395439	United Kingdom	28-Jun-2005/	POLESTAR	28 Int.: Fishing poles, fishing reels, fishing line, and fishing tackle.
16849/ 72446-C	Bolivia	20-Nov-1997/ 08-Apr-1999	SHAKESPEARE	28 Int.: Fishing tackle; namely rods, reels, and line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
344009/ 185033	Canada	29-Jun-1971/ 25-Aug-1972	SHAKESPEARE	NA : Sporting goods in the nature of anglers' supplies, namely, rods, reels, lines, artificial baits and lures, trolling motors and remote controls therefor, worm raiser preparations, hooks. Golfers' supplies, namely, balls and clubs. Archery supplies, namely, bow strings, arrowheads and points and res and stabilizers and nocks and feathers, bows, arrows, shooting tabs and gloves, archery crests, wrist straps, arm guards. Snowmobile accessories, namely, safety

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
182052/ 17620	Canada	16-Jan-1943/ 16-Jan-1943	SHAKESPEARE	NA : Fishing rods, fishing reels, fishing lines, and artificial baits and lures.(Extension of Wares) Athletic clothing, casual clothing, dress clothing; headwear namely caps, visors, beanies, handkerchiefs, bandanas & headbands; footwear namely athletic shoes, casual shoes and dress shoes, boots, sandals, thongs, slippers and booties; wrist bands, gloves, mittens.
523.473/ 619.781	Chile	04-Apr-2001/ 25-Jan-2002	SHAKESPEARE	28 Int.: All goods in class 28.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
4039729 Pending	China (Peoples Republic)	27-Apr-2004	SHAKESPEARE	22 Int.: Monofilame nts for use in the manufacture of paper machine clothing, fasteners, tire reinforceme nt, grass cutting line, suspension seating, fishing line, and industrial applications; textile fibers.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
488981	European Community	07-Mar-1997/ 09-Dec-1998	SHAKESPEARE	17 Int.: IC 17: Threads, fibers or monofilame nts of synthetic materials for non-textile use.22 Int.: IC 22: Rope, string, cord and twines, raw fibrous textile materials.23 Int.: IC 23: Yarns and threads for textile use, sewing thread.28 Int.: IC 28: Toys; sporting articles; fishing line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
D00.200502492 6	Indonesia	14-Nov-2005/ 09-Apr-2007	SHAKESPEARE	28 Int.: Fishing rods; fishing reels; fishing line; fishing tackle; artificial fishing baits and lures; fishing accessories, namely floats, hooks, jigs, sinkers, swivels, hand held nets, and fishing line counters; fishing tackle boxes.
97/34030/ 206,962	Paraguay	26-Nov-1997/ 15-Sep-1998	SHAKESPEARE	28 Int.: Fishing tackle; namely rods, reels, and line.
1549623	Spain	16-Feb-1990/ 10-Mar-1994	SHAKESPEARE	28 Int.: Fishing tackle; including rods, reels, hooks, line, artificial lures, floats, and weights.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
81/050713/ 616873	Taiwan	09-Oct-1992/ 16-Oct-1993	SHAKESPEARE	79 Nat.: Rods, reels, fishing lines, fishing hooks, artificial bait, bobs, floats, sinkers, portable creels, fishing spears, harpoon gun, fishing nets.
VA 02.650/19/ VR1979 02738	Denmark	16-Jun-1978/ 21-Sep-1979	SHAKESPEARE & DESIGN	28 Int.: Toys, gymnastic and sporting appliances, articles for anglers, namely fishing rods, fishing lines, fishing hooks, wheels for fishing rods, snoods and shells, artificial bait, floats, thin floats, lead and shallow seekers.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
15664/28WZ/ 967 849	Germany	17-Dec-1977/ 20-Feb-1978	SHAKESPEARE & DESIGN	28 Int.: Fishing equipment, namely fishing-rods, fishing-lines, fishing- hooks, fishing reels, artificial baits, floats, quills and plumets, ground- finders.
781643/ 105695	Norway	14-Jun-1978/ 14-Aug-1980	SHAKESPEARE & DESIGN	28 Int.: Games and sporting apparatus, fishing equipment, namely fishing-rods, fishing lines, fishing- hooks, fishing reels, artificial baits, floats, quills and plumets, ground- finders.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
437 994	Int'l Registration - Madrid	17-Dec-1977/ 26-Apr-1978	SHAKESPEARE & DESIGN (COLOR)	28 Int.: Apparatus for playing and sport; fishing articles, walking sticks and lines for fishing, fish hooks, winches, advance, artificial baits, floats, pipes of pens and leads, leads for recognize surface.
76/507,204/ 2,831,616	United States	17-Apr-2003/ 13-Apr-2004	SHAKESPEARE & DESIGN 1897 (COLOR)	IC 28: Fishing rods, reels, and line; tackle boxes; fishing line counters.
815165803	Brazil	06-Oct-1989/ 18-Feb-1992	SHAKESPEARE (STYLIZED)	28 Int.: Fishing rods, fishing reels, fishing tackle, fishing accessories and fishing line.
2933/98/ 109434	Costa Rica	30-Apr-1998/ 26-Nov-1998	SHAKESPEARE (STYLIZED)	28 Int.: Fishing tackle; namely rods, reels, and line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
69 358 1/ 693 581	Germany	17-Dec-1955/	SHAKESPEARE (STYLIZED)	28 Int.: Fishing spools, fishing lines, fishing rods, artificial baits.
321168/ 734395	Italy	24-Dec-1955/ 09-Jan-1956	SHAKESPEARE (STYLIZED)	28 Int.: Reels for fishing, lines for fishing, rods for fishing, artificial fishing baits and flies.
1983-109/ 39087-1	Korea, Republic of	11-Oct-1983/ 28-Feb-1984	SHAKESPEARE (STYLIZED)	28 Int.: IC 28: Fishing spools, fishing rods, fishing lines, fishing floats, artificial fishing baits, fishing sinkers, fishing creels, fishing reels, fishing hooks, bamboo fishing, fishing nets, and fishing rod supports.
108319/ 4-1996110665	Philippines	23-May-1996/ 21-Feb-2000	SHAKESPEARE (STYLIZED)	28 Int.: Fishing reels, fishing lines, fishing rods, and artificial fishing baits and lures.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
159166/ 2P-283411	Switzerland	23-Dec-1955/	SHAKESPEARE (STYLIZED)	28 Int.: Fishing gear, fishing line, fishing rods, fishing bait, artificial bait.
2004/21173	Turkey	09-Jul-2004/ 09-Jul-2004	SHAKESPEARE (STYLIZED)	28 Int.: . . . fishhook, triple fishhooks, fishhooks with a fish- shaped lure etc, swivels, double fish line swivels, triple fish line swivels, clip on fish line swivels, locked clip on fish line swivels, cast net swivels, normal roller swivels, roller clip on swivels..fish ing poles, telescopic fishing poles, two part boat fishing poles, uni- part boat fishing poles, two part light carbon fishing poles, telescopic carbon fishing poles,

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
				ringless lake fishing poles, spinning reels, spinning reels adjusted by the head, spinning reels adjusted by the back, drag-net spinning reels, spinning looms for the boats; fishing lines, bobbin, bobbin fishing lines, carbon fishing lines, silicon fishing lines, string fishing lines, hank fishing lines, sachet fishing lines. Artificial fishing worms, artificial fish worms made of plastic, metal, and silicon.with a fish- shaped lure etc, swivels, double fish line swivels, triple fish line swivels, clip on fish

Decision and Order

Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
				line swivels, locked clip on fish line swivels, cast net swivels, normal roller swivels, roller clip on swivels..fish ing poles, telescopic fishing poles, two part boat fishing poles, uni- part boat fishing poles, two part light carbon fishing poles, telescopic carbon fishing poles, ringless lake fishing poles, spinning reels, spinning reels adjusted by the head, spinning reels adjusted by the back, drag-net spinning reels, spinning looms for the boats; fishing lines,

Decision and Order

Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
				bobbin, bobbin fishing lines, carbon fishing lines, silicon fishing lines, string fishing lines, hank fishing lines, sachet fishing lines. Artificial fishing worms, artificial fish worms made of plastic, metal, and silicon.
71/406,155/ 359,879	United States	09-May-1938/ 30-Aug-1938	SHAKESPEARE (STYLIZED)	28 Int.: Fishing reels, fishing lines, fishing rods, and artificial fishing baits and lures.
1029739	Australia	15-Nov-2004/ 22-Mar-2005	SHAKESPEARE SUPREME	28 Int.: Fishing rods, fishing reels, and fishing line.
1,226,111 Pending	Canada	05-Aug-2004	SHAKESPEARE SUPREME	NA : Fishing rods, fishing reels, and fishing line.
4131471	European Community	15-Nov-2004/ 26-Jan-2006	SHAKESPEARE SUPREME	28 Int.: Fishing rods, fishing reels, and fishing line.
78/418,441/ 3225575	United States	13-May-2004/ 2007	SHAKESPEARE SUPREME	28 Int.: Fishing rods, fishing reels, and fishing line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class- Goods
1002659/ 700611	Benelux	21-Dec-2001	SIGMA	28 Int.: Fishing equipment, namely fishing rods, fishing reels, and fishing line.
848620/ 492748	Canada	19-Jun-1997/ 09-Apr-1998	SIGMA	NA : Fishing gear, namely, rods, reels, lines and electric fishing motors.
776846	Int'l Registration - Madrid	16-Jan-2002/	SIGMA	28 Int.: Fishing equipment, namely fishing rods, fishing reels, and fishing line.
300930	New Zealand	04-Nov-1998/ 26-Apr-1999	SIGMA	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
74/340,743/ 1,785,691	United States	17-Dec-1992/ 03-Aug-1993	SIGMA	28 Int.: Fishing rods, reels, and line.
549258	Australia	22-Jan-1991/ 23-Aug-1994	SIGMA & DESIGN	28 Int.: Fishing tackle including rods, fishing reels and fishing lines.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
1,432,697	United Kingdom	19-Jul-1990/ 06-Nov-1992	SIGMA & DESIGN	28 Int.: Fishing tackle, fishing rods, fishing reels, and fishing lines.
16968/28 Wz/ 1 002 166	Germany	10-Apr-1980/ 19-May-1980	SIGMA & DESIGN	28 Int.: Fishing equipment, namely fishing-rods, fishing-lines, fishing- hooks, fishing reels, artificial baits, floats, quills and plumets, ground- finders.
777228	Australia	30-Oct-1998/ 18-Jun-1999	SNAKE RIVER	28 Int.: Equipment in this class for fishing; fishing tackle, including rods, reels and line.
71/110,640/ 123,029	United States	04-May-1918/ 08-Oct-1918	SUPREME (STYLIZED)	28 Int.: Fishing reels
3231263	European Community	18-Jun-2003/ 03-Jan-2005	TPD	28 Int.: Fishing tackle, including rods, reels, fly line and fishing tackle accessories.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class, Goods
75/627,653/ 2,418,237	United States	04-Aug-1999/ 02-Jan-2001	TRAVEL MATE	28 Int.: Fishing rods, reels and line sold as a kit with a carrying case.
2387888	United Kingdom	24-Mar-2005/ 16-Sep-2005	TRION	28 Int.: Fishing rods, fishing reels, fishing line, fishing tackle.
416529	Australia	09-Oct-1984/ 01-Sep-1987	UGLY STIK	28 Int.: Fishing tackle, including rods, reels and line.
15 173/28WZ/ 960 577	Germany	09-Oct-1976/ 19-Jul-1977	UGLY STIK & DESIGN	28 Int.: Games and sporting apparatus, landing nets for anglers, landing net- sticks for anglers, fishing equipment, namely fishing-rods, fishing lines, fishing- hooks, fishing reels, artificial baits, floats, quills and plumets, ground- finders.
75/452,120/ 2,294,742	United States	16-Mar-1998/ 23-Nov-1999	UGLY STIK TIGER	28 Int.: Fishing tackle, namely, rods, reels and line.

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Application / Registration No.	Jurisdiction	Application /Registration Date	Description	Class: Goods
4602249	European Community	23-Aug-2005/ 13-Feb-2006	XCEDE	28 Int.: Fishing tackle, fishing rods, fishing reels, fishing line.
2387367	United Kingdom	18-Mar-2005/ 02-Sep-2005	XCEDE	28 Int.: Fishing tackle, fishing rods, fishing reels, fishing line.
2381792	United Kingdom	11-Jan-2005	ZEO	28 Int.: Fishing tackle, fishing rods, fishing reels, fishing line.

Analysis to Aid Public Comment

**ANALYSIS OF CONSENT ORDERS 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 Jarden Corporation (“Jarden”) and K2 Incorporated (“K2”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise be likely to result from Jarden’s acquisition of K2. Under the terms of the proposed Consent Agreement, Jarden and K2 are required to divest assets related to K2’s Cajun Line®, Omniflex®, Outcast®, and Supreme™ monofilament fishing line products.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from 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 or make it final.

Pursuant to an Agreement and Plan of Merger dated April 24, 2007, Jarden proposes to acquire K2 in a transaction valued at approximately \$1.2 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 market for monofilament fishing line in the United States. The proposed Consent Agreement would remedy the alleged violations by replacing the competition that would be lost in this market as a result of the Proposed Acquisition.

Analysis to Aid Public Comment

II. The Parties

Jarden is a leading provider of branded consumer products, including outdoor sporting goods, kitchen appliances, firelogs, playing cards, and a wide variety of consumer and medical plastic products. In 2006, Jarden's revenues were approximately \$3.85 billion. In April 2007, Jarden acquired Pure Fishing Inc. ("Pure Fishing"), a fishing tackle company that sells products under several brands, including Abu Garcia®, Berkley®, Stren®, Mitchell®, and Spider®.

K2 is a leading provider of branded consumer outdoor sports equipment. K2 reported annual sales of \$1.4 billion in 2006, attributable to four primary business segments: Marine and Outdoor, Team Sports, Action Sports, and Apparel and Footwear. K2 participates in the fishing tackle markets through its Shakespeare division, marketing products under several brand names including Shakespeare®, Ugly Stik®, Penn®, Pflueger®, and Cajun Line®.

III. Monofilament Fishing Line

Monofilament fishing line is the most widely-used and least expensive type of fishing line. While other specialized types of fishing line, including braided (or super line) and fluorocarbon, appear to be growing in popularity, especially among avid anglers, the vast majority of fishing line purchases in the United States are of monofilament line. Monofilament line is acceptable for a broad range of fishing conditions, but is particularly well-suited for situations in which it is important for the fishing line to be flexible and stretch. Due to its low cost and ease of use, monofilament line is popular with both novices and more avid anglers. The evidence indicates that anglers, if faced with a five to ten percent increase in the price of monofilament line, would not switch to braided line or fluorocarbon line. Therefore, monofilament line is the relevant product market in which to analyze the competitive effects of the proposed acquisition.

Analysis to Aid Public Comment

The relevant geographic market in which to assess the impact of the Proposed Acquisition is the United States. Although monofilament line appears to be routinely sourced by U.S. sellers from contract manufacturers worldwide, no foreign firm is a significant seller in the U.S. and, in light of the entry conditions discussed below, none is likely to become significant within two years.

The market for monofilament fishing line is highly concentrated, with Pure Fishing's three brands, Berkley®, Stren®, and Spider®, dominating the market. Although Shakespeare has a smaller presence in the market than Pure Fishing, Shakespeare appears to be the second-largest firm in the monofilament fishing line market and Pure Fishing's most significant competitor, due, in part, to the recent success of its Cajun Line, a red monofilament that is growing in popularity.

Entry into the market for monofilament fishing line that would be sufficient to deter or counteract the anticipated competitive effects of the proposed transaction is unlikely to occur in the next two to three years. Although obtaining a source of supply for monofilament line does not constitute a significant barrier to entry, the need to develop brand equity, distribution, infrastructure, and a marketing presence for the brand poses a significant barrier to *de novo* entry and to entry by participants in adjacent markets. The relatively limited sales opportunities in the monofilament fishing line market make it unlikely that a new entrant could justify the investment required to develop and market a new fishing line brand.

The Proposed Acquisition raises significant competitive concerns in the U.S. market for monofilament fishing line. Pure Fishing's sales account for a substantial share of the monofilament market. Shakespeare is Pure Fishing's most significant competitor. Consumers have benefitted from competition between Shakespeare and Pure Fishing on pricing, promotional spending, and product innovations. Thus, unremedied, the Proposed Acquisition likely

Analysis to Aid Public Comment

would cause anticompetitive harm by enabling Jarden to profit by raising the prices of its monofilament fishing line unilaterally, as well as reducing its incentives to innovate and develop new monofilament fishing line products.

IV. The Consent Agreement

The proposed Consent Agreement effectively remedies the Proposed Acquisition's likely anticompetitive effects in the market for monofilament fishing line. The proposed Consent Agreement preserves competition by requiring the divestiture of Cajun Line®, Omniflex®, Outcast®, and Supreme_ (the "Divested Assets") to W.C. Bradley/Zebco ("Zebco") within fifteen (15) days after the Proposed Acquisition is consummated.

Shakespeare's Penn® monofilament fishing line was not included in the divested assets because the evidence revealed that this is a rapidly declining brand and did not represent any competitive constraint to Pure Fishing's fishing line brands. Furthermore, Penn is best known for its high-end fishing reels, and as a result, any remedy involving this brand would unnecessarily present complex brand splitting concerns.

The Commission is satisfied that Zebco is a well-qualified acquirer of the divested assets. Zebco is a significant market participant in the fishing tackle market with a variety products, including fishing rods, fishing reels, and fishing rod and reel combination kits. Zebco already has a strong distribution network and knowledgeable sales force with existing relationships with fishing tackle retailers.

The proposed Consent Agreement contains several provisions designed to ensure the success of the divested assets to Zebco by requiring that (1) Jarden and K2 take steps to ensure that confidential information relating to the divested assets will not be used by Jarden; (2) Zebco will have the opportunity to enter into employment contracts with certain key individuals who have

Analysis to Aid Public Comment

experience relating to the divested assets; and (3) certain management employees of K2 who were substantially involved in the research, development, or marketing of the divested assets be precluded from working on competitive fishing line products at Jarden for a period of two years.

The Order to Maintain Assets that is included in the proposed Consent Agreement requires that Jarden and K2 protect the viability, marketability, and competitiveness of the divestiture assets between the time the Commission accepts the proposed Consent Agreement for placement on the public record and when the divestitures take place.

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 Decision and Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

RITE AID CORPORATION
AND
THE JEAN COUTU GROUP (PJC), INC.

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

Docket C-4191; File No. 061 0257
Complaint, June 1, 2007 – Decision, September 17, 2007

This consent order addresses the \$3.5 billion acquisition by Rite Aid Corporation (“Rite Aid”) of certain assets from the Brooks/Eckerd retail pharmacies of The Jean Coutu Group (PJC), Inc. (“Jean Coutu”) (collectively “Respondents”). The complaint alleges that Respondents combined account for up to 100 percent of the pharmacies in the market, and the acquisition, if consummated, would likely allow Rite Aid to raise prices for pharmacy services to cash customers in several markets nationwide. There is a significant disparity in profit margins between sales to cash customers and sales to customers covered by third party payors. The consent order requires Respondents to divest one store in each of the twenty-three geographic areas to a Commission-approved acquirer.

Participants

For the *Commission*: Thomas A. Cohn, Daniel P. Ducore, Alan Loughnan, Jonathan W. Platt, and David P. Wales, Jr.

For the *Respondents*: Philip Proger, Jones Day; David T. Beddow, O’Melveny & Meyers.

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and the Clayton Act, and by virtue of the authority vested in it by said Acts, the Federal Trade Commission (“Commission”), having reason to believe that Respondent Rite Aid Corporation (“Rite Aid”) has entered into an agreement to (1) acquire 100 percent of the common and preferred shares of the wholly-owned subsidiary, The

Complaint

Jean Coutu Group (PJC) USA, Inc. (“Jean Coutu USA”) from its parent company, Respondent The Jean Coutu Group (PJC), Inc. (“Jean Coutu”), and (2) issue 30 percent of its own common stock to Jean Coutu, all subject to the jurisdiction of the Commission, in violation of Section 5 of the Federal Trade Commission 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 Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and that a proceeding in respect thereof would be in the public interest, hereby issues its complaint, stating its charges as follows:

RITE AID CORPORATION

PARAGRAPH ONE: Respondent Rite Aid 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 30 Hunter Lane, Camp Hill, Pennsylvania 17011.

PARAGRAPH TWO: Respondent Rite Aid is a retail drug store chain which, at all times relevant hereto, has been engaged in the retail sale of pharmaceutical items, cosmetics, beauty supplies and perfume, convenience foods, and other items in the United States. Rite Aid operates 3,319 stores under the Rite Aid trade name.

PARAGRAPH THREE: Respondent Rite Aid is, and at all times relevant hereto 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 affecting commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

JEAN COUTU

PARAGRAPH FOUR: Respondent Jean Coutu is a corporation organized, existing, and doing business under and by virtue of the

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laws of the Province of Quebec, with its office and principal place of business located at 530 Beriault Street, Longueuil, Quebec, Canada J4G1S8.

PARAGRAPH FIVE: Respondent Jean Coutu owns and operates retail drug store chains and at all times relevant hereto, has been engaged in the retail sale of pharmaceutical items, cosmetics, beauty supplies and perfume in the United States. Jean Coutu, through its wholly-owned subsidiary, Jean Coutu USA, operates 1,858 stores under the Brooks and Eckerd trade names.

PARAGRAPH SIX: Respondent Jean Coutu is, and at all times relevant hereto 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 affecting commerce as “commerce” is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

THE PROPOSED ACQUISITION

PARAGRAPH SEVEN: On or about August 23, 2006, Rite Aid entered into a Stock Purchase Agreement to acquire and merge with Jean Coutu USA (“the Acquisition”). Pursuant to this Stock Purchase Agreement, Rite Aid will acquire Jean Coutu USA, and thus the Eckerd and Brooks retail pharmacy chains, in exchange for approximately \$3.5 billion worth of cash and stock. As a result of the merger, Rite Aid will hold 100 percent of the common and preferred shares of Jean Coutu USA and Jean Coutu will acquire approximately 30 percent of the voting securities of Rite Aid.

THE RELEVANT MARKETS

PARAGRAPH EIGHT: For purposes of this Complaint, the relevant line of commerce (*i.e.*, the product market) in which to analyze the Acquisition is the retail sale of pharmacy services to cash customers in local markets. Pharmacy services include the provision of prescription medications by a licensed pharmacist who is able to provide usage advice and other relevant information as

Complaint

may be required by law. Cash customers are consumers of pharmacy services that do not pay a price negotiated by or paid through a third party (such as an insurance plan or a pharmacy benefits manager). Cash customers generally pay the full posted or list price set by a pharmacy for a prescription drug or some discounted amount of a posted or list price set by a pharmacy.

PARAGRAPH NINE: For purposes of this Complaint, the relevant sections of the country in which to analyze the effects of this Acquisition are:

- a. the town of Stafford, Connecticut;
- b. the town of Denton, Maryland;
- c. the town of Gardiner, Maine, and the town and census-designated place of Randolph, Maine;
- d. the city of Berlin, New Hampshire;
- e. the town of Pelham, New Hampshire;
- f. the town of Peterborough, New Hampshire;
- g. the borough of Penns Grove, New Jersey;
- h. the towns of Arcade and Yorkshire, New York;
- i. the town of Boonville, New York;
- j. the town of Grand Island, New York;
- k. the village of Lake Placid, New York;
- l. the village of Le Roy, New York;

Complaint

- m. the city of Mechanicville, New York;
- n. the town of Owego, New York;
- o. the borough of Brownsville, Pennsylvania, and the census-designated place of Grindstone-Rowes Run, Pennsylvania;
- p. the borough of Mercer, Pennsylvania;
- q. the borough of Moscow and the township of Covington, Pennsylvania;
- r. the census-designated place of Mountain Top, Pennsylvania;
- s. the boroughs of Zelienople and Harmony, Pennsylvania;
- u. the incorporated village of Bellows Falls, Vermont, and the town of Walpole, New Hampshire;
- v. the village of Lyndonville, Vermont;
- w. the town of St. Johnsbury, Vermont; and
- x. the city of Franklin, Virginia.

Complaint

PARAGRAPH TEN: The relevant markets set forth in Paragraph Nine are highly concentrated, whether measured by the Herfindahl-Hirschmann Index (“HHI”) or two-firm and four-firm concentration ratios. The Acquisition would substantially increase concentration in each such market.

ENTRY CONDITIONS

PARAGRAPH ELEVEN: Entry would not be timely, likely, or sufficient to prevent anticompetitive effects in the relevant markets.

EFFECTS OF THE ACQUISITION

PARAGRAPH TWELVE: The effect of the acquisition, if consummated, may be to substantially lessen competition 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 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 Rite Aid and Brooks or Eckerd in the relevant markets; and
- b. by increasing the likelihood that the combined Rite Aid/Brooks-Eckerd will unilaterally exercise market power in the relevant markets; each of which increases the likelihood that the prices of pharmacy services to cash customers will increase, and the quality and selection of such services will decrease, in the relevant sections of the United States.

VIOLATIONS CHARGED

PARAGRAPH THIRTEEN: The acquisition agreement described in Paragraph Seven violates Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and the proposed

Order to Maintain Assets

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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this first day of June, 2007, 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 Rite Aid Corporation (“Rite Aid”) of 100 percent of the common and preferred shares of The Jean Coutu Group USA, Inc. from Respondent The Jean Coutu Group (PJC), Inc. (“Jean Coutu”), and Jean Coutu’s proposed acquisition of 30 percent of the common stock of Rite Aid pursuant to the Stock Purchase Agreement between Rite Aid and Jean Coutu, hereinafter referred to collectively as “Respondents,” and Respondents 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 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

Order to Maintain Assets

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 Rite Aid 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 30 Hunter Lane, Camp Hill, Pennsylvania 17011.
2. Respondent Jean Coutu is a corporation organized, existing, and doing business under and by virtue of the laws of the Province of Quebec, with its office and principal place of business located at 530 Beriault Street, Longueuil, Quebec, Canada J4G1S8.

The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

Order to Maintain Assets

ORDER**I.**

IT IS ORDERED that, as used in this Order to Maintain Assets, the definitions used in the Consent Agreement and the attached Decision and Order shall apply. In addition, “Drug Store to be Maintained” means any Retail Drug Store business identified as a part of the Assets To Be Divested.

II.

IT IS FURTHER ORDERED that:

- A. Respondents shall maintain the viability, marketability, and competitiveness of the Assets To Be Divested, and shall not cause the wasting or deterioration of the Assets To Be Divested, nor shall they cause the Assets To Be Divested to be operated in a manner inconsistent with applicable laws, nor shall they sell, transfer, encumber or otherwise impair the viability, marketability or competitiveness of the Assets To Be Divested. Respondents shall comply with the terms of this Paragraph until such time as Respondents have divested the Assets To Be Divested pursuant to the terms of the attached Decision and Order. Respondents shall conduct or cause to be conducted the business of the Assets To Be Divested in the regular and ordinary course and in accordance with past practice (including regular repair and maintenance efforts) and shall use reasonable best efforts to preserve the existing relationships with suppliers, customers, third-party payors, employees, and others having business relations with the Assets To Be Divested in the ordinary course of business and in accordance with past practice.
- B. Respondents shall not terminate the operation of any Drug Store To Be Maintained. Respondents shall continue to maintain the inventory of each Drug Store To Be Maintained

Order to Maintain Assets

at levels and selections (*e.g.*, stock-keeping units) consistent with those maintained by such Respondent(s) at such Drug Store in the ordinary course of business consistent with past practice. Respondents shall use best efforts to keep the organization and properties of each Drug Store To Be Maintained intact, including current business operations, physical facilities, working conditions, and a work force of equivalent size, training, and expertise associated with the Drug Store. Included in the above obligations, Respondents shall, without limitation:

1. maintain operations and departments, and not reduce hours, at each Drug Store To Be Maintained;
2. not transfer inventory from any Drug Store To Be Maintained, other than in the ordinary course of business consistent with past practice;
3. continue to offer those customers who receive pharmacy services at each Drug Store To Be Maintained the same type and quality of pharmacy services that are offered at the Proposed Respondents' Retail Drug Stores that are not subject to the Decision and Order's divestiture provisions;
4. make any payment required to be paid under any contract or lease when due, and otherwise pay all liabilities and satisfy all obligations associated with any Drug Store To Be Maintained, in each case in a manner consistent with past practice;
5. maintain the books and records (including prescription records) of each Drug Store To Be Maintained in the regular course of business and in accordance with past practice;

Order to Maintain Assets

6. not display any signs or conduct any advertising (*e.g.*, direct mailing, point-of-purchase coupons) that indicates that any Respondent is moving its operations at a Drug Store To Be Maintained to another location, or that indicates a Drug Store To Be Maintained will close;
7. not conduct any “going out of business,” “close-out,” “liquidation,” or similar sales or promotions at or relating to any Drug Store To Be Maintained; and
8. not change or modify in any material respect the existing advertising practices, programs and policies for any Drug Store To Be Maintained, other than changes in the ordinary course of business consistent with past practice for Drug Stores of the Respondents not being closed or relocated.

III.

IT IS FURTHER ORDERED that within thirty (30) days after the date this Order to Maintain Assets becomes final, and every thirty (30) days thereafter until Respondents have fully complied with Paragraph II. of the Decision and Order (*i.e.*, have assigned, licensed, divested, transferred, delivered, terminated, or otherwise conveyed all relevant assets or rights to the Commission-approved Acquirer in a manner that fully satisfies the requirements 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 in this matter becomes final, 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 VI. of the Decision and Order.

Order to Maintain Assets

IV.

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

- A. any proposed dissolution of Respondent Rite Aid;
- B. any proposed acquisition, merger or consolidation of Respondent Rite Aid; or
- C. any other change in Respondent Rite Aid 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 or the Decision and Order.

V.

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 made to their principal United States offices or headquarters address, Respondents shall, without restraint or interference, permit any duly authorized representative of the Commission:

- A. 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 Respondent related to compliance with this Order, which copying services shall be provided by Respondents at the request of the authorized representative(s) of the Commission; and
- B. to interview officers, directors, or employees of

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Respondents, who may have counsel present, regarding such matters.

VI.

IT IS FURTHER ORDERED that this Order to Maintain Assets shall terminate on 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. With respect to each Drug Store To Be Maintained, the day after Respondents' completion of the divestiture of Assets to Be Divested related to such Retail Drug Store, as described in and required by the attached Decision and Order.

Provided, however, that if the Commission, pursuant to Paragraph II.A. or II.B. of the Decision and Order, requires the Respondents to rescind any or all of the divestitures contemplated by the Purchaser Agreement, then, upon rescission, the requirements of this Order shall again be in effect with respect to the relevant Assets To Be Divested until the day after Respondents' completion of the divestiture(s) of the relevant Assets To Be Divested, as described in and required by the attached Decision and Order.

By the Commission.

DECISION AND ORDER

Decision and Order

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Respondent Rite Aid Corporation (“Rite Aid”) of 100 percent of the common and preferred shares of The Jean Coutu Group USA, Inc. from Respondent The Jean Coutu Group (PJC), Inc. (“Jean Coutu”), and Jean Coutu’s proposed acquisition of 30 percent of the common stock of Rite Aid pursuant to the Stock Purchase Agreement between Rite Aid and Jean Coutu, hereinafter referred to as “Respondents,” and Respondents 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 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;

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 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 has 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 Order to Maintain Assets, and 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

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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 makes the following jurisdictional findings and issues the following Decision and Order (“Order”):

- A. Respondent Rite Aid 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 30 Hunter Lane, Camp Hill, Pennsylvania 17011.
- B. Respondent Jean Coutu is a corporation organized, existing, and doing business under and by virtue of the laws of the Province of Quebec, with its office and principal place of business located at 530 Beriault Street, Longueuil, Quebec, Canada J4G1S8.
- C. The Commission has jurisdiction of the subject matter of this proceeding and of the Respondents, and the proceeding is in the public interest.

Decision and Order

ORDER**I.**

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

- A. “Rite Aid” means Rite Aid Corporation, its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Rite Aid Corporation and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Jean Coutu” means The Jean Coutu Group (PJC), Inc., its directors, officers, employees, agents, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by The Jean Coutu Group (PJC), Inc. and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Respondents” means Rite Aid and Jean Coutu, individually and collectively.
- D. “Acquisition” means Rite Aid’s proposed acquisition of the outstanding voting securities of Jean Coutu and Jean Coutu’s proposed acquisition of 30 percent of the voting securities of Rite Aid pursuant to the Stock Purchase Agreement Dated as of August 23, 2006, between Rite Aid and Jean Coutu.
- E. “Assets To Be Divested” means the assets that comprise the retail pharmacy businesses identified in Schedule A of this Order.

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- F. "Commission-Approved Acquirer" means any entity approved by the Commission to acquire any or all of the Assets To Be Divested pursuant to this Order.
- G. "Divestiture Trustee(s)" means any person or entity appointed by the Commission pursuant to Paragraph III. of this Order to act as a trustee in this matter.
- H. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or governmental entity, and any subsidiaries, divisions, groups or affiliates thereof.
- I. "Pharmacy" means any entity engaged in the retail sale of pharmaceuticals, other than entities whose retail sales are conducted exclusively via the internet, mail-order or telephone and whose transfer of pharmaceuticals to customers occurs exclusively through the mails or any other delivery service.
- J. "Prescription Files" means any and all files or databases containing customer prescription information.
- K. "Purchaser Agreements" means the asset purchase agreements listed below and all amendments, exhibits, attachments, related agreements, and schedules thereto, that have been approved by the Commission to accomplish the requirements of this Order:
 - 1. Asset Purchase Agreement between Rite Aid and Kinney Drugs, Inc., dated May 3, 2007;
 - 2. Asset Purchase Agreement between Rite Aid and Big Y Foods, Inc., dated May 3, 2007;

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3. Asset Purchase Agreement between Rite Aid and Weis Markets, Inc., dated May 11, 2007;
 4. Asset Purchase Agreement between Rite Aid and Walgreen Co. and Walgreen Eastern Co., dated May 15, 2007 ; and
 5. Asset Purchase Agreement between Rite Aid and Pharmacy Operations, Inc. and its subsidiary Pharmacy Operations of New York, Inc. (hereinafter “Medicine Shoppe International, Inc.”), dated May 9, 2007.
- L. “Retail Drug Store” means a full-line retail store that carries a wide variety of prescription and non-prescription pharmaceuticals and miscellaneous items, including, but not limited to, health and beauty aids, sundries, and other merchandise.
- M. “Apothecary-Style Drug Store” means a retail store that carries a wide variety of prescription and non-prescription pharmaceuticals, including specialty, compounded, or customized pharmaceuticals, nutritional and medical supplies, and provides services relating to, but not limited to, diabetes care and long-term care.
- N. “Third Party Consents” means all consents from any person other than the Respondents, including all landlords, that are necessary to effect the complete transfer to the Commission-Approved Acquirer(s) of the Assets To Be Divested.

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

- A. Respondents shall divest, absolutely and in good faith, the Assets To Be Divested, in accordance with the Purchaser

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Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of this Order), no later than

1. twenty (20) days after the date on which the Acquisition is consummated, or, in the case of the Assets To Be Divested to Medicine Shoppe International, Inc., forty (40) days after the date on which the Acquisition is consummated, or
2. four (4) months after the date on which Respondents sign the Agreement Containing Consent Order, whichever is earlier.

Provided, however, that if Respondents have divested any of the Assets To Be Divested pursuant to a Purchaser Agreement 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 purchaser identified at Definition K of this Order is not an acceptable acquirer of any of the Assets To Be Divested or that the manner in which the divestiture was accomplished is not acceptable, then Respondents shall immediately rescind the transaction with that purchaser and shall divest the assets transferred to that purchaser within three (3) months of the date the Order becomes final, absolutely and in good faith, at no minimum price, to a Commission-Approved Acquirer and only in a manner that receives the prior approval of the Commission.

- B. Any Purchaser Agreements that have been approved by the Commission between the Respondents (or a Divestiture Trustee) and an acquirer of the Assets To Be Divested shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Purchaser Agreements shall constitute a failure to comply with this Order.

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- C. Respondents shall obtain all required Third Party Consents prior to the closing of the Purchaser Agreements or any other agreement pursuant to which the Assets To Be Divested are divested.
- D. Pending divestiture of the Assets To Be Divested, Respondents shall take such actions as are necessary to maintain the full economic viability and marketability of the business associated with those assets, to minimize any risk of loss of competitive potential for such business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of those assets except for ordinary wear and tear.
- E. The purpose of the divestitures is to ensure the continuation of the Assets To Be Divested as ongoing viable enterprises engaged in the Retail Drug Store or Apothecary-Style Drug Store business and to remedy the lessening of competition resulting from the Acquisition alleged in the Commission's Complaint.

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

- A. If Respondents have not divested all of the Assets To Be Divested as required by Paragraph II. of this Order, the Commission may appoint a trustee to divest ("Divestiture Trustee") the remaining Assets To Be Divested in a manner that satisfies the requirements of Paragraphs II. and III. 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

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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 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. Within ten (10) days after 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 relevant divestiture or transfer required by the Order.
- D. If a Divestiture Trustee is appointed by the Commission or a court pursuant to this Order, 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,

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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; 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 III.D.3 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

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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, however, that Respondents shall select such Person 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 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 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 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

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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 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 misfeasance, 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 III.

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- 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.

IV.

IT IS FURTHER ORDERED that for a period of ten (10) years commencing on the date this Order becomes final, Respondents shall not acquire, directly or indirectly, through subsidiaries, partnerships or otherwise, without providing advance written notification to the Commission:

- A. Any ownership or leasehold interest in any facility that has operated a pharmacy within five (5) miles of any store to be divested pursuant to this Order within six (6) months prior to the date of such proposed acquisition.
- B. The prescription files from or any stock, share capital, equity, or other interest in any entity that owns any interest in or operates any pharmacy or owned any interest in or operated any pharmacy within five (5) miles of any store to be divested pursuant to this Order within six (6) months prior to such proposed acquisition.

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, 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 Respondents and not of any other party to the transaction.

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Respondents shall provide the notification to 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), Respondents shall not consummate the transaction until thirty (30) days after substantially complying with such request. 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.

V.

IT IS FURTHER ORDERED that, for a period of ten (10) years commencing on the date this Order becomes final, Respondents shall neither enter into nor enforce any agreement that restricts the ability of any person (as defined in Section 1(a) of the Clayton Act, 15 U.S.C. § 12(a)) that acquires any pharmacy, any leasehold interest in any pharmacy, or any interest in any retail location used as a pharmacy on or after January 1, 2007, within five (5) miles of any store divested pursuant to this Order, to operate a pharmacy at that site if such pharmacy was formerly owned or operated by Respondents.

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 the Respondents have fully complied with the provisions of

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Paragraphs II. and III. of this Order, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they intend to comply, are complying, and have complied with Paragraphs II. and III. of this Order. 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 this Order, including a description of all substantive contacts or negotiations for the divestitures and the identity of all parties contacted. Respondents shall include in their compliance reports copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations; and

- 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, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they are complying and have complied with this Order and the Purchaser Agreements.

VII.

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

- A. Any proposed dissolution of such Respondents;
- B. Any proposed acquisition, merger or consolidation of Respondents; or
- C. Any other change in the Respondents, including, but not limited to, assignment and the creation or dissolution of

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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, upon written request with reasonable notice to Respondents made to their principal United States office, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during 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 Respondents relating to any matters contained in this Order; and
- B. Upon five (5) days notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding any such matters.

IX.

IT IS FURTHER ORDERED that this Order shall terminate on September 17, 2017.

By the Commission.

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SCHEDULE A

Pursuant to the terms of the Consent Agreement and this Decision and Order the following assets shall be divested as follows:

1. Rite Aid Store #3342 located at 261 Utica Boulevard, Boonville, NY 13309 will be sold to Kinney Drug Inc.
2. Rite Aid Store #4119 located at Route 5 Memorial Drive, Lyndonville, VT 58511 will be sold to Kinney Drug Inc.
3. Rite Aid Store #4973 located at 957 Memorial Drive, St. Johnsbury, VT 05819 will be sold to Kinney Drug Inc.
4. Brooks Store #0590 located at 87-C West Stafford Road, Stafford Springs, CT 06076 will be sold to Big Y Foods, Inc.
5. Eckerd Store #6240 located at 225 South Mountain Blvd., Mountain Top, PA 18707 will be sold to Weis Markets Inc.
6. Rite Aid Store #0799 located at 234 South Main St., Zelienople, PA 16063 will be sold to Walgreen Co.
7. Brooks Store #0891 located at SWC Bridge & Willow Streets, Pelham, NH 03076 will be sold to Walgreen Co.
8. Rite Aid Store #2570 located at 14 Pinnacle Lane, Walpole, NH 03608 will be sold to Walgreen Co.
9. Eckerd Store #0797 located at 2 North Virginia Avenue, Penns Grove, NJ 08069 will be sold to Walgreen Co.
10. Rite Aid Store #1211 located at 3242 Route 39, Yorkshire, NY 14173 will be sold to Walgreen Co.
11. Rite Aid Store #3641 located at 100 South College Drive, Franklin, VA 23851 will be sold to Walgreen Co.

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12. Eckerd Store #6296 located at 40 Denton Plaza, Denton, MD 21629 will be sold to Medicine Shoppe International Inc.
13. Brooks Store #0386 located at 415 Water Street, Gardiner, ME 04345 will be sold to Medicine Shoppe International Inc.
14. Rite Aid Store #3355 located at 145 Main Street, Berlin, NH 03570 will be sold to Medicine Shoppe International Inc.
15. Rite Aid Store #4164 located at 5 Main Street, Peterborough, NH 03458 will be sold to Medicine Shoppe International Inc.
16. Rite Aid Store #0577 located at 941 State Route 17C, Owego, NY 13827 will be sold to Medicine Shoppe International Inc.
17. Rite Aid Store #1861 located at 2156 Grand Island Blvd., Grand Island, NY 14072 will be sold to Medicine Shoppe International Inc.
18. Rite Aid Store #2678 located at #2 Price Chopper Plaza, Mechanicville, NY 12118 will be sold to Medicine Shoppe International Inc.
19. Eckerd Store #5825 located at 45 Hadjus Way, Lake Placid, NY 12946 will be sold to Medicine Shoppe International Inc.
20. Eckerd Store #5961 located at 12 Bank Street, LeRoy, NY 14482 will be sold to Medicine Shoppe International Inc.

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21. Eckerd Store #5850 located at 208 South Main Street, Moscow, PA 18444 will be sold to Medicine Shoppe International Inc.
22. Eckerd Store #6008 located at 37 Market Street, Brownsville, PA 15417 will be sold to Medicine Shoppe International Inc.
23. Eckerd Store #8706 located at 533 Greenville Road, Mercer, PA 16137 will be sold to Medicine Shoppe International Inc.

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 with Rite Aid Corporation (“Rite Aid”) and The Jean Coutu Group (PJC), Inc. (“Jean Coutu”) (collectively “the Proposed Respondents”). The Agreement is designed to remedy the likely anticompetitive effects arising from Rite Aid’s proposed acquisition of the Brooks and Eckerd retail pharmacies from Jean Coutu. The 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 Agreement and the comments received, and will decide whether it should withdraw from the agreement or make the proposed Order final.

The purpose of this analysis is to invite public comment on the proposed consent Order. This analysis does not constitute an official interpretation of the agreement and proposed Order, and does not modify the terms in any way. Further, the proposed consent Order has been entered into for settlement purposes only, and does not constitute an admission by the Proposed Respondents that they violated the law or that the facts alleged in the Complaint against the Respondents (other than jurisdictional facts) are true.

On August 23, 2006, Rite Aid entered into a Stock Purchase Agreement whereby Rite Aid would acquire Jean Coutu’s Eckerd and Brooks retail pharmacy chains in exchange for approximately \$3.5 billion worth of cash and stock. As a result of the transaction, Rite Aid would hold 100% of the common and preferred shares of The Jean Coutu Group USA, Inc., and Jean Coutu would acquire approximately 30% of the voting securities of Rite Aid.

Analysis to Aid Public Comment

II. Respondents

Respondent Rite Aid, a publicly-traded Delaware corporation, is the third largest retail pharmacy chain in the United States. Rite Aid owns 3,333 stores in the United States, which are primarily located on the East and West Coasts.

Respondent Jean Coutu is a publicly-traded corporation headquartered in Longueuil, Quebec, Canada. Jean Coutu is the parent of The Jean Coutu Group USA, Inc., which owns and operates the Brooks and Eckerd retail pharmacy chains. Jean Coutu currently owns 1,517 Eckerd and 341 Brooks stores, which are located exclusively in the Northeast and Mid-Atlantic regions of the United States. The Jean Coutu stores collectively constitute the fourth largest retail pharmacy chain in the United States.

III. The Complaint

The complaint alleges that the relevant product market in which to analyze the acquisition is the retail sale of pharmacy services to cash customers in local markets. Pharmacy services include the provision of medications by a licensed pharmacist who is able to provide usage advice and other relevant information as may be required by law. Cash customers are consumers of pharmacy services that do not pay a price negotiated by or paid through a third party (such as an insurance plan or a pharmacy benefits manager). Cash customers generally pay the full posted or list price set by a pharmacy for a prescription drug or an amount reflecting a discount off of those prices. The evidence indicates that the sale of pharmacy services to cash customers is a separate market from the sale of pharmacy services to customers covered by third party payors. This is consistent with prior Commission investigations regarding pharmacy services.

The evidence indicates that pricing in the cash prescription market is not constrained by competitive conditions in the third party payor prescription market, nor by mail order pharmacies or discount cards. Cash customers pay prices that are consistently

Analysis to Aid Public Comment

higher than prices on the same drugs paid for by third party payors, and there is a significant disparity in profit margins between sales to cash customers and sales to customers covered by third party payors.

Cash customers are most likely unable to purchase health insurance or obtain health benefits from an employer in response to a post-merger price increase for cash prescriptions.

Evidence indicates that cash customers typically do not travel far to fill prescriptions and that pharmacies evaluate competition for cash customers on a localized basis. Therefore, it is appropriate to analyze the competitive effects of the proposed transaction in local geographic markets. The complaint identifies the specific twenty-three relevant geographic markets in which to analyze the effects of the proposed transaction, which include individual towns, cities, boroughs, villages and census-designated areas, or combinations thereof.

The local markets for the retail sale of pharmacy services to cash customers identified in the complaint are highly concentrated. In each of these markets, Rite Aid and Eckerd/Brooks are two of a small number of pharmacies offering cash services, and combined account for at least half, and up to 100 percent, of the pharmacies in the market. Moreover, there is evidence that a significant number of customers view the Rite Aid and Eckerd/Brooks pharmacies in these markets as their first and second choices based on their physical proximity, convenient locations and services offered. Therefore, the complaint alleges that the proposed transaction likely would allow Rite Aid to unilaterally exercise market power, thereby making it likely that cash pharmacy customers would pay higher prices in these areas.

The complaint further alleges that entry would not be timely, likely or sufficient to prevent the anticompetitive effects from the proposed transaction. Certain specific factors make entry into the twenty-three cash prescription markets unlikely. First, because the vast majority of a pharmacy's profits come from sales other than

Analysis to Aid Public Comment

cash prescriptions, including prescription sales to insured customers and the sale of front-end items (e.g., toothpaste), it is unlikely that an anticompetitive price increase in cash prescription sales would attract new entry. Second, most of the twenty-three markets are small towns or rural areas that may not have a sufficient number of potential customers to support a new pharmacy. Third, opening a new pharmacy requires obtaining zoning, planning and environmental approvals, which can take a significant amount of time. Finally, the limited availability of new pharmacists may serve as an impediment to entry in these areas.

The complaint also alleges that the proposed acquisition, if consummated, may substantially lessen competition in the retail sale of pharmacy services to cash customers in twenty-three local areas, 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, by eliminating actual, direct, and substantial competition between Proposed Respondents in the relevant markets and by increasing the likelihood that the combined Rite Aid/Brooks-Eckerd will unilaterally exercise market power in the relevant markets, each of which increases the likelihood that the prices of pharmacy services to cash customers will increase, and the quality and selection of such services will decrease.

IV. The Terms of the Agreement Containing Consent Orders

The proposed consent order effectively remedies the proposed acquisition's likely anticompetitive effects in the relevant product markets. Pursuant to the proposed consent order, the Proposed Respondents are required to divest one store in each of the twenty-three geographic areas to a Commission-approved acquiror. Specifically, the proposed consent order requires the proposed Respondents to divest one store in each relevant geographic area to one of five up-front buyers including Kinney Drugs, Medicine Shoppe International, Inc. ("Medicine Shoppe"), Walgreen Co., Big Y, and Weis Markets. Kinney Drugs is an employee-owned company headquartered in New York that has 80 retail drug stores in

Analysis to Aid Public Comment

central and northern New York and Vermont. Medicine Shoppe, headquartered in Missouri, operates 24 company-owned apothecary-style drugs stores and is the franchisor of approximately 1,000 apothecary-style franchised locations throughout the country. Walgreen Co., headquartered in Illinois, is the second largest retail drug store chain in the U.S., operating approximately 5,675 stores in 48 states and Puerto Rico. Big Y is one of New England's largest independent supermarket chains, with more than 50 locations throughout Massachusetts and Connecticut. Weis Markets is a Pennsylvania-based supermarket that operates more than 150 grocery stores, some of which contain pharmacy counters, in Pennsylvania, Maryland, New Jersey, West Virginia, and New York. Each of the up-front buyers is competitively and financially viable and each is well qualified to operate the divested stores. AS a result, the required divestitures to these companies will be sufficient to maintain competition in the relevant markets. A list of the specific pharmacies that the Proposed Respondents must divest to each of the up-front buyers is attached as Schedule A to the proposed Decision and Order.

The proposed consent order requires the divestitures to occur no later than twenty days, or, in the case of the divestitures to Medicine Shoppe, no later than forty days after the acquisition is consummated, or four months after the date on which the Proposed Respondents sign the proposed consent order, whichever is earlier. However, if the Proposed Respondents consummate the divestitures to any of the up-front buyers during the public comment period, and if, at the time the Commission decides to make the proposed consent order final, the Commission notifies the Proposed Respondents that any of the up-front buyers is not an acceptable acquirer or that any up-front buyer agreement is not an acceptable manner of divestiture, then the Proposed Respondents must immediately rescind the transaction in question and divest those assets within three months of the date the proposed consent order becomes final. At that time, the Proposed Respondents must divest those assets only to an acquirer, and only in a manner, that receives the prior approval of

Analysis to Aid Public Comment

the Commission.

The proposed consent order also contains an Order to Maintain Assets. This will serve to: (1) maintain the full economic viability and marketability of the pharmacies identified for divestitures, (2) minimize any risk of loss of competitive potential for such businesses, and (3) prevent the destruction, removal, wasting, deterioration, or impairment of any of these assets except for ordinary wear and tear.

The proposed consent order also gives the Commission the power to appoint a trustee to divest any pharmacies identified in the order that Proposed Respondents have not divested to satisfy the requirements of the order. In addition, the proposed consent order permits the Commission to seek civil penalties against the Proposed Respondents for non-compliance with the order.

For a period of ten years from the date the proposed consent order becomes final, the Proposed Respondents are required to provide written notice to the Commission prior to acquiring any ownership or leasehold interest in any facility that has operated as a pharmacy within the previous six months and is located within five miles of any store to be divested pursuant to the proposed consent order. The ten-year written notice requirement also applies to the acquisition by the Proposed Respondents of any prescription files, stock, share capital, equity, or other interest in any entity that owns any interest in or operates any pharmacy that is located within five miles of any store to be divested pursuant to the proposed consent order and has been in existence as a pharmacy within the previous six months. This provision does not restrict the Proposed Respondents from constructing new pharmacies in the relevant markets; nor does it restrict the Proposed Respondents from leasing facilities not operated as pharmacies within the previous six months.

The proposed consent order further prohibits the Proposed Respondents, for a period of ten years, from entering into or enforcing any agreement that restricts the ability of any person that

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acquires any pharmacy, any leasehold interest in any pharmacy, or any interest in any retail location used as a pharmacy on or after January 1, 2007 in the relevant markets to operate a pharmacy at that site if such pharmacy was formerly owned or operated by the Proposed Respondents.

The Proposed Respondents are required to provide to the Commission a report of compliance with the proposed consent order within thirty days following the date on which they sign the proposed consent order, every thirty days thereafter until the divestitures are completed, and annually for ten years.

Complaint

IN THE MATTER OF

AMERICAN RENAL ASSOCIATES, INC.,
AND
FRESENIUS MEDICAL CARE HOLDINGS, INC.

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

Docket C-4202; File No. 051 0234

Complaint, October 17, 2007 – Decision, October 17, 2007

This consent order addresses the \$4.4 million acquisition by American Renal Associates, Inc. (“ARA”) of certain assets from Fresenius Medical Care Holdings, Inc. In 2005, Fresenius and ARA, competitors in the provision of outpatient dialysis services, agreed to close three Fresenius clinics. The parties further agreed that Fresenius would not reopen any outpatient dialysis clinics within 10 to 12 miles of the closed facilities for at least five years, and would attempt to enforce the non-compete provisions of its agreements with the medical directors of the closed facilities for ARA’s benefit. The complaint alleges that this agreement was a horizontal agreement to eliminate competition and a *per se* violation of antitrust laws. The complaint further alleges that ARA’s purchase of outpatient dialysis clinics from Fresenius would reduce dialysis capacity; allocate dialysis customers, territories, or markets; and lessen competition in the outpatient dialysis services market in the Warwick/Cranston area. The consent order prohibits ARA and Fresenius from agreeing with other dialysis clinic operators to close any clinics or from allocating any dialysis service markets.

Participants

For the *Commission*: Bradley S. Albert, Leslie Farber, Mark Frankena, William Layher, Markus H. Meier, Martha H. Oppenheim, James E. Rhilinger, Gary H. Schorr, and Karan R. Singh.

For the *Respondents*: Robert Bloch, Mayer, Brown, Rowe & Maw; and Daniel L. Goldberg, Bingham McCutchen.

Complaint

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, having reason to believe that American Renal Associates, Inc. (“ARA”) and Fresenius Medical Care Holdings, Inc. (“Fresenius”), together hereinafter sometimes collectively referred to as “Respondents,” have violated Section 5 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 45, and, in addition, violated 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 this Complaint stating its charges in that respect as follows:

I. NATURE OF THE CASE

1. This matter concerns an agreement between ARA and Fresenius which, if consummated, would have resulted in: (a) Fresenius closing three of its outpatient dialysis clinics in Rhode Island and southeast Massachusetts, each of which is located near a competing ARA facility, in exchange for payments from ARA totaling \$1,641,000; and (b) ARA acquiring Fresenius’s five remaining Rhode Island clinics, two of which compete directly with a nearby ARA clinic, in exchange for payments to Fresenius totaling an additional \$2,759,000.

2. By agreeing to close three Fresenius clinics, Respondents would have denied consumers of outpatient dialysis services in Rhode Island and southeast Massachusetts the benefits of competition, by effectively allocating Fresenius’s patients in those areas to ARA. Further, the proposed acquisition of Fresenius’s two Warwick, Rhode Island, clinics would have left ARA as the sole provider of outpatient dialysis services in Warwick-Cranston area, likely resulting in increased prices and reduced service and quality to consumers of outpatient dialysis services in that area.

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II. RESPONDENTS

3. Respondent American Renal Associates, Inc. (“ARA”), 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 66 Cherry Hill Drive, Beverly, Massachusetts 01915. ARA is the parent of eight entities that are parties to the agreement at issue: Dialysis Center of Wakefield, L.L.C., Dialysis Center of Warwick, L.L.C., Dialysis Center of West Warwick, L.L.C., Dialysis Center of Westerly, L.L.C., Dialysis Center of Woonsocket, L.L.C., ARA-East Providence, L.L.C., ARA-Johnston Dialysis, L.L.C., and ARA-Fall River, L.L.C.

4. Respondent Fresenius Medical Care Holdings, Inc. (“Fresenius”), is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02420-9192. Fresenius is the parent of entities that are parties to the agreement at issue, including Renal Care Group, Inc. and Bio-Medical Applications of Rhode Island, Inc.

5. Respondents are corporations within the meaning of Section 4 of the FTC Act, 15 U.S.C. § 44.

6. The general business practices of ARA and Fresenius, and the acts and practices described below, affect the interstate movement of patients, the interstate purchase of supplies and products, and the interstate flow of funds, and are in or affect commerce within the meaning of Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44, and Section 1 of the Clayton Act, as amended, 15 U.S.C. § 12.

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**III. THE RESPONDENTS' ASSET PURCHASE
AGREEMENT**

7. ARA and Fresenius entered into an Asset Purchase Agreement dated August 3, 2005, involving payments from ARA to Fresenius totaling \$4.4 million.

8. The Asset Purchase Agreement required Fresenius to close its clinics in East Providence and North Providence, Rhode Island, and in Fall River, Massachusetts, in exchange for ARA's payment of \$1,641,000 ("the Clinic Closing Agreement").

9. The Asset Purchase Agreement also provided for ARA's acquisition of Fresenius's five remaining clinics in Rhode Island – located in Wakefield, Westerly, Woonsocket, Warwick, and West Warwick – for \$2,759,000 ("the Clinic Acquisition Agreement").

10. After Commission staff learned of the Asset Purchase Agreement and contacted Respondents with several concerns about the agreement's terms, Respondents terminated the Asset Purchase Agreement on March 13, 2006.

IV. THE CLINIC CLOSING AGREEMENT**A. Description of the Clinic Closing Agreement**

11. During discussions between ARA and Fresenius concerning the sale of Fresenius's outpatient dialysis clinics in Rhode Island, the Respondents entered into an agreement whereby Fresenius agreed to close three clinics in East Providence and North Providence, Rhode Island, and Fall River, Massachusetts, in return for the sum of \$1,641,000 from ARA.

12. Respondents further agreed that Fresenius would not reopen any outpatient dialysis clinics within 10-12 miles of the closed facilities for at least five years, and would attempt to enforce the

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non-compete provisions of its agreements with the medical directors of the closed facilities, preventing those physicians from serving as medical directors for any potential new entrant.

13. Each of the Fresenius clinics to be closed was located in close proximity to ARA outpatient dialysis clinics in East Providence and Johnston, Rhode Island, and Fall River, Massachusetts, respectively.

14. The Respondents memorialized their agreement in a written contract, listing each Fresenius clinic to be closed, along with the specific amount of money to be paid for closing each clinic allocated to the three ARA clinics in closest proximity to the clinics to be closed. The contract was signed by officials from both ARA and Fresenius.

B. Effects of the Clinic Closing Agreement

15. The Clinic Closing Agreement, if implemented, would have had the effect of unreasonably restraining trade and hindering competition in the provision of outpatient dialysis services, by, among others:

- a. eliminating actual, direct, and substantial competition between ARA and Fresenius;
- b. increasing the ability of ARA to unilaterally raise prices; and
- c. reducing ARA's incentives to improve service or quality.

16. Neither ARA nor Fresenius offered a plausible pro-competitive justification for the Clinic Closing Agreement.

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V. THE CLINIC ACQUISITION AGREEMENT**A. The Relevant Market**

17. The relevant product market in which to assess the competitive effects of the Clinic Acquisition Agreement is the provision of outpatient dialysis services. End stage renal disease (“ESRD”) is 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. ESRD may be treated through dialysis, a process whereby a person’s blood is filtered, inside or outside the body, by machines that act as artificial kidneys.

18. Most ESRD patients receive dialysis treatments at dialysis centers three times per week in sessions lasting between three and five hours. These treatments are done on an outpatient basis, whereby the patient’s time spent at the dialysis center is solely for treatment.

19. The only alternative to outpatient dialysis treatments for patients suffering from ESRD is a kidney transplant. The wait-time for donor kidneys, during which ESRD patients must receive dialysis treatments, however, can exceed five years. Additionally, many ESRD patients are not viable transplant candidates. As a result, many ESRD patients have no alternative to ongoing dialysis treatments.

20. The relevant geographic market in which to assess the competitive effects of the Clinic Acquisition Agreement is the Cranston and Warwick area in Rhode Island (“the Cranston-Warwick market”).

21. The relevant geographic market for the provision of outpatient dialysis services is defined by the distance ESRD patients are willing or able to travel to receive dialysis treatments, and is thus local in nature. Because ESRD patients often suffer from multiple

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health problems and may require assistance traveling to and from the dialysis clinic, and because of the high frequency of treatments, these patients are unwilling or unable to travel long distances to receive dialysis treatment. The time and distance a patient will travel in a particular location are significantly affected by local traffic patterns; whether an area is urban, suburban, or rural; local geography; and a patient's proximity to the nearest dialysis clinic. The size and dimensions of relevant geographic markets are also influenced by a variety of other factors including population density, roads, geographic features, and political boundaries.

B. The Structure of the Market

22. The market for the provision of outpatient dialysis services in the Cranston-Warwick market is highly concentrated, as measured by the Herfindahl-Hirschman Index ("HHI"). Given that ARA and Fresenius are the only two providers of outpatient dialysis services in the market, the Clinic Acquisition Agreement would leave ARA as the sole provider of dialysis services in that area.

C. Entry Conditions

23. The most significant impediment to entry into the relevant market is locating a nephrologist with an established referral base who is willing and able to enter into a contract with a dialysis clinic to serve as the clinic's medical director. Federal law requires that each dialysis clinic have a physician medical director. Having a nephrologist serve as medical director is essential to the competitiveness of the clinic, because he or she is the clinic's primary source of referrals. A medical director's contract with a clinic typically prevents the medical director (and often his or her partners) from serving as a medical director for a competing clinic while serving as the clinic's medical director. The lack of available nephrologists with an established referral stream is a significant impediment to entry into the relevant market.

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24. New entry into the relevant market sufficient to deter or counteract the potential anticompetitive effects of the Clinic Acquisition Agreement is unlikely to occur, and would not occur in a timely manner because it would take over two years to enter and achieve significant market impact.

D. Effects of the Clinic Acquisition Agreement

25. The Clinic Acquisition Agreement, if consummated, would have had the effect of substantially lessening competition in the relevant market by, among others:

- a. eliminating actual, direct, and substantial competition between ARA and Fresenius;
- b. increasing the ability of ARA to unilaterally raise prices; and
- c. reducing ARA's incentives to improve service or quality.

VII. VIOLATIONS CHARGED**A. The Clinic Closing Agreement**

26. The Clinic Closing Agreement 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.

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B. The Clinic Acquisition Agreement

27. The effects of the Clinic Acquisition Agreement, 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.

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this seventeenth day of October, 2007, issues its complaint against the Respondents.

By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent American Renal Associates, Inc., of certain assets owned by Respondent Fresenius Medical Care Holdings, Inc., (hereinafter “Respondents”) and of certain acts and practices of the Respondents, and the 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

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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 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 American Renal Associates Inc. 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 66 Cherry Hill Drive, Beverly, Massachusetts 01915.

2. Respondent Fresenius Medical Care Holdings, Inc., is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02420.

3. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of Respondents, 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. “ARA” means American Renal Associates, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by ARA including, but not limited to, ARA-East Providence Dialysis LLC, ARA-Johnston Dialysis LLC, ARA-Fall River Dialysis LLC, and Dialysis Center of West Warwick LLC, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “Fresenius” means Fresenius Medical Care Holdings, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Fresenius Medical Care Holdings, Inc. (including Renal Care Group, Inc. and Bio-Medical Applications of Rhode Island, Inc.), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Clinic” means a facility that provides Dialysis Services.
- D. “Clinic Operator” means a person who owns or engages in the Operation of a Clinic, or who attempts to own or engage in the Operation of a Clinic.
- E. “Commission” means the Federal Trade Commission.
- F. “Cranston-Warwick Area” means the area within ZIP codes 02818, 02886, 02888, 02889, 02893, 02905, 02907, 02909, 02910, 02920, 02921, that portion of 02919 south of U.S.

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Route 6, and those portions of 02831 and 02816 east of Route 116, which are the ZIP codes in and around the cities of Cranston and Warwick, Rhode Island.

- G. “Dialysis Services” means the provision of outpatient hemodialysis or peritoneal dialysis services to patients suffering from kidney disease.
- H. “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.
- I. “Joint Venture Clinic” means a Clinic in which a Respondent owns an interest of at least 50%, but less than 100%.
- J. “Joint Venture Partner” means a Person other than a Respondent that owns an interest in a Joint Venture Clinic.
- K. “Material Confidential 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.
- L. “Operation Of A Clinic” means 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

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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.
- M. "Ordinary Patient Transfer" means the occasional or periodic transfer of an individual patient from one Clinic to another Clinic at the request of the patient, or the patient's family, care giver or physician.
- N. "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

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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.

- O. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- P. “Physician” means a doctor of allopathic medicine (“M.D.”) or a doctor of osteopathic medicine (“D.O.”).
- Q. “Relating To” or “Related To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.

II.

IT IS FURTHER ORDERED that each Respondent shall not, expressly or implicitly, directly or indirectly, enter into, continue, maintain, enforce, or offer to enter into any agreement with any Clinic Operator to (1) close any Clinic, or (2) allocate any Dialysis Services market, territory, or customer.

Provided, however, that nothing in this Paragraph shall prohibit each Respondent from (i) unilaterally deciding to close any of its own Clinics (or, in the case of a Joint Venture Clinic, from making any such decision with its Joint Venture Partner for that Clinic), (ii) assisting the owner of any Clinic managed by such Respondent with respect to the closure of such managed Clinic, (iii) entering into non-competition agreements of reasonable duration and geographic scope (a) ancillary to a lawful sale, acquisition, or formation of a Clinic or Joint Venture Clinic, or (b) ancillary to a contract for employment or professional services of an employee or medical

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director, or (iv) continuing the current non-competition agreements of employees, medical directors, Clinics and Joint Venture Clinics.

Provided further, however, that nothing in this Paragraph shall apply to any agreement entered into for an Ordinary Patient Transfer.

III.

IT IS FURTHER ORDERED that, for a period of ten (10) years from the date this Order becomes final, Respondent ARA shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly:

- A. acquire any assets of or financial interest in any Clinic located in the Cranston-Warwick Area, except to the extent that the acquisition is in:
 - 1. Clinics owned or operated by Respondent ARA at the time this Order becomes final; or
 - 2. in *de novo* Clinics opened by Respondent ARA.
- B. enter into any contract to participate in the management or Operation Of A Clinic located in the Cranston-Warwick Area, except to the extent that the contract relates exclusively to:
 - 1. off-site lab services or social worker support materials;
 - 2. the management of Clinics owned or operated by Respondent ARA at the time this Order becomes final;
 - 3. the management of a *de novo* Clinic opened by Respondent ARA; or
 - 4. billing services, collection services, bookkeeping services, accounting services, supply purchasing and

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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 Material Confidential Information of the Clinic from being disclosed to anyone participating in any way in the operation or management of any Clinic owned by ARA 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 ARA and not from any other party to the transaction. ARA 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), ARA 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 Bureau of Competition.

Provided, however, that prior notification shall not be required by this paragraph for a transaction for which Notification is required to

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be made, and has been made, pursuant to Section 7A of the Clayton Act, 15 U.S.C. § 18a.

IV.

IT IS FURTHER ORDERED that ninety (90) days after the date this order becomes final, 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 ten (10) years, Respondents shall submit to the Commission verified written reports setting forth in detail the manner and form in which they are complying and have complied with this Order.

V.

IT IS FURTHER ORDERED that, each 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.

VI.

IT IS FURTHER ORDERED that, with respect to its own organization, for the purpose of determining or securing compliance with this Order, subject to any legally recognized privilege, and upon written request with reasonable notice to Respondent, each Respondent shall permit any duly authorized representative of the Commission:

Analysis to Aid Public Comment

- 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 related to compliance with this Order; 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 October 17, 2017.

By the Commission.

**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 American Renal Associates, Inc., and affiliates including, but not limited to, ARA-East Providence Dialysis LLC, ARA-Johnston Dialysis LLC, ARA-Fall River Dialysis LLC, and Dialysis Center of West Warwick LLC; and Fresenius Medical Care Holdings, Inc. and affiliates, including

Analysis to Aid Public Comment

Renal Care Group, Inc. and Bio-Medical Applications of Rhode Island, Inc. Under the terms of the Consent Agreement, ARA and Fresenius are prohibited from agreeing with other dialysis clinic operators to close any clinics, or allocate any dialysis service markets. ARA is further required to notify the Commission of acquisitions of dialysis clinic assets in the Warwick/Cranston, Rhode Island, area.

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 Asset Purchase Agreement dated August 3, 2005, ARA proposed to acquire five Fresenius clinics in the Providence, Rhode Island/Fall River, Massachusetts area, and pay Fresenius to close another three competing clinics, for approximately \$4.4 million. ARA's agreement to pay Fresenius to close its clinics is a *per se* violation of the antitrust laws. In addition, the Commission's Complaint alleges, as summarized below, that the Asset Purchase Agreement, 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, by reducing dialysis capacity; allocating dialysis customers, territories, or markets; and lessening competition in the market for the provision of outpatient dialysis services in the Warwick/Cranston area.

Analysis to Aid Public Comment

II. The Parties

American Renal Associates, Inc., which is headquartered in Danvers, Massachusetts, operates 65 dialysis centers in 15 states and the District of Columbia. ARA is the sixth-largest provider of outpatient dialysis services in the United States, serving 2,300 dialysis patients, with 2004 revenues exceeding \$80 million. In 2005, ARA owned six clinics in Rhode Island, which were located in Cranston, East Providence, Johnston, Pawtucket, Providence, and Tiverton, and one in nearby Fall River, Massachusetts.

Fresenius Medical Care Holdings, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of New York, with its principal place of business located at 95 Hayden Avenue, Lexington, Massachusetts 02420-9192. Fresenius is the parent of entities that are parties to the Consent Agreement, including Renal Care Group, Inc. and Bio-Medical Applications of Rhode Island, Inc.

III. The Asset Purchase Agreement

ARA and Fresenius entered into an Asset Purchase Agreement dated August 3, 2005, under which Fresenius agreed to sell five clinics located in Rhode Island – the Wakefield, Westerly, Woonsocket, Warwick, and West Warwick clinics – to ARA for \$2,759,000. The agreement also required Fresenius to close its clinics in East Providence and North Providence, Rhode Island, and in Fall River, Massachusetts, in exchange for ARA's payment of \$1,641,000. The parties terminated this agreement on March 13, 2006, after the FTC staff raised antitrust concerns.

Analysis to Aid Public Comment

IV. The Complaint**A. Agreement Between Competitors to Close Clinics**

The Commission's complaint charges that first and foremost, the agreement between Fresenius and ARA – competitors in the provision of outpatient dialysis services – to close three Fresenius clinics was a horizontal agreement to eliminate competition and to reduce dialysis capacity in the three affected areas. Each of the Fresenius clinics to be closed was located close to a competing ARA outpatient dialysis clinic. The parties memorialized their agreement in a written contract, listing each Fresenius clinic to be closed and the specific amount of money to be paid by ARA for closing each clinic, and allocating each amount to the ARA clinic closest to the clinic to be closed. The parties further agreed that Fresenius would not reopen any outpatient dialysis clinics within 10 to 12 miles of the closed facilities for at least five years, and would attempt to enforce the non-compete provisions of its agreements with the medical directors of the closed facilities for ARA's benefit, preventing those physicians from serving as medical directors for any potential new entrant.

Agreements to pay a competitor to exit a market, such as the one negotiated by ARA and Fresenius, are per se unlawful. Indeed, the parties offered no competitive justification for their conduct, and it is unlikely that there is any plausible justification for such an agreement. Such a naked restraint, like a market division agreement or price fixing, is a per se violation of the antitrust laws.

B. Agreement to Eliminate Competition by Acquiring Clinics

The Commission also charges that ARA's proposed acquisition of Fresenius's two Warwick, Rhode Island, facilities would have substantially reduced competition for outpatient dialysis services by eliminating competition between these Warwick clinics and ARA's nearby Cranston, Rhode Island, clinic. Outpatient dialysis services is the relevant product market in which to assess the effects of the

Analysis to Aid Public Comment

clinic acquisition portion of the asset purchase agreement. End stage renal disease (ESRD) is 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. ESRD may be treated through dialysis, a process whereby a person's blood is filtered by machines that act as artificial kidneys. Most ESRD patients receive dialysis treatments in an outpatient dialysis clinic three times per week, in sessions lasting between three and five hours. The only alternative to outpatient dialysis treatments for ESRD patients 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, many ESRD patients have no alternative to ongoing dialysis treatments.

The Commission's complaint also alleges that the relevant geographic market in which to assess the competitive effects of the clinic acquisition portion of the asset purchase agreement is the Cranston and Warwick area in Rhode Island. The relevant geographic market for the provision of outpatient dialysis services is defined by the distance ESRD patients are willing and able to travel to receive 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, and because of the high frequency of treatments, these patients are unwilling and unable to travel long distances for dialysis treatment. The time and distance a patient will travel in a particular location are significantly affected by local traffic patterns; whether an area is urban, suburban, or rural; local geography; and a patient's proximity to the nearest dialysis clinic. The size and dimensions of relevant geographic markets are also influenced by a variety of other factors including population density, roads, geographic features, and political boundaries.

With respect to the clinic acquisition portion of the asset purchase agreement, the Commission's complaint alleges that the

Analysis to Aid Public Comment

market for outpatient dialysis services in the Warwick/Cranston area is highly concentrated. The market has only two dialysis providers, ARA and Fresenius, and the transaction as originally proposed would result in a monopoly in the Warwick/Cranston area. The evidence shows that health plans and other private payers who pay for dialysis services used by their members benefit from direct competition between ARA and Fresenius when negotiating the rates of the dialysis provider. As a result, the proposed combination likely would result in higher prices and reduced incentives to improve service or quality in the Warwick/Cranston outpatient dialysis services market defined in the complaint. Also, the complaint alleges that in this market, entry on a level sufficient to deter or counteract the likely anticompetitive effects of the proposed transaction is not likely to occur in a timely manner. The primary barrier to entry is the difficulty associated with locating nephrologists with established patient pools who are willing and able to serve as medical directors. Federal law requires each dialysis clinic to have a physician medical director. As a practical matter, having a nephrologist serve as medical director is essential to the success of a clinic because medical directors are the primary source of referrals.

V. The Consent Agreement

The proposed relief in this case is narrowly tailored to address both the agreement to close clinics and the attempted acquisition of clinics in the Warwick/Cranston area. The order would prohibit ARA and Fresenius for ten years from agreeing with any person to close a dialysis clinic, or allocate any dialysis customer, territory, or market. The consent order also would require ARA to give the Commission prior notice before acquiring any interest in a dialysis clinic in the Warwick/Cranston area because there is a risk that ARA remains interested in expanding in the area, but any such further acquisition likely would fall below Hart-Scott-Rodino Act premerger notification thresholds.

Analysis to Aid Public Comment

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 to modify its terms in any way.

Complaint

IN THE MATTER OF

**MYLAN LABORATORIES, INC.,
AND
E. MERCK oHG****CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT***Docket C-4200; File No. 071 0164**Complaint, September 26, 2007 – Decision, November 1, 2007*

The consent order addresses the \$6.6 billion proposed acquisition by Mylan of Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly by Merck Generics. The complaint alleged that the Merger Agreement violates of Section 5 of the FTC Act, and the acquisition, if consummated, would violate of Section 7 of the Clayton Act by substantially lessening competition and creating a monopoly in the U.S. markets for the manufacture and sale of (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets. The Consent Agreement requires Mylan and Merck are to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically the consent order requires that Merck divest its assets in the Products to Amneal.

Participants

For the *Commission*: Daniel P. Ducore, Leslie Farber, Mark Frankena, Roy Levy, Michael R. Moiseyev, David Von Nirschl, David P. Wales, Kari A. Wallace, and Alissa N. Wantman.

For the *Respondents*: Alexandra Carter and Katherine Forrest, Cravath, Swaine & Moore LLP; Andrea Haggerty and Mary Lou Steptoe, Skadden, Arps, Slate, Meagher & Flom LLP.

Complaint

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 Mylan Laboratories, Inc. (“Mylan”), a corporation subject to the jurisdiction of the Commission, has agreed to certain assets of E. Merck oHG and its controlled entity Merck KGaA (collectively “Merck”), 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 (“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. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “FDA” means the United States Food and Drug Administration.
3. “Respondents” means Mylan and Merck, individually and collectively.

II. RESPONDENTS

4. Respondent Mylan is 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, Canonsburg, Pennsylvania 15317. Mylan is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

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5. Respondent Merck is a corporation organized, existing, and doing business under and by virtue of the laws of Germany with its headquarters address at 250 Frankfurter Street, Darmstadt, Germany. Merck markets and sells generic products in the United States through its U.S. subsidiary, Genpharm L.P., located at 150 Motor Parkway, Suite 309 in Hauppauge, New York 11788. Merck also has an agreement with Par Pharmaceutical Companies, Inc. (“Par”), whereby Merck manufactures a number of generic products and Par markets them in the United States. Merck receives a royalty payment on Par’s sales of these products. Merck is engaged in the research, development, manufacture, and sale of generic pharmaceutical products.

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 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 PROPOSED ACQUISITION

7. On May 12 and 13, 2007, Mylan and Merck entered into an Agreement and Plan of Merger (the “Merger Agreement”) whereby Mylan proposes to acquire Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries for approximately \$6.6 billion.

IV. THE 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 pharmaceutical products:

- a. acebutolol hydrochloride capsules;

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- b. flecainide acetate tablets;
- c. guanfacine hydrochloride tablets;
- d. nicardipine hydrochloride capsules; and
- e. sotalol hydrochloride AF tablets.

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 line of commerce.

V. THE STRUCTURE OF THE MARKETS

10. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Acebutolol is a beta blocker used to treat hypertension. The market for generic acebutolol capsules is already highly concentrated with a preacquisition HHI of 5,158 points. The proposed merger would raise the HHI concentration by 4,842 points and create a monopoly in the acebutolol market.

11. Generic flecainide tablets are produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (“Roxane”), Barr Pharmaceuticals Inc. (“Barr”), and Ranbaxy Pharmaceuticals Inc. (“Ranbaxy”). Flecainide is an anti-arrhythmia drug used to treat heart problems. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. Combined, Barr and Ranbaxy account for less than 5 percent market share. The proposed acquisition would increase the market concentration by 2,344 points, resulting in a post-merger HHI of 6,369 points.

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12. Guanfacine, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (“Watson”), Merck/Par, Actavis Group hf. (“Actavis”), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States. Mylan, Merck/Par, Watson and Actavis, however, are the only suppliers of the 2 mg formulation of guanfacine. The proposed acquisition would raise the current HHI concentration in the generic guanfacine tablet market from 3,824 points to 4,908 points.

13. Nicardipine is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (“Teva”) are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed acquisition would raise the HHI from its current level of 4,170 points to 7,631 points and leave Teva as the only competitor to the combined Mylan/Merck in the generic nicardipine market.

14. Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is led by Apotex Inc. (“Apotex”). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007.

VI. ENTRY CONDITIONS

15. Entry into the relevant product 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 drug approval requirements takes at least two years. Entry would not be likely because the relevant

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markets are relatively small and in decline, limiting sales opportunities for any potential new entrant.

VII. EFFECTS OF THE ACQUISITION

16. 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 Mylan and Merck in the market for the manufacture and sale of generic acebutolol capsules, thereby: (1) increasing the likelihood that Mylan will be able to unilaterally exercise market power in this market, (2) increasing the likelihood that customers would be forced to pay higher prices; and

b. by eliminating this actual, direct, and substantial competition between Mylan and Merck in the markets for the manufacture and sale of generic flecainide tablets, generic guanfacine tablets, generic nicardipine capsules, and generic sotalol AF tablets, thereby: (1) increasing the likelihood that Mylan 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.

VIII. VIOLATIONS CHARGED

17. The Merger Agreement described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 7, if consummated, would constitute a violation of Section 7 of the Clayton Act, as

Order to Maintain Assets

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-sixth day of September, 2007, 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 Mylan Laboratories Inc. (“Mylan”) of the Merck Generics Business of Respondent E. Merck oHG (“Merck”), and Respondents 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 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 Mylan Laboratories Inc. is 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.

2. Respondent E. Merck oHG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address at Frankfurter Strasse 250, D-64293, Germany and the address of the principal place of business of its United States subsidiary, EMD, Inc. at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

3. Merck Generic Business includes the following: Merck dura GmbH, Merck Generics Group B.V., EMD, Inc., Merck Generics Belgium B.V.B.A. and Merck Genericos S.L.

4. The Commission has jurisdiction of the subject matter of this proceeding and of Respondents, and the proceeding is in the public interest.

Order to Maintain Assets

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 attached hereto as Appendix A and incorporated herein by reference and made a part hereof, shall apply:

- A. “Mylan” means Mylan 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 Mylan and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include the Merck Generics Business of Respondent Merck.
- B. “Merck” means E. Merck oHG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck (including, but not limited to, the Merck Generics Business), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Merck Generics Business” means the generic pharmaceutical business operated by Merck KgaA including, the following: Merck dura GmbH (Alsfelder Str. 19, 64289, Darmstadt, Germany); Merck Generics Group B.V. (Rokin 55, Amsterdam, Netherlands 1012 KK); EMD, Inc. (2751 Napa Valley Corporate Drive, Napa, CA 94558); Merck Generics Belgium B.V.B.A. (3090 Overijse, Brusselsesteenweg 288); Merck Genericos S.L. (Poligono Merck, Mollet de Valles Spain 8100; and all other such

Order to Maintain Assets

entities as are listed item 6(a) of the *Notification and Report Form for Certain Mergers and Acquisitions* filed by Respondent Merck dated June 5, 2007, in connection with the Acquisition, and the directors, officers, employees, agents, representatives, predecessors, successors, and assigns of the foregoing entities; and the joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by the foregoing entities, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

- D. “Respondents” means Mylan and Merck, individually and collectively.
- E. “Commission” means the Federal Trade Commission.
- F. “Divestiture Assets” means the Acebutolol Product Assets, Flecainide Product Assets, Guanfacine Product Assets, Nicardipine Product Assets, and the Sotalol Product Assets, as defined in the attached Decision and Order.
- G. “Divestiture Product Business(es)” means the relevant Respondent’s business 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, but not limited to, the Divestiture Assets.
- H. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order to Maintain Assets or Paragraph III of the Decision and Order.
- I. “Orders” means the Decision and Order and this Order to Maintain Assets.

Order to Maintain Assets

- J. “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 Divestiture Product Businesses

II.

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

- A. Respondents shall take such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses, to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of the Divestiture Product Businesses except for ordinary wear and tear. Respondents shall not sell, transfer, encumber or otherwise impair the 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 Divestiture Product Businesses.
- B. Respondents shall maintain the operations of the 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 businesses) and/or as may be necessary to preserve the marketability, viability, and competitiveness of the Divestiture Product Businesses 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 Divestiture Product Businesses. Respondents’

Order to Maintain Assets

responsibilities shall include, but are not limited to, the following:

1. providing the 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 businesses and to carry on, at least at their scheduled pace, all capital projects, business plans and promotional activities for the Divestiture Product Businesses;
2. continuing, at least at their scheduled pace, any additional expenditures for the Divestiture Product Businesses authorized prior 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. provide such resources as may be necessary to respond to competition against the Divestiture Products and/or to prevent any diminution in sales of the Divestiture Products during and after the Acquisition process and prior to divestiture of the related Divestiture Assets;
4. provide such resources as may be necessary to maintain the competitive strength and positioning of the Divestiture Products at the High Volume Accounts;
5. making available for use by the 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 the Divestiture Assets;
6. providing the Divestiture Product Businesses with such funds as are necessary to maintain the full economic

Order to Maintain Assets

viability, marketability and competitiveness of the Divestiture Product Businesses; and

7. providing such support services to the Divestiture Product Businesses as were being provided to these businesses by Respondents as of the date the Consent Agreement was signed by Respondents.
- C. 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 most recent Pre-Acquisition Marketing Plan.
- D. Until the Closing Date for each respective set of 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/or as may be necessary to preserve the marketability, viability and competitiveness of such Divestiture Products pending divestiture and to ensure successful execution of the Pre-Acquisition Marketing Plans related to the relevant Divestiture Products. Such incentives shall include a continuation of all employee benefits offered by Respondents until the Closing Date for the divestiture of the respective 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 a period of at least six (6) months from the relevant Closing Date, provide the relevant Acquirer with the opportunity to enter into employment contracts with the

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Divestiture Product Core Employees related to the Divestiture Products and assets acquired by such 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 the relevant Closing Date, provide the relevant Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant 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, not interfere with the hiring or employing by the relevant 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 relevant 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

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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.

F. Pending divestiture of the relevant 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 relevant Divestiture Product(s) other than as necessary to comply with the following:
 - a. the requirements of the Orders;
 - b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or
 - c. applicable Law;
2. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the relevant Acquirer or other persons specifically authorized by the 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 relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products; and

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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
 - b. do not solicit, access or use any Confidential Business Information that they are prohibited under this Order to Maintain Assets from receiving for any reason or purpose.
- G. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:
 1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition, and or that contain the same active pharmaceutical ingredient as the relevant Divestiture Products; and/or
 3. may have Confidential Business Information related to the Divestiture Products.

Respondents shall give such notification by e-mail with

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return receipt requested or similar transmission, and keep a file of such receipts for one (1) year after the relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondent Mylan's headquarters address 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 adhere to and abide by the Remedial Agreements (which agreements shall not vary or contradict, or be construed to vary or contradict, the terms of the Orders, it being understood that the Orders shall not 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.
- I. The purpose of this Order to Maintain Assets is to maintain the full economic viability, marketability and competitiveness of the Divestiture Product Businesses through their respective transfer to the Acquirer(s), to minimize any risk of loss of competitive potential for the Divestiture Product Businesses, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.

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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 Mylan, which consent shall not be unreasonably withheld. If Respondent Mylan 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 Mylan 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, Respondent Mylan 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.
- 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

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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;
3. The Interim Monitor shall serve until the date of completion by Respondents of the divestiture of all Divestiture Assets and the transfer of the 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 relevant Acquirer (or the Designee(s) of such Acquirer) 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 relevant Acquirer 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

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written notification from staff of the Commission that the relevant 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 the Commission may extend or modify this period as may be necessary or appropriate to accomplish the purposes of the Orders;

provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement to Contract Manufacture such Divestiture Product.

- 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 Respondents, such consultants, accountants, attorneys and other representatives and assistants as are

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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 misfeasance, gross negligence, willful or wanton acts, or bad faith by the Interim Monitor.
- H. Respondents 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 Respondents, and any reports submitted by the Acquirer with respect to the performance of Respondents' obligations under the Orders or the Remedial Agreement(s). Within one (1) month 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 Orders.
- 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.

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- 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 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 becomes final, and every thirty (30) days thereafter until Respondents have fully complied with their obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by Paragraph II.A., II.B., and II.C. 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 it intends to comply, is complying, and has complied with this Order to

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Maintain Assets and the related Decision and Order; *provided, however*, that, after the Decision and Order in this matter becomes final, 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 VI of the Decision and Order.

V.

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

- A. any proposed dissolution of Respondent Mylan;
- B. any proposed acquisition, merger or consolidation of Respondent Mylan; 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 the Order.

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 headquarter's 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

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Respondent related to compliance with this Order, which copying services shall be provided by Respondent at the request 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.

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 Divestiture 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(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 the related Decision and Order becomes final.
- By the Commission.

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APPENDIX A
TO THE ORDER TO MAINTAIN ASSETS
AGREEMENT CONTAINING CONSENT ORDER
AND
PROPOSED DECISION AND ORDER

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[Public Record Version]

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition by Respondent Mylan Laboratories Inc. (“Mylan”) of the Merck Generics Business of Respondent E. Merck oHG (“Merck”), and Respondents 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 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,

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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 Mylan Laboratories Inc. is 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.

2. Respondent E. Merck oHG is a corporation organized, existing and doing business under and by virtue of the laws of the Federal Republic of Germany, with its headquarters address at Frankfurter Strasse 250, D-64293, Germany and the address of the principal place of business of its United States subsidiary, EMD, Inc. at 2751 Napa Valley Corporate Drive, Napa, CA 94558.

3. Merck Generic Business includes the following: Merck dura GmbH, Merck Generics Group B.V., EMD, Inc., Merck Generics Belgium B.V.B.A. and Merck Genericos S.L.

4. The Commission has jurisdiction of the subject matter of this proceeding and of 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. “Mylan” means Mylan 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 Mylan and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Mylan shall include the Merck Generics Business of Respondent Merck.
- B. “Merck” means E. Merck oHG, its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by Merck (including, but not limited to, the Merck Generics Business), and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Merck Generics Business” means the generic pharmaceutical business operated by Merck KgaA including the following: Merck dura GmbH (Alsfelder Str. 19, 64289, Darmstadt, Germany); Merck Generics Group B.V. (Rokin 55, Amsterdam, Netherlands 1012 KK); EMD, Inc. (2751 Napa Valley Corporate Drive, Napa, CA 94558); Merck Generics Belgium B.V.B.A. (3090 Overijse, Brusselsesteenweg 288); Merck Genericos S.L. (Poligono Merck, Mollet de Valles Spain 8100; and all other such entities as are listed item 6(a) of the *Notification and Report Form for Certain Mergers and Acquisitions* filed by Respondent Merck dated June 5, 2007, in connection with the Acquisition, and the directors, officers, employees,

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agents, representatives, predecessors, successors, and assigns of the foregoing entities; and the joint ventures, subsidiaries, divisions, groups and affiliates in each case controlled by the foregoing entities, and the respective directors, officers, employees, agents, representatives, predecessors, successors, and assigns of each.

D. “Respondents” means Mylan and Merck, individually and collectively.

E. “Commission” means the Federal Trade Commission.

F. “Acebutolol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 75-047 (Acebutolol in the 200 mg and 400 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Acebutolol Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient acebutolol in the dosage strengths identified above.

G. “Acebutolol Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Acebutolol Products to the extent legally transferable, including the research, Development,

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manufacture, distribution, marketing, and sale of the Acebutolol Products, including, without limitation, the Categorized Assets related to the Acebutolol Products.

H. “Acquirer” means the following:

1. an entity 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; or
2. an entity 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.

I. “Acquisition” means the Respondent Mylan’s acquisition of fifty percent (50%) or more of the voting securities of the Merck Generics Business pursuant to the executed Share Purchase Agreement by and between Merck Generics Holding GmbH, Merck S.A., Merck Internationale Beteiligungen GmbH (collectively, “Sellers”), Merck KGaA (“Seller’s Guarantor” and “Seller’s Representative”) and Mylan Laboratories Inc. (“Purchaser”) dated May 12/13, 2007.

J. “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”).

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- K. “Amneal” means Amneal Pharmaceuticals, L.L.C., a limited liability company organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at 209 McLean Boulevard, Paterson, New Jersey 07504.
- L. “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 Respondents and the FDA related thereto. The term “Application” also includes an “Investigational New Drug Application” (“IND”) for a Product 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 Respondents and the FDA related thereto.
- M. “Categorized Assets” means the following assets related to the specified Divestiture Product(s):
1. all Product Intellectual Property related to such Divestiture Product(s)
 2. perpetual, fully paid-up and royalty-free license(s) with rights to sublicense to all Product Licensed Intellectual Property to use, make, distribute, offer for sale, promote, advertise, sell, import, export, or have used, made, distributed, offered for sale, promoted, advertised, sold,

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imported, or exported the Divestiture Product(s) within the specified Geographic Territory;

3. all Product Approvals related to such Divestiture Product(s);
4. all Product Manufacturing Technology related to such Divestiture Product(s);
5. all Product Marketing Materials related to such Divestiture Product(s);
6. all Website(s) related to such Divestiture Product(s);
7. a list of all of the NDC Numbers related to such Divestiture Product(s), and rights, to the extent permitted by Law:
 - a. to require Respondents to discontinue the use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
 - b. to prohibit Respondents 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 the Retained Product(s) (including the right to receive notification from Respondents of any such cross-referencing that is discovered by Respondents);
 - d. to seek cross-referencing from a customer of those NDC Numbers with the relevant Acquirer's NDC Numbers related to the Divestiture Product(s);

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- e. to approve the timing of Respondents' discontinued use of those NDC Numbers in the sale or marketing of Products other than with respect to returns, rebates, allowances, and adjustments for Divestiture Products sold prior to the Effective Date;
 - f. to approve any notification(s) from Respondents to any customer(s) regarding the use or discontinued use of such numbers by Respondents prior to such notification(s) being disseminated to the customer(s);
- 8. all rights to all of Respondents' Applications related to such Divestiture Product(s);
 - 9. Right of Reference or Use to the Drug Master Files related to the above-described Applications including, but not limited to, the pharmacology and toxicology data contained in all Application(s);
 - 10. all Product Development Reports related to such Divestiture Product(s);
 - 11. at the relevant Acquirer's option, all Product Assumed Contracts related to such Divestiture Product(s) (copies to be provided to the relevant Acquirer on or before the Closing Date);
 - 12. all strategic safety program(s) submitted to the FDA related to such Divestiture Product(s) that is designed to decrease product risk by using one or more interventions or tools beyond the package insert;
 - 13. all patient registries related to such Divestiture Product(s), and any other systematic active post-marketing surveillance program to collect patient data, laboratory data and identification information required to

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be maintained by the FDA to facilitate the investigation of adverse effects related to such Divestiture Product(s);

14. a list of all customers and/or targeted customers for such Divestiture Product(s) and the net sales (in either units or dollars) of such Divestiture 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 such Divestiture Products on behalf of the High Volume Account and his or her business contact information
15. at the relevant 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, packaging materials, work-in-process and finished goods related to such Divestiture Product(s);
16. copies of all unfilled customer purchase orders for such Divestiture Product(s) as of the Closing Date, to be provided to the relevant Acquirer not later than two (2) days after the Closing Date;
17. at the relevant Acquirer's option, subject to any rights of the customer, all unfilled customer purchase orders for such Divestiture Products; and
18. all of the Respondents' books, records, and files directly related to the foregoing or to such Divestiture Product(s);

provided, however, that "Categorized Assets" shall not include: (1) documents relating to Respondents' general business strategies or practices relating to research,

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Development, manufacture, marketing or sales of generic pharmaceutical Products, where such documents do not discuss with particularity the Divestiture Products; (2) shall not include administrative, financial, and accounting records; (3) quality control records that are determined by the Interim Monitor or the Acquirer not to be material to the manufacture of the Divestiture Product(s); and (4) any real estate and the buildings and other permanent structures located on such real estate;

provided further, that in cases in which documents or other materials included in the relevant assets to be divested contain information: (1) that relates both to such Divestiture Product(s) and to other Products or businesses of the Respondents and cannot be segregated in a manner that preserves the usefulness of the information as it relates to such Divestiture Product(s); or (2) 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 relevant Acquirer, the relevant party shall provide such 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 Respondents provide the relevant Acquirer with the above-described information without requiring Respondents completely to divest themselves of information that, in content, also relates to Retained Product(s).

- N. “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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- O. "Closing Date" means, as to each Divestiture Product, the date on which Respondent(s) (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, Respondents 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 Divestiture Product(s); *provided however*, that the restrictions contained in this Order regarding the 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 Respondents;
 2. information related to the Divestiture Products that Respondent Mylan can demonstrate it obtained without the assistance of Respondent Merck prior to the Acquisition;
 3. information that is required by Law to be publicly disclosed;
 4. information that does not directly relate to the Divestiture Product(s);
 5. information relating to Respondents' general business strategies or practices relating to research, Development, manufacture, marketing or sales of generic pharmaceutical Products that does not discuss with particularity the Divestiture Product(s); or

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6. information specifically excluded from the Categorized Assets.
- Q. “Contract Manufacture” means the manufacture of a Divestiture Product to be supplied by Respondents or a Designee to an Acquirer.
- R. “Designee” means any entity other than Respondents that will manufacture a Divestiture Product for an Acquirer.
- 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 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 Divestiture Product, “Direct Cost” means such cost as is

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provided in such Remedial Agreement for that Divestiture Product.

- U. “Divestiture Product(s)” means the following Products: the Acebutolol Products, the Flecainide Products, Guanfacine Products, Nicardipine Products, and Sotalol Products, individually and collectively.
- V. “Divestiture Product Core Employees” means the Product Research and Development Employees and the Product Manufacturing Employees related to each Divestiture Product.
- W. “Divestiture Product Releasee(s)” means the Acquirer for the assets related to a particular Divestiture Product or any entity controlled by or under common control with such Acquirer, or any licensees, sublicensees, manufacturers, suppliers, distributors, and customers of such Acquirer, or of such Acquirer-affiliated entities.
- X. “Divestiture Trustee” means the trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- Y. “Domain Name” means the domain name(s) (universal resource locators), and registration(s) thereof, issued by any entity 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.
- Z. “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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AA. “Effective Date” means the date on which the Acquisition occurs.

BB. “Flecainide Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 75-442 (Flecainide in 50 mg, 100 mg, and 150 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Flecainide Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient flecainide in the dosage strengths identified above.

CC. “Flecainide Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Flecainide Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Flecainide Products, including, without limitation, the Categorized Assets related to the Flecainide Products.

DD. “Guanfacine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

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1. ANDA No. 75-109 (Guanfacine in 1 mg and 2 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Guanfacine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient guanfacine in the dosage strengths identified above.

EE. “Guanfacine Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Guanfacine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Guanfacine Products, including, without limitation, the Categorized Assets related to the Guanfacine Products.

FF. “Generic Divestiture Product Agreement(s)” means the following:

1. “Asset Purchase Agreement” by and between Genpharm, Inc., Genpharm LP, Alphapharm Pty. LTD. and Amneal Pharmaceuticals, LLC, dated August 30, 2007, and all amendments, exhibits, attachments, agreements, and schedules thereto;
2. “Transitional Supply Agreement” by and between Genpharm, Inc. and Amneal Pharmaceutical LLC (attached as “Exhibit A” to the “Asset Purchase Agreement”), and all amendments, exhibits, attachments, agreements, and schedules thereto; and

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3. “Transitional Supply Agreement” by and between Alphapharm PTY. LTD..and Amneal Pharmaceutical LLC (attached as “Exhibit B” to the “Asset Purchase Agreement”), and all amendments, exhibits, attachments, agreements, and schedules thereto;

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

GG. “Geographic Territory” shall mean the United States of America (including all of the territories within its jurisdiction or control) unless otherwise specified.

HH. “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.

II. “High Volume Account(s)” means any retailer, wholesaler or distributor whose annual and/or projected annual aggregate purchase amounts (on a company-wide level), in units or in dollars, of a Divestiture Product in the United States from either Respondent (whichever Respondent is relevant to such Divestiture Product) was, is, or is projected to be among the top twenty highest of such purchase amounts by that Respondent’s (whichever Respondent is relevant to such Divestiture Product) 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 Effective Date; (3) the end of the last quarter that immediately preceded the Closing Date

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for the relevant assets; or 4) the end of the last quarter following the Acquisition and/or the Closing Date.

JJ. “Interim Monitor” means any monitor appointed pursuant to Paragraph III of this Order or Paragraph III of the related Order to Maintain Assets.

KK. “Law” means all laws, statutes, rules, regulations, ordinances, and other pronouncements by any Government Entity having the effect of law.

LL. “NDC Numbers” means the National Drug Code number(s), including both the labeler code assigned by the FDA and the additional numbers assigned by the Application holder as a product code for a specific Product.

MM. “Nicardipine Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 74-928 (Nicardipine in 20 mg and 30 mg dosage strengths); and
2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Nicardipine Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient nicardipine in the dosage strengths identified above.

NN. “Nicardipine Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to

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Respondent Merck's business within the Geographic Territory related to the Nicardipine Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Nicardipine Products, including, without limitation, the Categorized Assets related to the Nicardipine Products.

OO. "Order to Maintain Assets" means the Order to Maintain Assets incorporated into and made a part of the Agreement Containing Consent Orders.

PP. "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 (*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).

QQ. "Person" means any individual, partnership, joint venture, firm, corporation, association, trust, unincorporated organization, joint venture, or other business or Government Entity, and any subsidiaries, divisions, groups or affiliates thereof.

RR. "Product" means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically, or genetically active ingredient.

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SS. “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.

TT. “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 relevant Closing Date and segregated in a manner that clearly identifies the purpose(s) of each such contract):

1. that make specific reference to the Divestiture Product(s) and pursuant to which any Third Party is obligated to purchase, or has the option to purchase without further negotiation of terms, the Divestiture Product(s) from Respondent (whichever Respondent is relevant to such Divestiture Product) unless such contract applies generally to the divesting entity’s sales of Products to that Third Party;
2. pursuant to which Respondent (whichever Respondent is relevant to such Divestiture Product) purchases the active pharmaceutical ingredient(s) or other necessary ingredient(s) or had planned to purchase the active pharmaceutical ingredient(s) or other necessary ingredient(s) from any Third Party for use in connection with the manufacture of the Divestiture Product(s);
3. relating to any clinical trials involving the Divestiture Product(s);
4. with universities or other research institutions for the use of the Divestiture Product(s) in scientific research;

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

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Divestiture Product(s) or the Divestiture Product(s) business;

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

UU. “Product Copyrights” means rights to all original works of authorship of any kind directly related to the Divestiture Product(s) 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; educational materials for the sales force; copyrights in all preclinical, clinical and process development data and reports relating to the research and Development of the Divestiture Product(s) or of any materials used in the research, Development, manufacture, marketing or sale of the Divestiture Product(s), including all copyrights in raw data relating to clinical trials of the Divestiture Product(s), 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 Product(s) sales forecasting models, medical education materials, sales training materials, and advertising and display materials; all copyrights in records relating to employees who accept employment with the Acquirer (excluding any personnel records the transfer of which is prohibited by applicable Law); all records, including customer lists, sales force call

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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 the Divestiture Product(s) 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.

VV. “Product Development Reports” means:

1. Pharmacokinetic study reports related to the specified Divestiture Product(s);
2. Bioavailability study reports (including reference listed drug information) related to the specified Divestiture Product(s);
3. Bioequivalence study reports (including reference listed drug information) related to the specified Divestiture Product(s);
4. all correspondence to the Respondent (whichever Respondent is relevant to such Divestiture Product) from the FDA and from the Respondent (whichever Respondent is relevant to such Divestiture Product) to the FDA relating to the Application(s) submitted by, on behalf of, or acquired by, the Respondent (whichever Respondent is relevant to such Divestiture Product) related to the specified Divestiture Product;

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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(s);
7. currently used product package inserts (including historical change of controls summaries) related to the specified Divestiture Product(s);
8. FDA approved patient circulars and information related to the specified Divestiture Product(s);
9. adverse event/serious adverse event summaries related to the specified Divestiture Product(s);
10. summary of Product complaints from physicians related to the specified Divestiture Product(s);
11. summary of Product complaints from customers related to the specified Divestiture Product(s); and
12. Product recall reports filed with the FDA related to the specified Divestiture Product(s).

WW. “Product Employee Information” means the following, for each Divestiture 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 employees who were employed by Respondents within ninety (90) days of the execution date of any Remedial Agreement);
2. with respect to each such employee, the following information:

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- 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, Respondents 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 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; 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.

XX. "Product Intellectual Property" means all of the following related to a Divestiture Product (other than Product Licensed Intellectual Property):

1. Patents;

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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 and copyrights and registrations thereof;

provided, however, “Product Intellectual Property” does not include the corporate names or corporate trade dress of “Mylan” or “Merck”, or the corporate names or corporate trade dress of any other corporations or companies owned by Respondents or the related logos.

YY. “Product Licensed Intellectual Property” means the following:

1. Patents that are related to a Divestiture Product that Respondents can demonstrate have been routinely used, prior to the Effective Date, by either Respondent (whichever Respondent is relevant to such Divestiture Product) for a Retained Product(s) that:
 - a. has been marketed or sold on an extensive basis by either Respondent (whichever Respondent is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or
 - b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by either Respondent; and

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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 Respondents can demonstrate have been routinely used, prior to the Effective Date, by either Respondent (whichever Respondent is relevant to such Divestiture Product) for a Retained Product(s) that:
 - a. has been marketed or sold on an extensive basis by either Respondent (whichever Respondent is relevant to such Divestiture Product) within the two-year period immediately preceding the Acquisition; or
 - b. for which, prior to the announcement of the Acquisition, there was an approved marketing plan to market or sell such a Retained Product on an extensive basis by either Respondent;

provided however, that, in cases where the aggregate retail sales in dollars within the two-year period immediately preceding the Acquisition of the Retained Product(s) collectively are less than the aggregate retail sales in dollars within the same period of the Divestiture Product(s) collectively, the above-described intellectual property shall be considered, at the Acquirer's option, to be Product Intellectual Property and, thereby, subject to assignment to the Acquirer; *provided further, however*, that in such cases, Respondents may take a license back from the Acquirer for such intellectual property for use in connection with the Retained Products and such a license to Respondents may be perpetual, fully paid-up and royalty-free license(s) with rights to sublicense.

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ZZ. “Product Manufacturing Employees” means all salaried employees of Respondents who have directly participated in the planning, design, implementation or operational management of the Product Manufacturing Technology of the specified Divestiture Product(s) (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.

AAA. “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 Divestiture Product(s), 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 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 relevant Divestiture Product(s); 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 Divestiture Product(s).

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BBB. “Product Marketing Materials” means all marketing materials used specifically in the marketing or sale of a Divestiture Product(s) 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 purchases 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 Product(s); provided however, “Product Marketing Materials” excludes the pricing of each of the Divestiture Products to customers.

CCC. “Product Research and Development Employees” means all salaried employees of Respondents who directly have participated in the research, Development, or regulatory approval process, or clinical studies of the specified Divestiture Product(s) (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.

DDD. “Product Trade Dress” means the current trade dress of the Divestiture Product, including but not limited to, Product packaging, and the lettering of the Product trade name or brand name.

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EEE. “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).

FFF. “Proposed Acquirer” means an entity proposed by Respondents (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondents pursuant to this Order.

GGG. “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;
2. any agreement between Respondents and a Third Party to effect the assignment of assets or rights of Respondents 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;

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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 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 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.

HHH. “Retained Product” means any Product(s) other than a Divestiture Product.

III. “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, including the ability to make available the underlying raw data from the investigation for FDA audit.

JJJ. “Sotalol Products” means all of the following: all Products in Development, manufactured, marketed or sold by Respondent Merck pursuant to the following of Respondent Merck’s ANDAs:

1. ANDA No. 77-070 (Sotalol AF in 80 mg, 120 mg, and 160 mg dosage strengths); and

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2. any supplements, amendments, or revisions thereto;

provided, however, that for the purposes of the Contract Manufacture provisions of this Order, the term “Sotalol Products” shall include all presentations of any Retained Product that, as of the Effective Date, are being manufactured, marketed or sold by Respondent Mylan for sale within the United States that contain the active pharmaceutical ingredient sotalol in the dosage strengths identified above.

KKK. “Sotalol Product Assets” means all of Respondent Merck’s rights, title and interest in and to all assets related to Respondent Merck’s business within the Geographic Territory related to the Sotalol Products to the extent legally transferable, including the research, Development, manufacture, distribution, marketing, and sale of the Sotalol Products, including, without limitation, the Categorized Assets related to the Sotalol Products.

LLL. “Supply Cost” means a cost not to exceed the manufacturer’s average direct per unit cost in United States dollars of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective 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.

MMM. “Third Party(ies)” means any private entity other than the following: Respondents or the relevant Acquirer for the affected assets, rights and Divestiture Product(s).

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NNN. “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 Respondents; *provided, however*, “Website” shall not include the following: (1) content owned by Third Parties and other Product Intellectual Property not owned by Respondents that are incorporated in such Website(s), such as stock photographs used in the Website(s), *except* to the extent that Respondents can convey their rights, if any, therein; or (2) content unrelated to the Product(s).

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

- A. Not later than ten (10) days after the Effective Date, Respondents shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, absolutely and in good faith, to Amneal pursuant to, and in accordance with, the Generic Divestiture Product Agreements (which agreements shall not vary 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 Amneal or to reduce any obligations of Respondents under such agreements), and each such agreement, if it becomes a Remedial Agreement related to the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, respectively, is incorporated by reference into this Order and made a part hereof;

provided, however, that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets,

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the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal 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 Amneal is not an acceptable purchaser of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets then Respondents shall immediately rescind the transaction with Amneal, in whole or in part, as directed by the Commission, and shall divest the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, as is relevant, within one hundred eighty (180) days from the date the Order becomes final, absolutely and in good faith, at no minimum price, to a(n) Acquirer(s) and only in a manner that receives the prior approval of the Commission;

provided further that if Respondents have divested the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal 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 Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets to Amneal (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. 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 the relevant Acquirer(s), and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing or distribution of the Divestiture Products;

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

- C. Respondents shall transfer the Product Manufacturing Technology related to the relevant Divestiture Product to the relevant 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 Product Manufacturing Technology to a committee for the purposes of communicating directly with such Acquirer and the Interim Monitor (if any has been appointed) for the purposes of effecting such transfer;
 2. prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the relevant Divestiture Product, 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 transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all Product 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 (or the Designee of the Acquirer) to:
 - a. manufacture the relevant Divestiture Products in the same quality achieved by the Respondents and in commercial quantities;
 - b. obtain any Product Approvals necessary for the Acquirer to manufacture, sell, market or distribute the relevant Divestiture Product; and
 - c. receive, integrate, and use such Product Manufacturing Technology.

D. Respondents shall:

1. upon reasonable written notice and request from the Acquirer to Respondents, Respondents shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of each of the relevant Divestiture Products at Respondents' Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain all of the relevant Agency approvals necessary to manufacture in commercial quantities, and in a manner consistent with cGMP, the relevant finished drug product independently of Respondents and to secure sources of supply of the relevant active pharmaceutical ingredients, excipients, other ingredients, and/or necessary components specified in the Respondents' Application(s) for the Product from entities other than Respondents;

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2. Respondents shall make representations and warranties to the Acquirer that the Product(s) supplied through Contract Manufacture pursuant to a Remedial Agreement meet the relevant Agency-approved specifications. For the Product(s) to be marketed or sold in the Geographic Territory, 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 Product(s) supplied to the Acquirer pursuant to a Remedial Agreement by Respondents to meet cGMP. 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. Any 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 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 Acquirer that exceed the representations and warranties made by Respondents to the Acquirer; *provided further* that 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, each such agreement may contain limits on Respondents' aggregate liability resulting from the failure of the Products supplied to the Acquirer pursuant to such Remedial Agreement by Respondents to meet cGMP;

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3. Respondents shall 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 Products in a timely manner as required by a Remedial Agreement 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 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 Respondents' aggregate liability for such a breach;
4. during the term of the Contract Manufacture between Respondents and the Acquirer, upon request of the Acquirer or Interim Monitor (if any has been appointed), Respondents shall make available to the Acquirer and the Interim Monitor (if any has been appointed) all records that relate to the manufacture of the relevant Divestiture Products that are generated or created after the Closing Date;
5. during the term of the Contract Manufacture between Respondents and the Acquirer, maintain manufacturing facilities necessary to manufacture each of the Divestiture Products in finished form (suitable for sale to the ultimate consumer/patient); and
6. during the term of the Contract Manufacture between Respondents and the Acquirer, provide consultation with knowledgeable employees of Respondents and training, at the request of the Acquirer and at a facility chosen by

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the Acquirer, for the purposes of enabling the Acquirer (or the Designee of the Acquirer) to obtain all Product Approvals to manufacture the relevant Divestiture Products in the same quality achieved by the Respondents 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 Designee's personnel) are adequately trained in the manufacture of the relevant Divestiture Products;

The foregoing provisions, II.D.1. - 6., shall remain in effect with respect to each Divestiture Product until the earliest of: (1) the date the relevant Acquirer (or the Designee(s) of such Acquirer) 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; (2) the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or (3) the date of written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product.

E. Respondents shall:

1. submit to the Acquirer, at Respondents' expense, all Confidential Business Information related to the relevant Divestiture Product(s);
2. deliver such Confidential Business Information as follows:

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- 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 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 relevant Divestiture Product(s) 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 relevant Divestiture Product(s) other than as necessary to comply with the following:
 - a. the requirements of this Order;
 - b. Respondents' obligations to the Acquirer under the terms of any Remedial Agreement related to relevant Divestiture Product(s); or
 - c. applicable Law;
5. not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except

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the Acquirer or other persons specifically authorized by the 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 relevant Divestiture Products to the employees associated with business related to those Retained Products that are approved by the FDA for the same or similar indications or purposes as the relevant Divestiture Products.
- F. 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 Product Manufacturing Technology related to the relevant Divestiture Product(s) or related equipment 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 Product Manufacturing Technology.
- G. 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.F. that allows the Third Party to provide the relevant Product Manufacturing Technology or related equipment 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.
- H. Respondents shall:
1. for each Divestiture Product, for a period of at least twelve (12) months from the relevant Closing Date or upon the hiring of ten (10) Divestiture Product Core

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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 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 the relevant Closing Date, provide the relevant Acquirer or the relevant Proposed Acquirer with the Product Employee Information related to the relevant 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 relevant Acquirer of the Divestiture Product Core Employees related to the particular Divestiture Products and assets acquired by such Acquirer, and remove any impediments within the control of Respondents that may deter these employees from accepting employment with the relevant Acquirer, including, but not limited to, any noncompete or nondisclosure provision of employment with respect to a Divestiture Product or other contracts with Respondent (whichever Respondent is relevant to such Divestiture Product) that would affect the ability or incentive of those individuals to be employed by the relevant Acquirer. In addition, Respondents shall not

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make any counteroffer to such a Divestiture Product Core Employee who has received a written offer of employment from the relevant Acquirer;

provided, however, that, subject to the conditions of continued employment prescribed in this Order, this Paragraph II.H.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;

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(s) consistent with past practices and/or as may be necessary to preserve the marketability, viability and competitiveness of the Divestiture Product(s) and to ensure successful execution of the pre-Acquisition plans for such Divestiture Product(s). Such incentives shall include a continuation of all employee compensation and benefits offered by Respondent (whichever Respondent is relevant to such Divestiture Product) until the Closing Date(s) for the divestiture of the assets related to the Divestiture Product(s) has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that, subject to those conditions of continued employment prescribed in this Order, this Order does not require nor shall be construed to require Respondents to terminate the employment of any employee or to prevent Respondents from continuing to

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employ the Divestiture Product Core Employees in connection with the Acquisition; and

5. for a period of one (1) year from the relevant Closing Date, not:
 - a. directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to a Divestiture Product (“Divestiture Product Employee”) to terminate his or her employment relationship with the relevant Acquirer; or
 - b. hire any Divestiture Product Employee; *provided, however,* Respondents may hire any former Divestiture Product Employee whose employment has been terminated by the relevant Acquirer or who independently applies for employment with Respondent, as long as such employee was not solicited in violation of the nonsolicitation requirements contained herein;

provided, however, 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 Respondents.

- I. 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

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pursuant to which such employee shall be required to maintain all Confidential Business Information related to the Divestiture Products as strictly confidential, including the nondisclosure of such information to all other employees, executives or other personnel of Respondents (other than as necessary to comply with the requirements of this Order).

- J. Not later than thirty (30) days after the Effective Date, Respondents shall provide written notification of the restrictions on the use of the Confidential Business Information related to the Divestiture Products by Respondents' personnel to all of Respondents' employees who:
1. are or were directly involved in the research, Development, manufacturing, distribution, sale or marketing of each of the relevant Divestiture Products;
 2. are directly involved in the research, Development, manufacturing, distribution, sale or marketing of Retained Products that are approved by the FDA for the same or similar indications as each of the relevant Divestiture Products prior to the Acquisition, and or that contain the same active pharmaceutical ingredient as the relevant Divestiture Products; and/or
 3. may have Confidential Business Information related to the Divestiture Products.

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 relevant Closing Date. Respondents shall provide a copy of such notification to the Acquirer. Respondents shall maintain complete records of all such agreements at Respondents' principal place of business within the United States and shall provide an officer's certification to the Commission stating

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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.

K. Until Respondents complete the divestitures required by Paragraph II.A. and fully transfer the related Product Manufacturing Technology,

1. Respondents shall take such actions as are necessary to:

- a. maintain the full economic viability and marketability of the businesses associated with each Divestiture 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 Divestiture Product;
- d. ensure the assets required to be divested are transferred 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 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 each Divestiture Product.

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- L. Respondents shall not join, file, prosecute or maintain any suit, in law or equity, against the relevant Acquirer(s) or the Divestiture Product Releasee(s) for the research, Development, manufacture, use, import, export, distribution, or sale of the Divestiture Product(s) under the following:
1. any Patent owned or licensed by Respondents as of the Effective Date that claims a method of making, using, or administering, or a composition of matter, relating to the respective Divestiture Product, or that claims a device relating to the use thereof;
 2. any Patents owned or licensed at any time after the Effective Date by Respondents that claim any aspect of the research, Development, manufacture, use, import, export, distribution, or sale of the respective Divestiture Products, other than such Patents that claim inventions conceived by and reduced to practice after the Effective Date;

if such 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 relevant Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of the relevant Divestiture Products within the Geographic Territory. Respondents shall also covenant to the relevant 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 relevant Acquirer or the related Divestiture Product Releasee(s) under such Patents, if the 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 relevant Divestiture Products; or (2) the use, import, export, supply, distribution, or sale of the

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relevant Divestiture Products within the Geographic Territory.

- M. 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 related to the Product Intellectual Property related to the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and/or the Sotalol Product Assets.
- N. 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 or for such suit as such 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 in the research, Development, manufacture, use, import, export, distribution or sale of any Divestiture Product, Respondents shall:
1. cooperate with the relevant 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 either 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 relevant Acquirer of all of the litigation files and any related attorney work-product in

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the possession of Respondents' outside counsel relating to such Divestiture Product.

O. Respondents shall not, in the Geographic Territory:

1. use the Product Trademarks related to the Divestiture 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 such Product Trademarks;
4. challenge or interfere with the Acquirer(s)'s use and registration of such Product Trademarks; or
5. challenge or interfere with the Acquirer(s)'s efforts to enforce their trademark registrations for and trademark rights in such Product Trademarks against Third Parties;

provided however, that this Order shall not preclude Respondents from continuing to use those trademarks, tradenames, or service marks related to the Retained Products as of the Effective Date.

- P. 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 this Order and/or the remedial purposes thereof.

III.

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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 Mylan, which consent shall not be unreasonably withheld. If Respondent Mylan 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 Mylan 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, Respondent Mylan 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

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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 Respondents of the divestiture of all Divestiture Assets and the transfer of the Product Manufacturing Technology in a manner that fully satisfies the requirements of this Order and until the earliest of:
 - (1) with respect to each Divestiture Product, the date the relevant Acquirer (or the Designee(s) of such Acquirer) 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;
 - (2) with respect to each Divestiture Product, the date the relevant Acquirer notifies the Commission and the Respondents of its intention to abandon its efforts to manufacture such Divestiture Product; or
 - (3) with respect to each Divestiture Product, the date of written notification from staff of the Commission that the relevant Interim Monitor, in consultation with staff of the Commission, has determined that the relevant Acquirer has abandoned its efforts to manufacture such Divestiture Product;

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

provided, further, that, with respect to each Divestiture Product, the Interim Monitor's service shall not exceed five (5) years from the Closing Date on the Remedial Agreement(s) to Contract Manufacture such Divestiture Product.

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 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.
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. Respondents shall indemnify the Interim Monitor and hold the Interim Monitor harmless against any losses,

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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 misfeasance, 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/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 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.
 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

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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 Respondents have not fully complied with the obligations to assign, grant, license, divest, transfer, deliver or otherwise convey relevant assets as required by this Order, the Commission may appoint a trustee (“Divestiture Trustee”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant 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 Respondent Mylan, which consent shall not be unreasonably withheld. The Divestiture Trustee shall be a person with experience and expertise in acquisitions and divestitures. If Respondent Mylan 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 Mylan

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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 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 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

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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 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; and, *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 Respondent, on such reasonable and customary terms and conditions as

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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. 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 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 misfeasance, 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

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

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

Respondents shall assure that, in any instance wherein their counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer(s) or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the

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Acquirer(s), that Respondents' counsel does so only in order to do the following:

- A. comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any applicable Government Entity, or any taxation requirements; or
- B. 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 assets and businesses associated with those Products; *provided, however*, that Respondents may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement or arrangement;

provided, however, that pursuant to this Paragraph V, 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 the relevant Acquirer withholds such agreement unreasonably); and (2) use their best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication.

VI.

IT IS FURTHER ORDERED that:

- A. Within five (5) days of the Acquisition, Respondent Mylan shall submit to the Commission a letter certifying the date on which the Acquisition occurred.

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- B. Within thirty (30) days after the date this Order becomes final, 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.G., II.H., II.J., and II.K.; and
 2. all of their responsibilities to render transitional services to the relevant Acquirer as provided by this Order and the Remedial Agreement(s),

Respondent Mylan shall submit to the Commission a verified written report setting forth in detail the manner and form in which Respondents intend to comply, are complying, and have complied with this Order. Respondent Mylan 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. Respondent Mylan 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 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.

- A. One (1) year after the date this Order becomes final, annually for the next nine years on the anniversary of the date this Order becomes final, and at other times as the Commission may require, Respondent Mylan 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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VII.

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

- A. any proposed dissolution of Respondent Mylan;
- B. any proposed acquisition, merger or consolidation of Respondent Mylan; 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.

VIII.

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 a Divestiture Product, 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(s) pursuant to this Order.
- D. Respondents shall also include in each Remedial Agreement a representation from the relevant 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 such Divestiture Product and to have any such

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manufacture to be independent of Respondents, all as soon as reasonably practicable.

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

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 any Respondent made to its principal United States offices, registered office of its United States subsidiary, or its headquarters address Respondent, 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.

X.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Acebutolol Product Assets, the Flecaïnide Product

Decision and Order

Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets, the transfer of the Product Manufacturing Technology related to the Acebutolol Products, the Flecainide Products, the Guanfacine Products, the Nicardipine Products, and the Sotalol Products, respectively, and the related obligations imposed on the Respondents by this Order is:

- A. to ensure the continued use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the research, Development, and manufacture of each of the respective Divestiture Products;
- B. to provide for the future use of the Acebutolol Product Assets, the Flecainide Product Assets, the Guanfacine Product Assets, the Nicardipine Product Assets and the Sotalol Product Assets in the distribution, sale and marketing of each of the respective Divestiture Products;
- C. to create a viable and effective competitor, who is independent of the Respondents, in the research, Development, manufacture, distribution, sale and marketing of each of the respective Divestiture Products; and,
- D. to remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

XI.

IT IS FURTHER ORDERED that this Order shall terminate on November 1, 2017.

By the Commission.

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

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

Analysis to Aid Public Comment

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 Mylan Laboratories (“Mylan”) and E. Merck oHG (“Merck”) which is designed to remedy the anticompetitive effects of the acquisition of certain assets of Merck by Mylan. Under the terms of the proposed Consent Agreement, the companies would be required to assign and divest the Merck rights and assets necessary to manufacture and market generic: (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine hydrochloride tablets; (4) nifedipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets to Amneal Pharmaceuticals LLC (“Amneal”).

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”).

Pursuant to an Agreement and Plan of Merger executed on May 12 and 13, 2007, Mylan proposes to acquire Merck’s generic subsidiary (“Merck Generics”) and all subsidiaries held directly or indirectly by Merck Generics, by acquiring 100 percent of the issued shares of those subsidiaries for approximately \$6.6 billion. 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 the manufacture and sale of the following generic pharmaceutical products: (1) acebutolol hydrochloride capsules; (2) flecainide acetate tablets; (3) guanfacine

Analysis to Aid Public Comment

hydrochloride tablets; (4) nicardipine hydrochloride capsules; and (5) sotalol hydrochloride AF tablets (the “Products”). The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

Mylan is a leading developer, manufacturer, marketer, and distributor of generic pharmaceutical drugs. Headquartered in Pennsylvania, Mylan sells generic pharmaceuticals in the United States and has manufacturing facilities throughout the country. Merck is a German pharmaceutical company that develops and manufactures pharmaceutical products for sale in the United States. Merck sells generic pharmaceutical products directly to customers in the United States through its subsidiary Genpharm L.P., as well as indirectly through distribution agreements with other generic companies, including Par Pharmaceutical Companies, Inc. (“Par”).

The Products and Structure of the Markets

The proposed acquisition of certain assets of Merck by Mylan would strengthen Mylan’s worldwide position in generic pharmaceuticals and provide Mylan with a stronger pipeline of generic products. The companies overlap in a number of generic pharmaceutical markets, and if consummated, the transaction likely would lead to anticompetitive effects in five of these markets.

The transaction would reduce the number of competing generic suppliers in the overlap markets. The number of generic suppliers has a direct and substantial effect 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, the branded versions no longer significantly constrain the generics’ pricing.

In the market for generic acebutolol capsules, Mylan and Merck are the only companies manufacturing and selling products in the

Analysis to Aid Public Comment

United States. For the four other generic products, Mylan and Merck currently are two of a small number of suppliers offering the product. In each of these markets, there are a limited number of competitors.

Generic acebutolol hydrochloride is a beta blocker used to treat hypertension. Mylan and Merck/Par are the only suppliers of generic acebutolol capsules in the United States, with respective market shares of approximately 59 and 41 percent. Therefore, the proposed transaction would give Mylan a monopoly in this market.

Generic flecainide acetate is an anti-arrhythmia drug used to treat heart problems. Flecainide is produced and sold by five companies in the United States: Mylan, Merck/Par, Roxane Laboratories Inc. (“Roxane”), Barr Pharmaceuticals Inc., and Ranbaxy Pharmaceuticals Inc. Mylan is the market leader with nearly 57 percent share, followed by Merck/Par with 21 percent, and Roxane with 19 percent. After Mylan’s acquisition of Merck Generics, Mylan’s market share would increase to approximately 78 percent and the number of suppliers of generic flecainide would decrease from five to four.

Guanfacine hydrochloride, the generic version of the branded drug Tenex, is an alpha blocker used to treat hypertension that comes in both 1 mg and 2 mg strengths. Mylan is the market leader with nearly 53 percent share. Watson Pharmaceuticals Inc. (“Watson”), Merck/Par, Actavis Group hf. (“Actavis”), Major Pharmaceuticals Inc. and Qualitest Pharmaceuticals Inc. also manufacture and sell generic guanfacine tablets in the United States, although not all six suppliers are capable of supplying all formulations. For instance, Mylan, Merck/Par, Watson and Actavis are the only suppliers of the 2 mg formulation of guanfacine. Because many customers prefer to purchase the 1 mg and 2 mg formulations of the product from one supplier, the competitive significance of the other four suppliers who do not sell these formulations is limited.

Analysis to Aid Public Comment

Nicardipine hydrochloride is a calcium channel blocker used to treat hypertension. Mylan, Merck, and Teva Pharmaceutical Industries Ltd. (“Teva”) are the only manufacturers of generic nicardipine capsules in the United States, with respective market shares of 54 percent, 32 percent and 14 percent. The proposed transaction would thus result in an increase in Mylan’s market share to approximately 86 percent and reduce the number of suppliers from three to two.

Generic sotalol AF is a beta blocker used to treat hypertension. The market for sotalol AF is led by Apotex Inc. (“Apotex”). Merck and Mylan are the only other significant competitors to Apotex in the generic sotalol AF tablet market. Merck launched its sotalol AF product in late 2006, followed by Mylan in the spring of 2007. Therefore, the proposed transaction would reduce the number of suppliers from three to two.

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 FDA drug approval requirements takes at least two years. Entry would not be likely because the relevant markets are relatively small and in decline, so the limited sales opportunities available to a new entrant are likely insufficient to warrant the time and investment necessary to enter.

Analysis to Aid Public Comment

Effects

The proposed acquisition would cause significant anticompetitive harm to consumers in the U.S. markets for the manufacture and sale of generic acebutolol hydrochloride capsules, flecainide acetate tablets, guanfacine hydrochloride tablets, nicardipine hydrochloride capsules, and sotalol hydrochloride AF tablets. In generic pharmaceutical markets, pricing is heavily influenced by the number of competitors that participate in a given market. Here, the evidence shows that, given the small number of suppliers, the prices of the generic pharmaceutical products at issue decrease with the entry of each additional competitor. Evidence gathered during our investigation indicates that anticompetitive effects – whether unilateral or coordinated – are likely to result from the proposed transaction due to a decrease in the number of independent competitors in the markets at issue.

The acquisition of Merck by Mylan would create a monopoly in the market for generic acebutolol hydrochloride tablets. The evidence indicates that the presence of more than one competitor allows customers to negotiate lower prices and that the reduction in the number of competitors in this market would allow the merged entity to unilaterally exercise market power with a resulting increase in prices. In the markets for generic flecainide acetate tablets, generic nicardipine hydrochloride capsules, and generic sotalol AF tablets, the proposed acquisition would leave only two significant current competitors: the combined firm and one other company. The evidence indicates that the presence of three or more independent competitors in these markets allows customers to negotiate lower prices, and that a reduction in the number of competitors in these markets would allow the merged entity and other market participants to raise prices. Likewise, in the generic guanfacine hydrochloride tablet market, the reduction in the number of competitors also would likely lead to higher prices.

The competitive concerns can be characterized as both unilateral and coordinated in nature. The homogenous nature of the products

Analysis to Aid Public Comment

involved, the minimal incentives to deviate, and the relatively predictable prospects of gaining new business all indicate that the firms in the market will find it profitable to coordinate their pricing.

The impact that a reduction in the number of firms would have on pricing can also be explained in terms of unilateral effects, as the likelihood that the merging parties would be the first and second choices in a significant number of bidding situations is enhanced where the number of firms participating in the market decreases substantially.

The Consent Agreement

The proposed Consent Agreement effectively remedies the proposed acquisition's anticompetitive effects in the relevant product markets. Pursuant to the Consent Agreement, Mylan and Merck are required to divest certain rights and assets related to the Products to a Commission-approved acquirer no later than ten (10) days after the acquisition. Specifically, the proposed Consent Agreement requires that Merck divest its assets in the Products to Amneal.

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. A proposed acquirer of divested assets must not itself present competitive problems.

Amneal, a small but growing generic manufacturer, is particularly well-positioned to manufacture and market its acquired products and compete effectively in those markets. Amneal develops, manufactures, sells, and distributes generic pharmaceuticals within the United States. Moreover, Amneal will not present competitive problems in any of the markets in which it will acquire a divested asset because it currently does not compete in those markets. With its resources, capabilities, good reputation, and

Analysis to Aid Public Comment

experience marketing generic products, Amneal is well-positioned to replicate the competition that would be lost with the proposed acquisition.

If the Commission determines that Amneal is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures to Amneal is not acceptable, the parties must unwind the sale and divest the assets within six (6) months of the date the Order becomes final to another Commission-approved acquirer. If the parties fail to divest within six (6) months, the Commission may appoint a trustee to divest the Products.

The proposed remedy contains several provisions to ensure that the divestitures are successful. The Order requires Mylan and Merck to provide transitional services to enable the Commission-approved acquirer 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 Merck.

The Commission has appointed R. Owen Richards of Quantic Regulatory Services, LLC (“Quantic”) to oversee the asset transfer and to ensure Mylan and Merck’s compliance with all of the provisions of the proposed Consent Agreement. Mr. Richards is President of 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 Mylan and Merck 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

Analysis to Aid Public Comment

an official interpretation of the proposed Order or to modify its terms in any way.

Complaint

IN THE MATTER OF

LAWRENCE A. JORDAN
AND
STEPHANIE L. JORDAN,
TRADING AND DOING BUSINESS AS
SPRINGBOARD AND PRO HEALTH LABS

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4203; File No. 072 3140

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses the deceptive advertising and promotion of respondent's ProBalance and ProBalance Plus transdermal creams. The complaint alleged that respondent represented that ProBalance and ProBalance Plus contained, among other ingredients, natural progesterone. The complaint further alleged that respondent violated the FTC Act by advertising without substantiation that its creams were effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The consent order requires respondent to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis; in reducing the risk of estrogen-induced endometrial cancer or breast cancer; or in mitigating, treating, preventing, or curing any disease, illness, or health condition. Respondent is also barred from representing that its creams reduce the user's risk of developing breast cancer, is safe for human use, or has no side effects. The order further prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the *Commission*: Gregory A. Ashe, Laura DeMartino,
Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the *Respondents*: Not represented by counsel.

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Lawrence A. Jordan and Stephanie L. Jordan, individuals trading and doing business as Springboard and Pro Health Labs (“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 Lawrence A. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with his principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs, including the acts and practices alleged in this complaint.

2. Respondent Stephanie L. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with her principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs, including the acts and practices alleged in this complaint.

3. 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.

4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a

Complaint

general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including ProBalance™ and ProBalance Plus™. Respondents primarily advertise and offer the products for sale through the Internet sites www.springboard4health.com and www.sb3.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, ProBalance™ and ProBalance Plus™ are “drugs” as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. ProBalance™ is a drug labeled as containing Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube) and other ingredients. A two fluid ounce tube costs \$19.95 plus shipping and handling. ProBalance Plus™ is a drug labeled as containing Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Estriol (900 mcg per 1/4 measuring teaspoon), Estradiol (100 mcg per 1/4 measuring teaspoon), and other ingredients. A two fluid ounce tube costs \$27.00 plus shipping and handling. ProBalance™ and ProBalance Plus™ are applied transdermally.

8. To induce consumers to purchase ProBalance™ and ProBalance Plus™, Respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondents' websites:

A. All Progesterone creams are not created equal!

Complaint

Natural Progesterone

ProBalance reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy.

* * *

Natural Progesterone With a Blend of Phytoestrogens
ProBalance Plus™ is a safe and natural menopause alternative for women over 45 without the side effects often associated with HRT.

* * *

USP Pharmaceutical grade progesterone. Non-greasy. Absorbs quickly. No carcinogens or unnecessary ingredients. We have yet to find a doctor who has been recommending ProBalance to his/her patients switch to any other brand of progesterone cream. The saliva test results prove the effectiveness, and the feel makes applying it a pleasure.
(Exhibit A at 1.)

B. Breaking News - On Health

Switching to Natural Hormones Now That HRT Is No Longer Every Woman's Answer
The recent headlines about the risks of synthetic hormone replacement (HRT) have forced women to scramble to find ways to balance their hormones naturally. Natural, bio-identical hormones are the safe alternative to HRT and hundreds of thousands of women are already using them. The following information from John R. Lee, M.D., one of

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the leading experts on the subject of natural hormones, are offered here to answer questions you may have about switching from synthetic HRT to natural.

While the abrupt cancellation of The Women's Health Initiative (WHI) made headline news around the country, it did not surprise those who have kept up with all the studies over the last decade which warned of the risks of HRT. The WHI analyzed the health of 16,000 women aged 50 to 79 years over five years of using HRT in the form of Premarin, Provera or PremPro. The researchers found an increased incidence of just about every major disease the hormones were supposed to be preventing! The data showed:

- A 41 percent increase in strokes
- A 29 percent increase in heart attacks
- A 26 percent increase in breast cancer
- A 22 percent increase in total cardiovascular disease
- A doubling of the rate of blood clots.

* * *

Stretch these numbers out over a decade, and nearly 40,000 women will have been harmed by taking these drugs, not counting all the women who have suffered the dismal side effects of this form of HRT — weight gain, fatigue, depression, irritability, headaches, insomnia, bloating, low thyroid, low libido, and gallbladder disease. That is an epidemic. If we dare to multiply 40,000 women harmed times three — the number of decades women have been using synthetic HRT— we are talking about an epidemic of the worst proportions.

* * *

And so it has gone, until the Women's Health Initiative, expecting to document the lifesaving benefits of HRT,

Complaint

found life threatening risk instead. The study was stopped in its tracks – three years short of its scheduled end.

To readers of the works of Dr. John Lee, Dr. David Zava and other pioneers of the natural hormone movement, the risks and side effects of conventional HRT are not news. The evidence of harm has been showing up in the scientific research for at least a decade. This particular study was finally large enough and prestigious enough that conventional medicine was forced to pay attention. The challenge now for doctors is to inform themselves and their patients about the efficacy, use and prescribing of natural hormones.

Questions and Answers About Natural Hormone
Replacement Therapy with Dr. John Lee

(Provided with permission of Dr. John Lee, author of
WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT
MENOPAUSE and co-author with Dr. David Zava of
WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT
BREAST CANCER)

*Do the results of the WHI apply to using natural estrogen
and progesterone as you recommend?*

Not at all.

* * *

Looking at this another way, from puberty until menopause, a healthy woman's body is making its own natural hormones in synchrony and balance, without giving her cancer, heart disease or strokes. What I recommend is attempting to regain or mimic this natural balance as closely as possible.

Complaint

Conventional HRT not only fails to measure hormones and use physiologic doses, it uses synthetic, not-found-in-nature hormones that are foreign to the human body and cause a long list of unwanted side effects.

* * *

My doctor says that I cannot use estrogen and progesterone cream, because progesterone cream will not protect my uterus the way the progestins do.

Progesterone cream protects the uterus just fine. Not only did I not have any problems in my hundreds of menopausal patients before I retired from practice, I am in touch with dozens of physicians who have thousands of patients between them, who have never had a problem. Some of them have been doing this for over a decade.

* * *

What are bio-identical hormones and can you explain the difference between natural progesterone and the synthetic version?

Bio-identical hormones (BHRT) are synthesized from natural substances and are identical in structure and function to those our bodies produced naturally, pre-menopause. When production drops below normal levels at perimenopause and menopause, BHRT is the best and safest way for women to supplement. Bio-identical hormones are available by prescription through compounding pharmacists. Natural progesterone is a bio-identical hormone as opposed to progestin which is the synthetic version (the “pro” in Prempro). Natural progesterone is just like the progesterone your ovaries made and is available in a topical form over-the-counter

Complaint

and by prescription (when compounded with natural estrogens and other hormones).

* * *

(Exhibit A at 3-6.)

C. ProBalance Natural Progesterone Cream

Natural progesterone reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects associated with synthetic hormone replacement therapy.

* * *

“The signs and symptoms of osteoporosis cleared in every patient using progesterone cream and incidence of fractures dropped to zero.” - John R. Lee, M.D.

* * *

(Exhibit A at 7.)

D. More on ProBalance Natural Progesterone

* * *

Apparently, nature intended that estrogen and progesterone be balanced. Progesterone counters every undesirable effect of excess estrogen. Progesterone stimulates bone growth. It protects against reproductive organ and breast cancer, it helps the body to use fat for energy, it is a natural diuretic, it normalizes blood clotting, it aids thyroid hormone action, it helps to normalize blood sugar levels, it restores libido, and it is a natural antidepressant. Progesterone has also been found to be effective in treating PMS, ovarian cysts, breast fibrocysts,

Complaint

endometriosis, pelvic disorders, and uterine fibroid tumors.

* * *

Progestins such as Provera ® , are synthetic progesterones, synthesized from natural progesterone, but because the structure is altered, there is a long list of side effects including mental depression, insomnia, cervical erosion, edema, acne and pulmonary embolism. When taken in combination with estrogens, a woman may experience nervousness, dizziness, hair loss, fatigue, or hypertension, to name a few. Although many doctors believe that there is no difference between synthetic and natural progesterone, some synthetic progesterones can produce masculinizing effects in women whereas natural progesterone does not cause masculinization.

Transdermal absorption of natural progesterone has been established as an effective and safe delivery method. Rubbed into thin-skinned areas such as the palms of the hands, face, neck, breasts, inner arms, or soles of the feet, the progesterone is absorbed into the skin and stored in the fatty tissues. It is then taken into the bloodstream where it circulates to receptor sites throughout the body.

* * *

(Exhibit A at 9-11.)

- E. Osteoporosis is often caused by a lack of progesterone. Very rarely is it a lack of calcium. New bone is formed by osteoblasts, and old bone is removed by osteoclasts. When the osteoclast activity goes faster than the osteoblast activity bone loss occurs. Progesterone is the key factor in osteoblast or building of new bone. Dr. John R. Lee checked this out with 63 women over a 3 year period, doing bone mineral density tests every six months. At the

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end of a 3 year test on these women using progesterone cream, the average increase in bone density was 15.4%. These were all postmenopausal women who would normally expect to have a 1/5% bone loss per year, or a total bone loss for 3 years of 4.5%. There was a 19.9% difference between the expected loss and the real increase that occurred. This is very exciting, as medicine has been saying that you can't reverse osteoporosis; you can only slow it down. Estrogen does not reverse it. It only slows down bone loss for the two to three years of menopause, then has no further effect.

Dr. Lee tells of a woman 72 years old who had over 40% bone loss and was in pain because of a stress fracture in her lower spine. In spite of opposition from 5 doctors involved in her case, she decided to follow Dr. Lee's advice, and in only 16 months experienced a 23% increase in her bone density. All but one of the doctors wrote Dr. Lee telling him that they would not have believed it had they not seen it with their own eyes. This lady is now 80 years old, and is continuing to use the progesterone cream. Her total increase in bone density is up 38%. When Dr. Lee was asked how long she should continue using it, he responded: "Keep using it until you are 95, and then we'll reevaluate."

(Exhibit A at 14-15.)

F. ProBalance Plus - Natural Progesterone Cream with Phytoestrogens

ProBalance Plus™ is the safe and natural menopause treatment alternative for women over 45 without the side effects associated with synthetic hormone replacement therapy.

(Exhibit A at 16.)

Complaint

G. More On ProBalance Plus

Natural Progesterone Cream
ProBalancePlus

* * *

In the years following menopause, the risk of cardiovascular disease, osteoporosis, and cognitive decline increases dramatically. A growing number of research studies have linked some of these risks to the relative absence of estrogens and progesterone. For decades, physicians prescribed synthetic estrogen, such as Premarin®, without other accompanying hormones. When it was discovered that the risk of developing endometrial cancer due to unopposed estrogen replacement could be reduced by adding progesterone, physicians began prescribing progestins (synthetic progesterone which could be patented) such as Provera®. According to some estimates, standard hormone replacement therapy using synthetic hormones like Premarin® and Provera® may increase a woman's risk of breast cancer by as much as 30 percent. Many doctors think that the lower risks of heart disease and osteoporosis attributable to estrogen replacement make the odds acceptable. On the other hand, a majority of these doctors aren't women!

For women who find these odds unacceptable, considering natural hormone replacement is a "no brainer." The benefits include those of synthetic HRT plus a few more including:

§ Prevention of osteoporosis and increase of bone density

* * *

§ Reduced risk of endometrial cancer and breast cancer

Complaint

* * *

The benefits of progesterone are amazing. According to John R. Lee, M.D., the well-known proponent of supplemental progesterone, transdermal progesterone can:

- \$ Promote bone building and protect against osteoporosis
- \$ Help protect against breast cancer
- \$ Protect against endometrial cancer

* * *

(Exhibit A at 18-19.)

H. Breast Cancer and Natural Progesterone

* * *

Progesterone Upregulates the Gene that Causes Cancer Cells to Die Estrogen Upregulates the Gene that Cause Cancer Cells to Not Die

* * *

What do we have? The BCL2 stimulates the risk of cancer. Gene P53 decreases the risk of cancer. Estradiol upregulates BCL2. Progesterone upregulates P53. Therefore progesterone decreases cancer. Unopposed estradiol causes the cancer. Simple.

(Exhibit A at 31.)

I. Breast Cancer & Natural Progesterone

* * *

It is Dr. John Lee's contention that progesterone prevents breast cancer, and if you already have breast cancer progesterone protects you against reoccurrence or late

Complaint

metastases. In his medical practice he treated many women who had mastectomies. In the 20 years since he started recommending the use of progesterone, not one of the hundreds of women he treated has died of breast cancer. Think about what the odds are on that number when you compare it to normal post mastectomy figures. (Exhibit A at 34.)

J. **Osteoporosis****Excerpts from a talk by John. R. Lee, M.D.**

Bone is living tissue and hormones have an effect on bone. Estrogen causes bone resorption while progesterone and testosterone cause new bone to be made.

* * *

So what I stumbled on to is that progesterone causes new bone formation.

* * *

What I learned is that progesterone turns on the processes which lead to new bone formation.

* * *

When I retired from practice nine years ago I asked my nurse to pick out 100 records of women on **progesterone**. Out of the 100 I took only those who had at least three years of bone mineral density tests every six months. I was left with 62 patients. The average increase in bone density in these postmenopausal women over three years was 15.4% versus a normal expected loss during that period of time of 4.5%. That is almost a 20% average difference between what normally happens and what happens when

Complaint

women are using **progesterone**. Estrogen only slows down bone loss for the period of menopause, and after menopause it doesn't even do that. **Progesterone**, however, causes new bone growth even in postmenopausal women.

* * *

Examples from my practice of how progesterone increased bone density

This first chart was in 1982. The lady was 72 years old and had very poor bones. She had broken her forearm lifting her sick husband. She went to her doctor who told her that she had such poor bones that she had to take fluoride treatment. She told him that was a bad idea because she had taken Dr. Lee's class at College of Marin on Optimal Health, and he said fluoride was a bad thing for bones. So he told her to go see Dr. Lee. I put her on **progesterone** and she had a 24% improvement in bone density over the next 30 months. Her bone density went from .669 to .865. Given her height and weight this is a perfectly fine bone mineral density.

* * *

The woman stuck with my thinking and told her husband she was going to try **progesterone** cream despite his objection. Finally her husband gave in saying, "Then in six months we're going to make you get another bone mineral density test." In six months she went from .446 up to .516. That's over 14% in six months! Another test was done ten months later and her bone density was still increasing.

* * *

Complaint

There are things in life that do not need a double blind, placebo-controlled study. . . . If they say that after age 65 osteoporosis cannot be reversed, and you reverse it in 62 women using just progesterone, you don't need a double blind study! I'm not against someone doing a double blind study, but they know that no one will pay for it. Progesterone is a real hormone and since it's not a patentable synthetic, there is no money to be made so no one is going to ante up the \$500,000 to \$1,000,000 to do a study.

(Exhibit A at 40-46.)

9. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that:

A. ProBalance™ and ProBalance Plus™ are effective in preventing, treating, or curing osteoporosis;

B. ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. ProBalance™ and ProBalance Plus™ do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made.

Complaint

Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that clinical testing proves that the ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer.

13. In truth and in fact, clinical testing does not prove that ProBalance™ and ProBalance Plus™ are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

14. The acts and practices 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.


THEREFORE, the Federal Trade Commission, on this thirteenth day of November, 2007, has issued this complaint against respondents.

By the Commission.

Complaint

Exhibit A

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Switching to Natural Hormones?
Now That HRT Is No Longer Every Woman's Answer.

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Development for Cardiovascular Health.

Phosphatidylserine
A Remarkable Brain Cell Nutrient.
Parris M. Kidd, PhD.

Candida Albicans
(Yeast Infection) Candida Albicans is a normal fungus inhabiting the mouth, throat and gastrointestinal tract. Excess development may result from certain types of life style and can be an indicator of immune status.

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Nattokinase (NSK-SD™)


Available in 60 and 180 softgels (1825 Fibrinolytic Units per softgel). "43% price drop per serving."

This new, more potent formula is approximately equivalent in potency to the earlier, more expensive formula.
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NSK-SD™ is a trademark of Japan BioScience Laboratory



Cholestatin - The Effect of Dietary Phytosterols On Cholesterol (currently unavailable)




- » As early as the 1930's it was shown that serum cholesterol levels could be effected by phytosterol supplementation.
- » Work in the 1950's confirmed the ability and numerous efficacy studies since, in animals and humans, have proven that phytosterols are

All Progesterone creams are not created equal!

Natural Progesterone

ProBalance reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy. [more info](#)



1- 5 tubes	19.95 ea.	BUY
6 tubes	17.95 ea.	BUY
12 tubes	15.95 ea.	BUY

Natural Progesterone With a Blend of Phytoestrogens

ProBalance Plus™ is a safe and natural menopause alternative for women over 45 without the side effects often associated with HRT. [more info](#)

1- 5 tubes	27.00 ea.	BUY
6 tubes	24.00 ea.	BUY
12 tubes	21.00 ea.	BUY

USP Pharmaceutical grade progesterone. Non-greasy. Absorbs quickly. No carcinogens or unnecessary ingredients. We have yet to find a doctor who has been recommending ProBalance to his/her patients switch to any other brand of progesterone cream. The saliva test results prove the effectiveness, and the feel makes applying it a pleasure.

Suggested Reading

Complaint

firm commitment to their customers privacy.

Shipping/Return Policy
If you are not completely satisfied with your order, return any unopened products within 30 days for a prompt refund.

Testimonials
We find it exciting that ProBalance is providing relief for women with a wide range of health challenges caused by hormonal imbalance.

Contact Springboard
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highly effective in lowering cholesterol levels. [Read more...](#)


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Minerals are the basic structural foundations of cellular life! These products give you what you need to fortify your body's system.

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- » Folic Acid Mineral Water
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The Very Best In Nutrition

Nutritional Supplements Most Used In Alternative Cancer Therapies




Springboard has made available the nutritional supplements most used in alternative cancer therapies. [View product list](#)

Autistique Antioxidant Body Cream

Parents of autistic children are faced with the daunting task of sifting through a mountain of treatment modalities to find the combination to help their child. The dietary, biomedical and alternative treatments are also a maze because like the syndrome itself, one size does not fit all.

Autistique is a transdermal antioxidant cream which bypasses the liver and goes directly into the bloodstream. [Read more...](#)




WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT BREAST CANCER

How Hormone Balance Can Help Save Your Life. POWER LEE M.D. M.D. Breast Cancer Specialist

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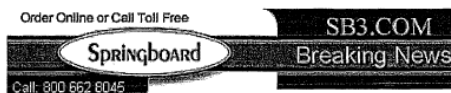
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Complaint

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Breaking News - On Health

Switching to Natural Hormones Now That HRT Is No Longer Every Woman's Answer

The recent headlines about the risks of synthetic hormone replacement (HRT) have forced women to scramble to find ways to balance their hormones naturally. Natural, bio-identical hormones are the safe alternative to HRT and hundreds of thousands of women are already using them. The following information from John R. Lee, M.D., one of the leading experts on the subject of natural hormones, are offered here to answer questions you may have about switching from synthetic HRT to natural.

While the abrupt cancellation of The Women's Health Initiative (WHI) made headline news around the country, it did not surprise those who have kept up with all the studies over the last decade which warned of the risks of HRT. The WHI analyzed the health of 16,000 women aged 50 to 79 years over five years of using HRT in the form of Premarin, Provera or PremPro. The researchers found an increased incidence of just about every major disease the hormones were supposed to be preventing! The data showed:

- A 41 percent increase in strokes
- A 29 percent increase in heart attacks
- A 26 percent increase in breast cancer
- A 22 percent increase in total cardiovascular disease
- A doubling of the rate of blood clots.

The makers of the drugs, Wyeth Pharmaceuticals, concludes that the increase in individual risk is relatively small based on a study which compared 10,000 women not taking hormones to 10,000 postmenopausal women with a uterus who are taking estrogen plus progestin. The study found that of the women on HRT,

- 7 more will have a heart attack,
- 8 more will have invasive breast cancer,
- 8 more will have a stroke and
- 18 more will have blood clots including blood clots in the lungs.

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The term, "relatively small individual risks" is definitely relative. Translated nationally, these figures are staggering...

— 4,200 additional cases of breast cancer,

— 4,800 cases of heart disease, and

— 10,800 women, wives and mothers who had a stroke in a five-year period because they were taking this form of HRT.

Stretch these numbers out over a decade, and nearly 40,000 women will have been harmed by taking these drugs, not counting all the women who have suffered the dismal side effects of this form of HRT — weight gain, fatigue, depression, irritability, headaches, insomnia, bloating, low thyroid, low libido, and gallbladder disease. That is an epidemic. If we dare to multiply 40,000 women harmed times three — the number of decades women have been using synthetic HRT — we are talking about an epidemic of the worst proportions.

One of the most disturbing aspects of this fiasco is that it was created in large part because of the negligence of conventional medical practice and prescribed without good supporting evidence of safety and efficacy. In 1966, when estrogen replacement therapy took off with a book entitled "Feminine Forever" by Dr. Robert Wilson (who was sponsored by Wyeth Pharmaceuticals), women were promised that they would remain "young, attractive and sexually active" if they took the hormone. Those who did not would see their breasts and genitalia shrivel; they would become dull, unattractive and unpleasant to live with. Despite the lack of evidence to back up these claims, women who complained of anything remotely like menopause were immediately placed on HRT. Their hormones were never measured to find out which ones they needed or how much, and they were subjected to a one-dose-fits-all mindset that led to the overdosing of millions of women on estrogen. When it became apparent that estrogen on its own was causing uterine cancer, natural progesterone in combination with estrogen was totally ignored in favor of the patentable (read: profitable) synthetic progesterones known as *progestins*.

And so it has gone, until the Women's Health Initiative, expecting to document the lifesaving benefits of HRT, found life threatening risk instead. The study was stopped in its tracks — three years short of its scheduled end.

To readers of the works of Dr. John Lee, Dr. David Zava and other pioneers of the natural hormone movement, the risks and side effects of conventional HRT are not news. The evidence of harm has been showing up in the scientific research for at least a decade. This particular study was finally large enough and prestigious enough that conventional medicine was forced to pay attention. The challenge now for doctors is to inform themselves and their patients about the efficacy, use and prescribing of natural hormones.

Questions and Answers About Natural Hormone Replacement Therapy with Dr. John Lee

(Provided with permission of Dr. John Lee, author of WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT MENOPAUSE and co-author with Dr. David Zava of WHAT YOUR DOCTOR MAY NOT TELL YOU ABOUT BREAST CANCER)

Do the results of the WHI apply to using natural estrogen and progesterone as you

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recommend?

Not at all. What I recommend is measuring saliva hormone levels to find out where the hormonal imbalance is, and then using natural hormones in *physiologic* doses, which means doses that the body would naturally produce itself if it were in balance, and in a natural monthly rhythm. (Please read any one of our books for details.)

Looking at this another way, from puberty until menopause, a healthy woman's body is making its own natural hormones in synchrony and balance, without giving her cancer, heart disease or strokes. What I recommend is attempting to regain or mimic this natural balance as closely as possible.

Conventional HRT not only fails to measure hormones and use physiologic doses, it uses synthetic, not-found-in-nature hormones that are foreign to the human body and cause a long list of unwanted side effects.

How do I get off PremPro?

Most women simply need to lower their dose of estrogen and replace the *progestin* (the "pro" part of the PremPro) with progesterone cream.

Estrogen is a prescription-only medication in the U.S., so you will need to ask your doctor for a separate prescription for estrogen, preferably estradiol, a combination of estradiol and estriol, or estriol alone (please read our breast cancer book for details on using estriol). Even Premarin, although ethically objectionable in the way it is obtained from pregnant mares, will work if it is used in the lowest dose needed, and in combination with natural progesterone. It is important not to go off of estrogen suddenly, or you are likely to suffer from hot flashes and night sweats.

Unless your doctor already has you on a low dose of estrogen, you can begin with half the dose you have been taking when you add progesterone cream in place of the progestin. Many menopausal women do not need any estrogen at all, and can gradually taper their dose down to nothing. Although progesterone alone will alleviate menopausal symptoms for many women, many women who do not have much body fat need a little bit of estrogen. Symptoms of estrogen deficiency include hot flashes, night sweats, and vaginal dryness. Again, you can find more specific information in our books.

My doctor says that I cannot use estrogen and progesterone cream, because progesterone cream will not protect my uterus the way the progestins do.

Progesterone cream protects the uterus just fine. Not only did I not have any problems in my hundreds of menopausal patients before I retired from practice, I am in touch with dozens of physicians who have thousands of patients between them, who have never had a problem. Some of them have been doing this for over a decade. Furthermore, a recently published double blind, placebo-controlled study by Helene Leonetti, M.D., indicates that progesterone cream is protective. Her study compared the uterine protection of PremPro with an estrogen/progesterone cream combination. In short, the women on the progesterone cream came out just fine.

You might also ask your doctor how he thinks that your premenopausal body protected itself against estrogen effects. It was the progesterone that your ovaries made every month!

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My doctor says that because blood tests do not show a rise in progesterone when progesterone cream is used, that it does not work, and I should use oral progesterone.

Blood tests only measure the serum, which is the watery part of the blood, and progesterone that comes from cream use is carried in the red blood cells, not in the serum. The most accurate way to measure hormone levels is with a saliva hormone level test, which measures your active or bioavailable hormones. When you use progesterone cream, a saliva hormone test will show a gradual rise in hormone over a four-hour period, and then a gradual drop over a four-hour period. This amount of time is an average, and can vary a bit from woman to woman.

What are bio-identical hormones and can you explain the difference between natural progesterone and the synthetic version?

Bio-identical hormones (BHRT) are synthesized from natural substances and are identical in structure and function to those our bodies produced naturally, pre-menopause. When production drops below normal levels at perimenopause and menopause, BHRT is the best and safest way for women to supplement. Bio-identical hormones are available by prescription through compounding pharmacists. Natural progesterone is a bio-identical hormone as opposed to progestin which is the synthetic version (the "pro" in Prempro). Natural progesterone is just like the progesterone your ovaries made and is available in a topical form over-the-counter and by prescription (when compounded with natural estrogens and other hormones). It is always best to be tested first for any hormonal imbalances and based on your test results, discuss natural hormone supplementation (BHRT) with your health care provider. (Consult Dr. Lee's books for a suggested list of progesterone creams.)

For more information, we suggest the following books:

What Your Doctor May Not Tell You About Menopause

What Your Doctor May Not Tell You About Premenopause

What Your Doctor May Not Tell You About Breast Cancer

To subscribe to The John R. Lee, M.D. Medical Letter, go to: www.johnleemd.com

For information on saliva hormone testing go to: www.salivatest.com

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Complaint

PROBALANCE Moisturizing Cream with Natural Progesterone

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ProBalance Natural Progesterone Cream

Natural progesterone reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy.

The liposome-mediated delivery system used in ProBalance™ carries the progesterone directly into the bloodstream, bypassing the metabolic processes required by other transdermals.

"The signs and symptoms of osteoporosis cleared in every patient using progesterone cream and incidence of fractures dropped to zero." - John R. Lee, M.D.

Hormone replacement is routinely advised by gynecologists for menopausal women, most commonly as protection against osteoporosis and relief from menopausal symptoms such as hot flashes. For most women, hormone replacement is synonymous with estrogen replacement.

Suggested Use:

The information herein is for general use and not intended to encourage self diagnosis, self treatment or replace the guidance of your health professional.

For PMS and premenopausal symptoms, begin using the cream 10 to 12 days after the first day of your period. Apply the cream twice a day from either Day 10 or 12 through Day 26 or 48 hours before the scheduled start of next period. If your period starts early, stop using the cream - Mother Nature is trying to balance your hormone levels. When your period starts count forward 12 days (10 if you normally have a shorter cycle than 28 days) and begin the program on that day. Be patient, it may take three cycles before you achieve synchrony with your normal cycle. If you have cramps, headache, swollen breasts, etc., the cream may be applied directly to the problem area.

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Menopausal women not taking estrogen have a wider latitude in using the cream. For convenience, you may choose a dosage schedule based on the calendar month. Use the cream twice a day from the 1st to the 14th or 21st of each month and none from the 15th or 22nd to the end of the month. Some women report that using a larger dab of cream at night helps them sleep.

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better.

Menopausal women taking estrogen should reduce their dosage by half when starting to use progesterone cream. This is important because in women deficient in progesterone, the cream may temporarily increase the sensitivity of estrogen receptors. If estrogen intake is not reduced, you may experience symptoms of estrogen dominance during the first couple of months. You may try lowering your estrogen dose by half again every two to three months. (The estrogen dose should be low enough that monthly bleeding does not occur, but high enough to prevent vaginal dryness and hot flashes.) Estrogen and progesterone can be used together for up to 25 days each month, with 7 days without either hormone.

Ingredients:

Deionized Water, Caprylic/Capric Triglycerides, Simulgel, Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Glycerin, Phospholipids, Grapefruit Seed Extract, Sodium Hydroxymethylglycinate, Potassium Sorbate, Tocopheryl Acetate, Citric Acid.
Contains no artificial fragrance, coloring or preservatives

Approx. 400 to 500 mg Natural Progesterone per ounce
Package Size: 2 fl. oz.

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This product is not intended to diagnose, treat, cure or prevent any disease or disorder. The statements contained herein have not been evaluated by the Food and Drug Administration.

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The liposome-mediated delivery system used in ProBalance™ carries the progesterone directly into the bloodstream, bypassing the metabolic processes required by other transdermals.

Reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy.

Hormone replacement is routinely advised by gynecologists for menopausal women, most commonly as protection against osteoporosis and relief from menopausal symptoms such as hot flashes. For most women, hormone replacement is synonymous with estrogen replacement.

Estrogen is not a hormone, but a class of hormones produced by the ovaries, the major members being estrone, estradiol, and estriol. Estrogen is important for childbearing and survival of the fetus. Menopause signals the end of a woman's childbearing years so it follows that estrogen levels would decrease. The question is, do women need estrogen replacement?

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Although estrogen can retard the progress of osteoporosis, studies indicate that it does not prevent or reduce it. In addition to the increased risk of reproductive organ cancer, high levels of estrogen can also increase the risk of breast cancer, body fat, salt and fluid retention, and blood clotting; interfere with thyroid hormone; impair blood sugar control; decrease libido; and reduce vascular tone.

Progesterone is the other main hormone made by the ovaries of menstruating women. Progesterone levels vary during the monthly cycle from a low of 2-3 mg per day to an average of 22 mg per day, a week or so after ovulation. This surge of progesterone during

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Complaint

ovulation is the source of the sex drive in women. If fertilization does not occur, progesterone production levels decline abruptly, triggering menstruation. If the ova is fertilized, progesterone production is taken over by the placenta. During the last three months of pregnancy, progesterone production can be as high as 400 mg per day. Progesterone is crucial to the survival of the fetus. If levels drop, abortion follows.

Apparently, nature intended that estrogen and progesterone be balanced. Progesterone counters every undesirable effect of excess estrogen. Progesterone stimulates bone growth. It protects against reproductive organ and breast cancer, it helps the body to use fat for energy, it is a natural diuretic, it normalizes blood clotting, it aids thyroid hormone action, it helps to normalize blood sugar levels, it restores libido, and it is a natural antidepressant. Progesterone has also been found to be effective in treating PMS, ovarian cysts, breast fibrocysts, endometriosis, pelvic disorders, and uterine fibroid tumors. In the 1950's it was found that natural progesterone could be derived from the Mexican wild yam.

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Progestins such as Provera ®, are synthetic progesterones, synthesized from natural progesterone, but because the structure is altered, there is a long list of side effects including mental depression, insomnia, cervical erosion, edema, acne and pulmonary embolism. When taken in combination with estrogens, a woman may experience nervousness, dizziness, hair loss, fatigue, or hypertension, to name a few. Although many doctors believe that there is no difference between synthetic and natural progesterone, some synthetic progesterones can produce masculinizing effects in women whereas natural progesterone does not cause masculinization.

Transdermal absorption of natural progesterone has been established as an effective and safe delivery method. Rubbed into thin-skinned areas such as the palms of the hands, face, neck, breasts, inner arms, or soles of the feet, the progesterone is absorbed into the skin and stored in the fatty tissues. It is then taken into the bloodstream where it circulates to receptor sites throughout the body.

ProBalance™ is a fragrance free cream containing 1.67% natural progesterone. The unique liposome-mediated delivery system carries the progesterone through the skin directly to the bloodstream. For most women, hormone balance is achieved by gently rubbing the cream into thin-skinned areas twice a day in monthly cycles of three weeks on and one week off. For detailed use in monthly cycles of three weeks on and one week off. For detailed use information, refer to the following books by John R. Lee, M.D.:

- Natural Progesterone:
- The Multiple Roles of a Remarkable Hormone
- What Your Doctor May Not Tell You About Menopause

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Using ProBalance™

The information herein is for general use and not intended to encourage self diagnosis, self treatment or replace the guidance of your health professional.

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stop using the cream – Mother Nature is trying to balance your hormone levels. When your period starts count forward 12 days (10 if you normally have a shorter cycle than 28 days) and begin the program on that day. Be patient, it may take three cycles before you achieve synchrony with your normal cycle. If you have cramps, headache, swollen breasts, etc., the cream may be applied directly to the problem area.

Menopausal women not taking estrogen have a wider latitude in using the cream. For convenience, you may choose a dosage schedule based on the calendar month. Use the cream twice a day from the 1st to the 14th or 21st of each month and none from the 15th or 22nd to the end of the month. Some women report that using a larger dab of cream at night helps them sleep better.

Menopausal women taking estrogen should reduce their dosage by half when starting to use progesterone cream. This is important because in women deficient in progesterone, the cream may temporarily increase the sensitivity of estrogen receptors. If estrogen intake is not reduced, you may experience symptoms of estrogen dominance during the first couple of months. You may try lowering your estrogen dose by half again every two to three months. (The estrogen dose should be low enough that monthly bleeding does not occur, but high enough to prevent vaginal dryness and hot flashes.) Estrogen and progesterone can be used together for up to 25 days each month, with 7 days without either hormone.

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Menopausal women taking an estrogen and progestin combination should refer to Dr. John Lee's book, *What Your Doctor May Not Tell You About Menopause*.

Sources and Suggested Reading

- Natural Progesterone: The Multiple Roles of a Remarkable Hormone, John R. Lee, MD, BLL Publishing.
- What's Wrong with My Hormones?, Gillian Ford, Desmond Ford Publications, 7955 Bullard Drive, Newcastle, CA 95658, 1992.
- My Body, My Health: The Concerned Woman's Guide to Gynecology; Felicia Stewart MD, Felicia Guest, Gary Stewart MD, and Robert Hatcher MD, John Wiley & Sons, 1979.
- PMS: Premenstrual Syndrome and You, Neils Lauersen, MD, Simon & Schuster, 1983.

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Natural progesterone reduces the symptoms and discomfort of PMS, premenopause and menopause without the side effects often associated with synthetic hormone replacement therapy. The liposome-mediated delivery system used in **ProBalance™** carries the progesterone directly into the bloodstream, bypassing the metabolic processes required by other transdermals. Hormone replacement is routinely advised by gynecologists for menopausal women, most commonly relief from menopausal symptoms such as hot flashes. For most women, hormone replacement is synonymous with estrogen replacement.

Suggested Use: The information herein is for general use and not intended to encourage self diagnosis, self treatment or replace the guidance of your health professional. For PMS and premenopausal symptoms, begin using the cream 10 to 12 days after the first day of your period. Apply the cream twice a day from either Day 10 or 12 through Day 26 or 48 hours before the scheduled start of next period. If your period starts early, stop using the cream – Mother Nature is trying to balance your hormone levels. When your period starts count forward 12 days (10 if you normally have a shorter cycle than 28 days) and begin the program on that day. Be patient, it may take three cycles before you achieve synchrony with your normal cycle. If you have cramps, headache, swollen breasts, etc., the cream may be applied directly to the problem area.

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Ingredients: Deionized Water, Caprylic/Capric Triglycerides, Simulgel, Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Glycerin, Phospholipids, Grapefruit Seed Extract, Sodium Hydroxymethylglycinate, Potassium Sorbate, Tocopheryl Acetate, Citric Acid.
Contains no artificial fragrance, coloring or preservatives

Approx. 400 to 500 mg Natural Progesterone per ounce

Package Size: 2 fl. oz.

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Springboard Natural Progesterone

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Complaint

PROGESTERONE USED TO TREAT, OSTEOPOROSIS, MISCARRIAGE, FIBROCYSTIC BREAST DISEASE

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Miscarriage

Progesterone is the progestation hormone. It keeps the bloody lining intact as a rich natural health food restaurant open 24 hours a day for the fertilized egg when it lands there and begins to multiply. This very tiny living being has to have a constant food supply, and as there is yet no placenta or umbilical cord to supply nutrients, the bloody lining is the baby's first food supply. Also the baby always has a different DNA than the mother, and the body's natural defense system always tries to reject nonself. The only thing known to biology that is capable of turning off this defense system in relation to the baby's different DNA is progesterone. Without progesterone the bloody lining is shed and the pregnancy is terminated. Many women who have experienced multiple miscarriages find that they can carry their babies to term by using natural progesterone. Dr. Lee has received hundreds of phone calls and letters telling him that they are so grateful to finally have a baby that they have named their baby after him when it was a boy.

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Osteoporosis

Osteoporosis is often caused by a lack of progesterone. Very rarely is it a lack of calcium. New bone is formed by osteoblasts, and old bone is removed by osteoclasts. When the osteoclast activity goes faster than the osteoblast activity bone loss occurs. Progesterone is the key factor in osteoblast or building of new bone. Dr. John R. Lee checked this out with 63 women over a 3 year period, doing bone mineral density tests every six months. At the end of a 3 year test on these women using progesterone cream, the average increase in bone density was 15.4%. These were all postmenopausal women who would normally expect to have a 1.5% bone loss per year, or a total bone loss for 3 years of 4.5%. There was a 19.9% difference between the expected loss and the real increase that occurred. This is very exciting, as medicine has been saying that you can't reverse osteoporosis; you can only slow it down. Estrogen does not reverse it. It only slows down bone loss for the two to three years of menopause, then has no further effect

Dr. Lee tells of a woman 72 years old who had over 40% bone loss and was in pain because of a stress fracture in her lower spine. In spite of opposition from 5 doctors involved in her case, she decided to follow Dr. Lee's advice, and in only 16 months experienced a 23% increase in her bone density. All but one of the doctors wrote Dr. Lee telling him that they would not have believed it had they not seen it with their own eyes. This lady is now 80 years old, and is continuing to use the progesterone cream. Her total increase in bone density is up 38%. When Dr. Lee was asked how long she should

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continue using it, he responded: "Keep using it until you are 95, and then we'll reevaluate."

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Fibrocystic Breast Disease

Fibrocystic breast disease is affecting a very high percentage of women. One of the major causes of this is too much estrogen. In an article in Fertility and Sterility, published by the 1995 American Society for Reproductive Medicine, a double blind study on the use of progesterone cream studying cellular proliferation, showed a 410% decrease in cellular proliferation in only 13 days. Estrogen applied topically caused an increase of cellular proliferation of 223% in the same period of time. Since many women and doctors alike believe fibrocystic breast disease a prelude to breast cancer, a number of women are having mastectomies for fibrocystic breasts.

Dr. Lee indicates that in hundreds of cases in his medical practice he never saw a case of fibrocystic breast disease fail to completely disappear within three months. We recently saw a case in Las Vegas with a woman who had over 200 fibrocysts the doctor quit counting at 200 and recommended a mastectomy. Instead she went on the progesterone cream, and 64 days later, feeling much better, went back to see her doctor. All the fibrocysts were gone, and this doctor couldn't understand it, and refused to even consider that a transdermal progesterone cream could be the cause of this disappearance of the problem.

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**For more complete information on progesterone,
please refer to the John R. Lee, M.D. Medical letter.
To subscribe call: (800) 528-0559**

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ProBalance Plus - Natural Progesterone Cream with Phytoestrogens

- » ProBalance Plus™ is the safe and natural menopause treatment alternative for women over 45 without the side effects associated with synthetic hormone replacement therapy.
- » The liposome-mediated delivery system used in ProBalance Plus™ carries the progesterone and phytoestrogens directly into the bloodstream, bypassing the metabolic processes other transdermals must undergo.
- » Menopause is not a disease, but a physical transition whose symptoms and discomforts can be managed without the use of synthetic drugs with a myriad of possible side effects. Although the FDA and a large number of medical practitioners consider menopause to be an age-related disease, women understand that it is simply a natural and inevitable transition from one stage of life to another. Puberty marked the onset of the reproductive stage and menopause marks the end of it.

Suggested Use:
In the beginning, use as often as necessary to alleviate symptoms. Gently massage a pea-sized dab of cream into thin-skinned areas such as breasts, thighs, abdomen, breasts, inner arms, or face. Rotate the areas daily to avoid saturation. Thereafter use twice daily – one dab in the morning and two dabs at night – in cycles of three weeks on, one week off.

Ingredients:
Deionized Water, Caprylic Capric Triglycerides, Simulgel, Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Glycerin, Phospholipids, Grapefruit Seed Extract, Sodium Hydroxymethylglycinate, Potassium Sorbate, Tocopheryl Acetate, Citric Acid, Estriol (900 mcg per 1/4 measuring teaspoon), Estradiol (100 mcg per 1/4 measuring teaspoon).
Contains no artificial fragrance, coloring or preservatives.

Net Wt. 2 fl. oz.

110-Daliance Natural Progesterone Cream with Phytoestrogens

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Natural Progesterone Cream ProBalancePlus

Menopause is defined as beginning after a woman's last period, but the monthly hormone secretion pattern starts to change when a woman reaches her early to mid-forties. The years before periods completely stop are called peri-menopause, a time marked by hormone imbalance signaled by hot flashes, night sweats, insomnia, dryness and thinning of the vaginal area, aging skin, diminished sex drive, anxiety, forgetfulness, depression, and other mood changes. The perimenopause phase can last as long as ten years. The milestone called menopause is reached when a woman has skipped 12 consecutive periods.

In the years following menopause, the risk of cardiovascular disease, osteoporosis, and cognitive decline increases dramatically. A growing number of research studies have linked some of these risks to the relative absence of estrogens and progesterone. For decades, physicians prescribed synthetic estrogen, such as Premarin®, without other accompanying hormones. When it was discovered that the risk of developing endometrial cancer due to unopposed estrogen replacement could be reduced by adding progesterone, physicians began prescribing progestins (synthetic progesterone which could be patented) such as Provera®. According to some estimates, standard hormone replacement therapy using synthetic hormones like Premarin® and Provera® may increase a woman's risk of breast cancer by as much as 30 percent. Many doctors think that the lower risks of heart disease and osteoporosis attributable to estrogen replacement make the odds acceptable. On the other hand, a majority of these doctors aren't women!

For women who find these odds unacceptable, considering natural hormone replacement is a "no brainer." The benefits include those of synthetic HRT plus a few more including:

- Prevention of osteoporosis and increase of bone density
- Improved maintenance of muscle mass and strength
- Protection against heart disease and stroke
- Improved cholesterol levels
- Reduced risk of endometrial cancer and breast cancer
- Reduced risk of depression
- Improved sleep, mood, concentration and memory
- Reduced risk of senility and cognitive decline
- Enhanced libido

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PROBALANCE Natural Progesterone Cream with Phytoestrogens-PRO-1110

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Most women produce enough estrogen in the perimenopause phase so they only need progesterone to achieve hormonal balance. The benefits of progesterone are amazing. According to John R. Lee, M.D., the well-known proponent of supplemental progesterone, transdermal progesterone can:

- Promote bone building and protect against osteoporosis
- Help protect against breast cancer
- Protect against endometrial cancer
- Protect against fibrocystic breasts
- Promote fat burning for energy
- Act as a natural antidepressant
- Aid thyroid hormone action
- Normalize blood clotting
- Increase libido
- Help keep blood sugar levels normal
- Normalize zinc and copper levels
- Promote proper cell oxygen levels

Some women in the menopause or post-menopause phase who have been using only transdermal progesterone may experience a recurrence of symptoms such as hot flashes, night sweats, etc. These women may need supplemental estrogen, but find the risks associated with synthetic estrogen are unacceptable. For these women, ProBalance Plus™ may be a viable alternative. ProBalance Plus™ is a transdermal cream of natural progesterone plus a proprietary blend of phytoestrogens from soya, dong quai, black cohosh, red clover blossom, and licorice root extracts. Phytoestrogens are plant estrogens which when ingested appear to function much like natural estrogens in many ways. Research studies indicate that phytoestrogens:

- Increase cell growth in vaginal walls in postmenopausal women
- Raise high density lipid (HDL) cholesterol
- Reduce the risk of cardiovascular disease
- Reduce the risk of osteoporosis
- Reduce the risk of endometrial and breast cancer

Exactly how phytoestrogens accomplish these feats is still under investigation, but it is thought that phytoestrogens may block access to estrogen receptors by such procarcinogenic estrogens as estradiol.

Soya is known to contain the cancer-fighting phytochemicals isoflavonoids and flavonoids. The most closely studied is genistein which animal studies have shown can significantly retard the growth of breast cancer.

Black cohosh was used by Native Americans to relieve menstrual cramps and in Europe it has been used for menopause induced depression. The phytochemicals in black cohosh appear to occupy estradiol receptors.

Dong quai appears to act as an estrogen modulator. If estrogen levels

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ProBalance Natural Progesterone Cream with Phytoestrogens

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are low, the phytoestrogens provide some estrogen stimulus by filling unoccupied receptor sites. If estrogen levels are too high, these same phytoestrogens block some of the estrogen by occupying receptor sites. Licorice is another estrogen modulator.

ProBalance Plus™ is made from all natural ingredients and contains no fragrance. The only preservative used is grapefruit seed extract which is highly effective against bacteria, fungi, yeast, and other harmful organisms. ProBalance Plus comes in a flip-top tube with an inner foil safety seal.

Suggested Use:

In the beginning, use as often as necessary to alleviate symptoms. Gently massage a pea-sized dab of cream into thin-skinned areas such as breasts, thighs, abdomen, breasts, inner arms, or face. Rotate the areas daily to avoid saturation. Thereafter use twice daily – one dab in the morning and two dabs at night – in cycles of three weeks on, one week off.

Ingredients: Deionized Water, Caprylic/Capric Triglycerides, Simulgel, Progesterone (20 mg per 1/4 measuring teaspoon or 960 mg per 2 ounce tube), Glycerin, Phospholipids, Grapefruit Seed Extract, Sodium Hydroxymethylglycinate, Potassium Sorbate, Tocopheryl Acetate, Citric Acid, Estriol (900 mcg per 1/4 measuring teaspoon), Estradiol (100 mcg per 1/4 measuring teaspoon).

Contains no artificial fragrance, coloring or preservatives.

Net Wt. 2 fl. oz.

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 Contains no artificial fragrance, coloring or preservatives.

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Read what people are saying about using natural progesterone cream

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Natural Progesterone Users

The following letters are unedited, and from real people.

We find it exciting that ProBalance is providing relief for women with a wide range of health challenges caused by hormonal imbalance. While skeptics may say the results are purely psychosomatic, we hope these stories will encourage women seeking natural alternative answers to consider transdermal natural progesterone. Regulations require that we inform you that you may not experience the same results or within the same time frames, but trying ProBalance will do you no harm.

Fibrocystic Breasts, Endometriosis, Miscarriages, Bloating, Hair Loss

November 15, 1997

My own experience supplementing with ProBalance topical progesterone cream cleaned up many of my serious health problems.



When my mother was pregnant with me she was given DES, a synthetic estrogen, which was given to help prevent miscarriages. Two to six million women in the United States and Europe were given DES. About 50,000 pounds of DES was dumped into livestock feed to fatten cattle until 1979. DES has been linked to cancer, infertility, birth defects and other reproductive problems in both sexes. I feel that it was due to DES that I have had the following health problems, which started at age 17:

3 lumpectomies from fibrocystic breast disease
 8 miscarriages & Infertility problems
 14 surgeries

- Bloating
- Thyroid problems
- Weight gain
- Hair loss
- Endometriosis

The endometriosis required numerous surgeries that were supposed to help with fertility and alleviate pain. They did neither. Then, along came Dr. John Lee and Larry Jordan with information about topical, natural progesterone cream.

Raising my progesterone levels helped tremendously. I became pregnant after eight miscarriages in a row. I delivered a child at age 43.

However, after the birth of my child the endometriosis became much worse and I had

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muscle and joint pain. I was diagnosed with systemic lupus erythematosus. Fortunately for me, my dear friend, Larry Jordan, got me in touch with Dr. John Lee and Dr. Michael Rosenbaum. Both of them suggested using ProBalance topical progesterone cream as the main protocol to fight this problem. Remarkably, in four months my fibrocystic breast disease was gone. In addition most of the symptoms of my hypothyroidism were gone.

In eight months the endometriosis pain had disappeared. I was very pleased, because Dr. Lee thought it might take as long as one to two years. He was absolutely correct about how long it would take the lupus indicators to drop to insignificant levels at about 18 to 24 months. The symptoms as well as the blood work improved dramatically.

I and my family will always be grateful to these farsighted health professionals. These are the kind of enlightened health practitioners who go after the cause and not merely the treating of symptoms. Thank you all for giving me my health back!

C.L. - Thousand Oaks, California

Cramps, Ovarian Cysts

March 9, 1999

I've been using the ProBalance progesterone cream for nearly six months now. At first I was skeptical that it would get rid of my cramping and ovarian cysts. It took around two months to balance out my hormones and my cysts are finally gone! I used to be bedridden for 24 hours while I was ovulating because of the cysts and now I don't feel a thing. And when I was menstruating, I was bedridden for the first 24 hours as well! I have never felt so great in my life. Thank you so much Springboard!!

H. S., Chicago, Illinois

Hot Flashes, Insomnia, Dry Skin, Hair Loss, Joint Pain, Age Spots

March 9, 1999

I was directed by a friend to Dr. John Lee's book in the spring of 1998, when I began having some pronounced menopausal symptoms, including frequent hot flashes, sleep disturbance, dry skin, hair loss, joint pain, and age spots on the back of the hands. His book made a logical, convincing argument in favor of using progesterone cream by itself or in addition to estrogen for menopausal therapy. Since then I have tried different brands of natural progesterone cream, including Progest and AIM Renewed Balance, but ProBalance Natural Progesterone cream is my favorite, due to its smooth and creamy texture which doesn't leave a heavy or greasy feeling on my skin, and because it comes in an easy-to-dispense tube. The first improvements I noticed were that the joint pain in my wrists disappeared, the age spots on the back of my hands disappeared, and the skin texture on my face became softer and smoother! Though I also use tri-estrogen cream as recommended by my doctor (due to previous hysterectomy), I only need to use half as much as prescribed because I combine it with progesterone cream, which also protects

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Read what people are saying about using natural progesterone cream

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the breast tissue from soreness, swelling, and the development of cancer. For me, used together they are an unbeatable pair, and I highly recommend ProBalance Natural Progesterone cream!

*Sincerely,
C.M., Pasadena, California*

Fibrocystic Breasts, Hot Flashes, Depression

March 10, 1999

Last October, I had my third lump removed from my left breast. I was diagnosed with Fibrocystic Breast Disease and my doctor advised me that she wanted to put me on Tamoxifen (Chemo Therapy). In order to do this she said I would have to get off of hormone replacement therapy because it would counteract the drug. This scared the hell out of me! I had been on hormone replacement therapy for twenty years! I feel like I've had almost all the side effects Dr. Lee listed in his book. My doctor's answer was to treat the symptoms. I quit taking the hormones in December 1998 which threw me into menopause. The hot flashes were almost unbearable, night sweats made sleeping impossible, and I became unbearable to live with. I started using ProBalance Progesterone Cream in January 1999. In the last 60 days I have discovered what it feels like to be normal once again. I had forgotten what normal was like. I still have some minor symptoms of menopause but I feel wonderful! My breast was not healing properly before the progesterone cream. The pain is gone, swelling is gone, and the cysts are diminishing. Even the scar tissue from the surgery is less sensitive. The depression has lifted and I even laugh, which my husband thinks is awesome! I was so depressed all the time on hormones it was diagnosed as Chronic Depression and I'd be on Prozac for the rest of my life. I am now drug free! Not once in 20 years did my doctors advise me that hormone replacement therapy was causing my problems! Thanks to ProBalance Progesterone Cream and that wonderful Doctor John Lee, I have my life back and I feel better than I have in at least 20 years. I have told all my friends about ProBalance Progesterone Cream and to read Dr. Lee's book, "What Your Doctor May Not Tell You About Menopause".

*Thank you, Thank You, Thank you! Sincerely,
P.A., Indianapolis, Indiana*

Varicose Veins

June 4, 1999

I've been using it (ProBalance) since 1st March and have only missed two days. I believe the cream helps me quite a lot. I had nasty thread veins on my feet and my toes looked mauve. They have improved immensely. Also I feel I look a little younger - is that wishful thinking I wonder? Ha ha!!

E.B. (age ... late 70's), England

Complaint

Water Retention, PMS, Fatigue*November 9, 1999*

I began using ProBalance in June, 1999. I was experiencing serious discomfort due to water retention, PMS symptoms, and fatigue. Since I began using ProBalance, on the recommended schedule for premenopausal women, all my difficulties with water retention have disappeared completely; my PMS symptoms have levelled out; and I have more energy than previously. I have even been able to begin a fitness program (and stick with it) due to being rid of the discomforts and restrictions of water retention, PMS, and fatigue. This has led to my reducing my clothing size by one full size. I feel great! I look great! I am very grateful that I found this excellent product and that I am able to obtain it as I need it. I am recommending ProBalance to my friends who suffer from similar discomforting symptoms. They plan to begin this program in November and we are all looking forward to seeing what results they will have! Thank you for making this wonderful product available and for your excellent customer service. Sincerely, U.G.K., Calgary, Alberta, Canada

Fibrocystic Breasts, PMS

I have been using ProBalance Natural Progesterone cream for almost a year now. I was using it due to fibrocystic breasts and PMS problems. The last breast exam my Dr. stated this was the best she had ever seen them. It has worked on the symptoms I have had with PMS. I am one of the BAD cases and it has relieved them all. I will not give this cream up. I have recommended it to many people.

*Thanks,
T.W., Houston, Texas*

Insomnia*November 10, 1999*

I am very impressed with your Progesterone Cream, I feel 100% better. I sleep much better, have more energy and just had the most pain free mammogram ever. Also, the other problems that I was having seem to have disappeared. My doctor admitted to me that he had never heard of women using this with any benefit. Spoken like a true doctor. I have shared not only my story with other women but also the book telling about it's use. So far, I have about 5 converts. All have experienced the same effects as me. Thank you so much!

You have my permission to use my initials and city. If just one woman benefits the same as me, it is worth it! Thanks for your product - it is GREAT!!!

L.J., Grapevine, Texas

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from those people are saying about using natural progesterone cream

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Fibrocystic Breasts, Hair Loss

November 12, 1999

To whom it may concern at Springboard:

This is a testimonial to the use of ProBalance (NATURAL Progesterone cream). I am 47 and for the past 22 years I have had fibrocystic breast disease. Every 6 months I go to the doctor and he would aspirate as many as 4 or 5, leaving the 3 or 4 that were too small for aspirating. Often the cysts would get as big as walnuts before I could get them aspirated. Needless to say they were painful. I was told that there was nothing that could be done outside of some radical hormone therapy. I was advised to wait patiently for menopause. At the same time I was losing my hair for "no apparent" reason and went to several doctors including an endocrinologist who took blood tests, estrogen tests, thyroid tests, etc. and could find no reason for the loss. I began to send away for wig catalogs in anticipation of needing a wig in the VERY NEAR future. I read Dr. Lee's book about menopause and progesterone cream. Springboard was a company that was listed in his book. I ordered a tube in July and began using it daily. In four and a half months my breast cysts have disappeared and my hair is beginning to grow back. Other people who knew of my hair loss have commented that my hair is definitely thicker than it has been in over two years. I have been so excited about this product that I have told MANY people about this product and at least four of them are now using it. I believe that this cream is a God send for me when no one else could help.

Sincerely,
L.M., Grand Marais, Minnesota

Fibrocystic Breasts

November 18, 1999

To Whom It May Concern: I have greatly benefited from the natural progesterone cream. For about three years now I have had fibrocystic breast disease which has made my breasts very lumpy. Each month, midcycle, my breasts would swell and become painful. I was very worried about all this as my mother had breast cancer. Since I started using the cream two months ago my symptoms have completely disappeared. I am so excited that I have both my mother-in-law and a friend using the cream. I use 1/4 tsp two times a day.

Sincerely,
T.B., Miami, Florida

Bloating, Fatigue, Heart Palpitations

November 13, 1999

Hi, my name is J.W., I am 52, I ordered and received your wonderful product, ProBalance. I had a hysterectomy nine years ago. I have been on Premarin all this time. I stopped taking the Premarin this past Saturday and I feel WONDERFUL. I do not bloat

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like I did, my legs do not swell like they did, I do not feel fatigued anymore and I do not have intestinal gas like I used to. Also my heart palpitations have gone away. By the way I have had more than one compliment on how well I look lately!!! I do not have that "fatigued" look anymore.

J.W.
Belleville, Pennsylvania

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PROGESTERONE PROMOTES APOPTOSIS
PROGESTERONE'S EFFECT AT THE GENE LEVEL

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Breast Cancer and Programmed Cell Death (Apoptosis)

Breast cancer is considered to be a hormone dependent cancer, which means that hormones have something to do with the growth and development of breast cancer. About two years ago Time magazine had an article referring to apoptosis in reference to looking for something that would work against cancer. More recently in the 1/28/98 issue of the Journal of the American Medical Association (JAMA) there was a reference to apoptosis in reference to cancer.

Almost all the cells in your body are being created, live a certain length of time, and then die to make place for the new cells coming along. White blood cells last only two days. Red blood cells last 120 days. Your skin cells are being made new all the time. They are the ones that flake off when you take a bath and make a ring in your tub. If you've had your arm in a cast for 6 weeks, when you take the cast off you can flake off a lot of old, dead cells. They die on their own. It is a planned cell suicide. They are designed to do this because the new cells are coming.

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What has been discovered is that the cells that become cancer cells are not only those that are multiplying rapidly, because the white blood cells multiply rapidly, and they don't become cancer cells. It's the ones that don't die on time; they don't go through this programmed cell suicide. Programmed cell suicide is called apoptosis. It means "without dropping away." Ptois means "dropping." If you have one eyelid that won't go up; that's called ptosis. The dropping way refers to the programmed cell suicide.

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Progesterone Promotes Apoptosis; Estrogen Turns It Off

Research has looked into what it is that makes a cell do this. It is not told to by some other cell. It is built into the DNA of the genes of that cell. It's designed that way. It turns out that there's a gene that will block apoptosis and try to get the cell to live longer. That gene is called BCL2. It leads to the cell becoming a cancer cell.

Breast Cancer Cells Need Apoptosis In Order To Die

The cancer cell doesn't think of itself as a bad cell. It thinks of itself as a cell that outsmarted you, and it is going to live on. You might die, but it is going to try to live on. But the gene that normally functions to cause that cell to commit programmed cell suicide is the gene called P53. In the 1/28/98 issue of the Journal of the American Medical Association (JAMA) is an article entitled "To Die or Not to Die." They are not talking about your life, though they well could be. They are talking about the cell and what controls and determines if it dies on time as it ought to. They refer to gene P53 as the gene that tells the cell to die on time, and BCL2 is the gene that blocks this. So if BCL2 is the dominant one you'll develop cancer. If P53 is the dominant one you won't. Inside your breast you have skin cells that line the milk ducts. You have miles of milk ducts in your breasts. These cells are like skin cells. They are being made; then they are supposed to die, and the specialized blood cells (macrophages) go and eat them up, because new cells are coming along all the time. Imagine that they didn't die on time, and your breast just retained all these cells that are being made all the time. Pretty soon your breasts would be dragging on the ground. The only way you keep normal size breasts is to have last month's cells die, because this month new cells are coming along.

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This doesn't happen to brain cells or muscle cells, but in all the other cells in your body this goes on all the time. What keeps you young and healthy is the new cells coming along.

Can You Cure Cancer if You Can Control Apoptosis?

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What they are admitting in the JAMA article is that the war on cancer has been a failure. The war on cancer has been trying to find medicine that stop rapidly growing cells from multiplying so rapidly, but in the process they are stopping your own white blood cells, your hair follicles and everything else. So if they give you a medicine strong enough to kill the cancer cells, they are in the process are killing you. They admit that chemotherapy is a failure, except for some leukemias and lymphomas in young children. Young children that have a real strong immune system will survive the chemotherapy and come back. But for those of us who are adults the chemotherapy strong enough to kill the cancer would have to be strong enough to kill us first. So now, the new treatment goal is how to control apoptosis to bring on cell death of the cancer cells. "New cancer therapies that aim to induce apoptosis, specifically in cancer cells and cells becoming cancer, are the source of much excitement and renewed hope for cure." You can cure cancer if you can control apoptosis.

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Progesterone Upregulates the Gene that Causes Cancer Cells To Die Estrogen Upregulates the Gene that Cause Cancer Cells to Not Die

Last year Dr. Ben Formby and Dr. T.S. Wiley at the University of California in Santa Barbara proved how to do that very thing. Dr. Ben Formby is from Copenhagen, Denmark. He is a molecular biologist who has learned how to build cell cultures, and how to tell the products of specific genes like BCL2 and P53. So he took the cell cultures of breast, endometrium, ovary and prostate, and he grew them in culture. On some he added a little estrogen (estradiol). Guess what happened. The estradiol turned on BCL2, and the cells grew rapidly and didn't die. Then he added some progesterone to it. Guess what happened. They stopped growing so rapidly; they died on time, and the cancer all disappeared. He did that for all these types of cancer.

What do we have? The BCL2 stimulates the risk of cancer. Gene P53 decreases the risk of cancer. Estradiol upregulates BCL2. Progesterone upregulates P53. Therefore progesterone decreases cancer. Unopposed estradiol causes the cancer. Simple. Estrogen dominance is the cause of the cancer growing and the inability of the body to cure it.

Progesterone and Estrogen Functions in Breast Cancer Supported by Major Medical Journals

The critics are saying that they don't see anything about this in the medical journals that they read. Maybe they aren't reading the correct journals. There are 12 references to tests on BCL2 and P53, and the difference between progesterone and estrogen. Some of the places these articles have occurred:

- The American Cancer Society

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- The Journal of Clinical Endocrinology
- The American Journal of Pathology
- International Journal of Cancer
- The Journal of the American Medical Association (JAMA)
- Fertility and Sterility - Journal of the American Society For Reproductive Medicine


For more complete information on breast cancer and progesterone, please refer to the John R. Lee, M.D. Medical letter. To subscribe call: (800) 528-0559 Mention Springboard to receive a \$20.00 Discount

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PROGESTERONE DECREASES CELL PROLIFERATION

NATIONAL CANCER INSTITUTE'S SYMPOSIUM ON ESTROGEN AS A- MAJOR CAUSE OF CANCER

- [Progesterone Decreases Cell Proliferation: Estrogen Increases It](#)
- [If You Want To Increase Cell Proliferation Use Estrogen If You Want To Decrease Cell Proliferation Use Progesterone](#)
- [Progesterone Levels At Time of Breast Cancer Surgery Affect Survival Rates](#)
- [Method of Measuring Cell Proliferation](#)
- [Progesterone Levels at the Time of Surgery](#)
- [Estrogen a Major Cause of Cancer](#)
- [National Cancer Institute's Symposium on Estrogen](#)
- [Estrogens as Endogenous Carcinogens in the Breast and Prostate](#)
-

Progesterone Decreases Cell Proliferation: Estrogen Increases It

The Fertility and Sterility Journal article was particularly interesting, as it was the first double blind, placebo controlled, randomized study using transdermal progesterone and transdermal estrogen (estradiol) on real women (40 of them) who were having breast biopsies. They had one at the beginning of the study and another biopsy 13 days later, and were able to check on several interesting things.

The first thing of note was that even though the estrogen and the progesterone did not show up in the serum, it showed up in the breast tissue at over 100% increased levels above the placebo cream.

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The most interesting finding was what happened to cell proliferation during this 13 day test. The following chart shows two ways of measuring cell proliferation. The PCNA (proliferating cell nuclear antigen) is the most accurate, but both methods were used.

Based on PCNA numbers (these tend to be the most accurate measurement) the numbers in the above chart showing increase or decrease of cell proliferation showed up in only 13 days. Translated into percentages the following 3 sentences summarize it.

Method of Measuring cell Proliferation	Placebo	Progesterone	Estrogen	Estrogen & Progesterone
Mitosis per 1000 Cells	0.51	0.17	0.83	0.52
PCNA	7.8	1.9	17.4	6.5

- Topical Progesterone reduced cell proliferation by 410%
- Topical Estrogen increased cell proliferation by 223%
- Topical Estrogen/Progesterone combination reduced cell proliferation by 16%

The numbers on this chart were excerpted from the Fertility and Sterility Journal, Vol. 63, No. 4, April, 1995. The exact reference is: Chang KJ, Lee TTY, Linares-Cruz G, Fournier S, de Lignieres B. Influences of percutaneous administration of estradiol on human breast epithelial cell cycle in vivo. Fertility and Sterility 1995; 63; 7865-7891.

**If You Want To Increase Cell Proliferation Use Estrogen
If You Want To Decrease Cell Proliferation Use
Progesterone**

The conclusion seems to be: if you want increased cell proliferation use estrogen. If you want decreased cell proliferation use progesterone. The entire study is worth reading, and is an excellent affirmation that what Dr. John Lee has been saying and writing is correct. This is not secret information, but it is being denied to the typical doctor of conventional medicine, even though similar information is in the AMA journal.

It is Dr. John Lee's contention that progesterone prevents breast cancer, and if you already have breast cancer progesterone protects you against reoccurrence or late metastases. In his medical practice he treated many women who had had mastectomies. In the 20 years since he started recommending the use of progesterone, not one of the hundreds of women he treated has died of breast cancer. Think about what the odds are on that number when you compare it to normal post mastectomy figures.

Progesterone Levels At Time of Breast Cancer Surgery

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Affect Survival Rates

In 1976 Dr. Mohr started a test at two major hospitals in London that did breast surgery. He requested that every time they had a breast surgery that they take a blood test and save it so that he could test the progesterone level at the time of surgery. He tested testosterone, progesterone and estrogen. He found that progesterone level at the time of surgery was correlated with better survival. The survival record was reviewed 18 years after breast cancer surgery in node positive patients: this means that the cancer had already spread, was already metastasizing.

Summary of Dr. Mohr's findings

Progesterone Level at The Time of Surgery	Survival percentage after 18 year
Adequate Progesterone (4ng/ml or more)	62%
Low Progesterone (less than 4 ng/ml)	30%

This was written up in the British Journal of Cancer in 1996. The title of the article is: "Serum Progesterone and Prognosis in Operable Breast Cancer." This is over a 100% improvement just by having adequate progesterone level at the time of surgery. There is no treatment that provides that degree of benefits. Progesterone is the treatment.

Estrogen a Major Cause of Cancer

Dr. Ercole Cavaliere, the head of cancer research at the University of Nebraska Medical Center (also one of the speakers at the NCI program shown below). He calls estrogen the angel of life, the angel of death. It is necessary at the beginning to create a successful pregnancy, and if you have estrogen dominance later in your life it is the angel of death. When the body tries to metabolize estradiol and estrone it is possible to end up in this pathway which ends up in cancer. This is real human estrogen, and the body is trying to get rid of it. If the body does it correctly it methylates it, and it is safely excreted. But if the person has been eating margarine or transfatty acids, things that are not real and are missing the essential fatty acids it falls into another pathway. If the same person is not getting the sulfated amino acids like methionine and cysteine that is in garlic and beans, it continues on in this pathway and binds to DNA, causes a mutation, and creates cancer and kills the person.

National Cancer Institute's Symposium on Estrogen as a Cause of Cancer

Estrogen is the cause of the cancer that women fear, and yet there are many doctors still giving them unopposed estrogen. The recent National Cancer Institute symposium March 16-17, 1998 basically states that estrogen is the cause of the cancer that is killing women. If

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Breast Cancer & Natural Progesterone Fact Sheet

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you look at the following program to see some of the major medical research organizations stating this in their presentations, it sort of make you wonder why we didn't hear any of this on the news in any of the major media. It makes you wonder why unopposed estrogen is still being so widely used. Look at the following program:

The following symposium sponsored by the National Cancer Institute March 16-17, 1998 was referred to by Dr. John R. Lee in his two tape series: "Progesterone Update". The content of the seminar fully supports Dr. Lee's assertion of the link between cancer and estrogen. Read the information below on their program, and you will find both the introduction and the titles of the presentations enough to make you pause before taking estrogen. Also listening to Dr. Lee's tapes will give you a good insight into some of the material presented at this symposium.

Estrogens as Endogenous Carcinogens in the Breast and Prostate

This symposium has been planned to explore the role of endogenous estrogens in the etiology of human breast and prostate cancer. An international group of scientists will share viewpoints and construct a more holistic understanding of the way estrogens induce cancer. Topics will include metabolic activations of estrogens to carcinogenic forms, deactivation of carcinogenic metabolites, and the role of estrogen receptor-mediated processes in tumor induction. One of the goals of this symposium is to provide the attendees with an overview of the direction of research on estrogen-induced cancer. Another goal is to identify biomarkers that can be useful in studies of cancer risk among humans and in the future development of preventive strategies. The overview of the role of estrogens in cancer obtained from this symposium will be useful for scientists engaged in a variety of cancer-related studies, as well as for epidemiologists, health planners, journalists and members of advocacy groups for breast and other human cancers.

The Program**Welcoming Remarks**

- Dr. David Longfellow
Chemical and Physical Carcinogenesis Branch
Division of Cancer Biology, NCI

Overview of Estrogens as Endogenous Carcinogens Introduction and Remarks**Co-Chairs:**

- Dr. David Longfellow
Dr. Richard Santen, University of Virginia Health Science Center

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ESTROGEN CANCER OF THE BREAST: A REVIEW

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Cellular and Molecular Interactions in Breast Cancer: Role of Estrogen and Its Receptors

Dr. Joe Russo, Fox Chase Cancer Center

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Dr. James Yager, The Johns Hopkins University

Estrogens as Endogenous Genotoxic Agents: DNA Adducts and Mutations Remarks:

Dr. Joachim Liehr, Stehlin Foundation for Cancer Research

Dr. Ercole Cavalieri, University of Nebraska Medical Center

Catechol Estrogen -3,4-Quinones and Apurinic Sites in Cancer Initiation

Dr. Ercole Cavalieri, University of Nebraska Medical Center

Endogenous Oxidants and DNA Damage

Dr. Krystyna Frenkel, New York University Medical Center

Estrogen-induced Gene Mutations

Dr. Deodutta Roy, University of Alabama at Birmingham

Tissue-Specific Synthesis and Oxidative Metabolism of Estrogens

Co-Chairs:

- Dr. James Yager Dr. Colin Jefcoate, University of Wisconsin-Madison

Estrogen Formation by Aromatase in Breast Tissue

Dr. Richard Santen Metabolic Activation of Estrogens by 4-Hydroxylation

Dr. Joachim Liehr

Estrogen 4-Hydroxylation by Cytochrome P4501B1

Dr. Thomas Sutter, The Johns Hopkins University

Estrogen Metabolism by Conjugation

Co-Chairs:

- Dr. Richard Weinshilboum, Mayo Medical School
Dr. Julius Axelrod, National Institute of Mental Health, Emeritus

Methylation of Catechol Estrogens by Catechol-O-methyltransferase (COMT)

Dr. Cyrus Creveling, National Institute of Diabetes and Digestive and Kidney Diseases

COMT Genetic Polymorphism and Breast Cancer

Dr. Patricia Thompson, National Center for Toxicological Research,

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FDA

COMT, CYP17, SRD5A Polymorphisms in Breast and Prostate Cancer

Dr. Douglas Bell, National Institute of Environmental Health Sciences

Estrogen Receptor-Mediated Processes in Normal and Cancer Cells

Co-Chairs:

- Dr. George Stancel, University of Texas Medical School
- Dr. Robert Dickson, Lombardi Cancer Center Dissection of the ER Signaling Pathway: Insights into the Mechanism of Tamoxifen Resistance
- Dr. Donald McDonnell, Duke University Medical Center

Investigating the Role of ER-Alpha in Carcinogenesis Through the Use of Transgenic Mouse Models with Altered Levels of Receptor Expression

Dr. John Couse, National Institute of Environmental Health Sciences

Structure and Function of Estrogen Receptor-Beta

Dr. Jan-Ake Gustafsson, Karolinska Institute

Estrogen Receptor Structure, Modulators, and Targets in Hormone Responsive Tissues and Cancers

Dr. Geoffry Green, University of Chicago

Regulation of the Cell Cycle and Cell Death in Mammary Cancer

Dr. Robert Dickson

Estrogens and Cancer in Human Populations

Co-Chairs:

- Dr. Louise Brinton, Environmental Epidemiology Branch
- Division of Cancer Epidemiology and Genetics, NCI
- Dr. Shukmei Ho, Tufts University

Estrogen Levels and Breast Cancer Risk

Dr. Paolo Toniolo, New York University School of Medicine

Study Design Considerations in the Assessment of Cancer Risk in Relation to Genetic Polymorphisms

Dr. Montserrat Garcia-Closas, Environmental Epidemiology Branch, DCEG, NCI

Estrogens and Estrogen Metabolites: Technical Hurdles in Population Studies

Dr. Susan Hankinson, Brigham and Women's Hospital

DNA Biomarkers for Predicting Human Breast, Ovarian, and Prostate Cancer

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Springboard to Natural Progesterone

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Dr. Donald Malins, Pacific Northwest Research Foundation

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Osteoporosis

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Excerpts from a talk by John. R. Lee, M.D.

- [Osteoporosis risk begins at age 35, not at menopause](#)
- [Half of the women in North America are progesterone deficient](#)
- [Progesterone is the key to new bone formation](#)
- [Real-life examples of progesterone increasing bone density](#)
- [Cortisone and cortisone derivative drugs increase osteoporosis risk](#)
- [Antacids \(Pepcid AC, Tagamet, etc\) increase osteoporosis risk](#)

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Bone is living tissue and hormones have an effect on bone. Estrogen causes bone resorption while progesterone and testosterone cause new bone to be made. Bone is always being torn apart and put back together again, just like your skin, hair, the lining of your intestines, and all the other cells in your body — except brain and muscle cells. They are all being replaced, and bone replaces itself. The long bones in the legs and the arms take 12 to 14 years for a total 100% replacement. The bones in your back-bone, heel and the more open bones called trabecular bones, are completely replaced every two to three years. So every two to three years every single molecule, every single mineral, everything in your trabecular bones have all been changed to new bone. Bone replacement is a continual process.

The ultimate strength and density of the bone is determined by the balance between these two effects: 1) the undoing and 2) the redoing. If the undoing is happening more rapidly than the redoing, the end result is you will be losing bone. If the new bone formation catches up, you will stay even, and if the new bone formation can be pushed higher than the undoing, then you will have new bone again.

So what I stumbled on to is that progesterone causes new bone formation. Many books have a graph that shows bone mass as a function of time. A safe range for bone mass for your backbone is 0.9. If your measurement is above 0.9 you will probably not have a fracture if you fall accidentally on something soft. But if it is below 0.9 and you trip over a step or fall pretty hard, you will probably break a bone. Therefore 0.9 is a kind of safe threshold I use to compare bone densities.

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The process starts when a girl is about age ten. Her skeleton begins growing and showing

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more and more bone. Around age 35 she reaches her peak of bone mass. From age 35 on she starts losing one to one and a half percent of her bone mass per year, so she could lose 15% to 25% before menopause. At menopause it falls more rapidly, and then returns to approximately the same rate of loss as before. This sounds wrong because the popular consensus is that menopause precipitates **osteoporosis**. Menopause is not the cause. Actually, it is something that happens 10 to 15 years before menopause while women are still making a lot of estrogen, having periods and losing bone. Bone loss is called **osteoporosis**.

What happens at age 35 while there are still good estrogen levels which cause the bones to start losing bone mass? Along comes a beautiful report in the New England Journal of Medicine from a woman doctor in Vancouver who was head of the Department of Endocrinology. She followed hormone levels, first in women athletes, then in other women, and she found a high incidence of anovulatory cycles. Anovulatory cycle means that the ovaries didn't make the eggs that month, and if women don't make the eggs, they don't make the progesterone. She found that at age 35 about 50% of the women in North America start missing ovulation, even though their periods continue to be regular. The woman doesn't produce eggs each month, and therefore she is not making progesterone. She also found that while this was taking place, the testosterone, cortisone, and estrogen levels stayed the same. Everything stayed the same on the hormone levels except progesterone. When progesterone went down or disappeared, that's when **osteoporosis** started happening. The doctor proved that the decline of progesterone is at least a cause of **osteoporosis**, even in the face of plenty of estrogen.

This study proved that estrogen deficiency is not the cause of **osteoporosis**. Doctors have been wrong for many years, because they have been measuring the loss when estrogen fell at menopause, and concluded that the bones were declining because estrogen levels fell. Bone loss is not due to estrogen going down. Bone loss happens because you are not ovulating and not making progesterone every month. You are becoming deficient in progesterone. You are not keeping up with new bone formation. This appears to be new information, and yet charts showing bone decline starting at age 35 have been around for a long time.

Apoptosis means normal, programmed cell death. The only reason you can stay healthy and young is because cells die on time, so new cells coming along will have a place to work. The word means "a falling away." It's like the leaves of the trees in the fall in Vermont and Maine. The trees look bare during the winter, but in the spring new leaves come back. The one set of leaves did their work during the growing season, and the next set of leaves will do their work during the next growing season.

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Bone apoptosis happens when osteoclast cells come along and eat up old bone that's been there for years and need to be taken away. There are millions of these little osteoclast cells. When they get down to good bone, they stop and leave. As soon as the osteoclasts leave, then another type of cells called osteoblasts come in. Their purpose is to put in new bone. The new bone they put in is stronger than the bone that was there before. This is why your bone mineral density goes up. They can make better bone. Once the osteoclasts take away the old bone the osteoblasts go in and build new bone. (Sometimes these osteoblasts are called osteocytes.) Real, living osteoblasts get embedded in the bone they are making. They stay alive, but not forever. They die off all the time. When they die, the

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bone they've made begins to get more porous, weaker and more likely to break, and that's when the next cycle begins.

Osteoclasts and osteoblasts are partners in the bone building process. First, the osteoclasts take out the old bone that is weak, then the osteoblasts move in to fill and make new bone. Bone mineral density measurements represent an average of these two processes. It reminds me of our bank account. When it gets too low my wife says, "Put more money in." And I say, "It wouldn't get so low if we didn't take so much money out." There are two processes going on. So when the doctor looks at a bone mineral density report, what he sees is the average of the two processes, but he doesn't know which one is predominant. If your bone mineral density is falling, your doctor does not know whether you're losing more bone than you ought to, or whether you're not able to make enough new bone to catch up.

What I learned is that progesterone turns on the processes which lead to new bone formation. Estrogen slightly slows up the loss of old bone. That's why at menopause, when estrogen decreases, you have an increase of bone loss, called bone resorption. However, within three or four years the body adjusts to the new estrogen level, and the bone loss goes back to the bone resorption rate to what it was before menopause, and then progesterone works again. During those three to five years prior to the onset of menopause, progesterone might not be able to accumulate enough new bone to catch up with the loss that is occurring, but after a few years it will.

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Now you know how bones are made. You're always making new bone, and you're always getting rid of old bone. The timing between a period of quiescence and an increase, then another quiescence followed by new bone being made again is a re-markable biological process. The time required to renew all of the molecules, atoms, calcium, magnesium, phosphorus and everything else in your long bones, such as the compact bones of your arm and your femur, is about 12 to 15 years. Your backbone, called trabecular bone where there are more open spaces and which do not have as much torsion pressure; turns over more rapidly. About every five years you will have 100% new bone in your backbone, heel bones, and kneecaps. Isn't that amazing? You are making yourself new every few years! So what you need is something to help the osteoblasts. In men the helper is testosterone, and in women it is progesterone.

Some doctors said my patients got well because there was some kind of placebo effect or the force of my personality was such that people got better, and it had nothing to do with progesterone. I told them, "If it's a placebo effect, it's an exceptional placebo effect, because the tests prove that the bones actually got stronger." There is a little acceleration of bone loss on these charts at age 50 to 55, which is around the time of menopause, but then it straightens out on its own and continues the same decline as was happening before menopause. So the big loss at menopause is only a temporary time. Some women may need a little estrogen during this period, but after they get past menopause all they need is progesterone, and the bones come back. What I found after three years, is that untreated, a woman will lose 1.5% to 2% of her bone mass a year. You might get a little surge of estrogen, but then it remains level. When progesterone was added, the average woman gained 15% new bone in three years. Such a thing was never before been reported by anyone, so I wrote a paper about it, and it got published in an international journal. I received letters from all over the world, but not one letter from a doctor in the United

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States.

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When I retired from practice nine years ago I asked my nurse to pick out 100 records of women on **progesterone**. Out of the 100 I took only those who had at least three years of bone mineral density tests every six months. I was left with 62 patients. The average increase in bone density in these postmenopausal women over three years was 15.4% versus a normal expected loss during that period of time of 4.5%. That is almost a 20% average difference between what normally happens and what happens when women are using **progesterone**. Estrogen only slows down bone loss for the period of menopause, and after menopause it doesn't even do that. **Progesterone**, however, causes new bone growth even in postmenopausal women.

I then divided my patients up into two groups – those with a lot of bone loss and those with pretty good density. I found that the worse the bone was at the beginning, the more it responded to **progesterone**. The women with good bone at the beginning essentially stayed the same. Doctors generally say that you can't help women over 70, because they are 20 years post menopause, and the bones are inactive. The bones are only inactive because they don't have the hormone **progesterone** to telling them to get to work! In dividing the results with those over 70 and those under 70 among my patients, the gain was essentially identical in both groups. So the bones do get to work again, and age has nothing to do with it.

Examples from my practice of how progesterone increased bone density

This first chart was in 1982. The lady was 72 years old and had very poor bones. She had broken her forearm lifting her sick husband. She went to her doctor who told her that she had such poor bones that she had to take fluoride treatment. She told him that was a bad idea because she had taken Dr. Lee's class at College of Marin on Opti-mal Health, and he said fluoride was a bad thing for bones. So he told her to go see Dr. Lee. I put her on **progesterone** and she had a 24% improvement in bone density over the next 30 months. Her bone density went from .669 to .865. Given her height and weight this is a perfectly fine bone mineral density.

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On the next lady I measured all four bones in her back with Dr. Malcolm Powell's dual photon bone mineral density test. All four of these bones increased in density. The bone density actually increases in all the bones throughout the body. It wasn't just that the bones that were specifically low did any better than the others. **Progesterone** had a positive effect on all the bones.

The next woman was from Pennsylvania. Her husband was a Ph.D. in the medical sciences and her son was a doctor. She woke up one morning with terrible back pain when she was 74 years old. They found she had advanced **osteoporosis**. Remember that I said 0.9 was a good number for bone density? Well, her's was .446. She had lost well over 50% of all the minerals in her bones. She had been a health nut. She exercised. She ate right. She took all the right supplements. She was doing everything right and looked great, and her mind was as sharp as a tack. She didn't seem to be aging at all, and yet her bones had lost all this bone mass. She had gone through menopause at age 44, and here she was

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at age 74, 30 years later doing everything right, and she still lost so much bone that she had a spontaneous compression fracture of her lumbar spine.

So she got another doctor who was an orthopedist and a radiologist. She had five people in the medical profession on her case when she called me. I had met her at an EPA meeting years before, and she had heard that I was writing a paper about osteoporosis. This was before I wrote my first book about **progesterone**. I told her I would send her the papers, but the treatment was in her case just to add some progesterone, a normal physiological dose, because I knew she was doing everything else right. She was getting the calcium and the phosphorus, and she was eating right.

When she told her husband she was going to use **progesterone** cream, he said that he had talked to a doctor who was an expert on the subject and there is nothing in any of the books that say **progesterone** would build bone. So she called me and asked if this information was written in any books. She asked if I had any references and things like that. I told her, "No, if it was already written in books I wouldn't have bothered to write it up myself." I was writing the book because I was reporting things I saw in real patients, but couldn't find in any books.

The woman stuck with my thinking and told her husband she was going to try **progesterone** cream despite his objection. Finally her husband gave in saying, "Then in six months we're going to make you get another bone mineral density test." In six months she went from .446 up to .516. That's over 14% in six months! Another test was done ten months later and her bone density was still increasing.

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Every year they send me these reports. One year she actually went down a little bit, and on this report her husband had written in, "Her lower value at the 23rd month is possibly due to a nerve block given to her." So I called her doctor and asked what he was giving her. He said, "Well, I felt a little out of the loop, and I wanted to do something." So he gave her two or three injections of methylprednisolone, which is cortisone. Cortisone blocks **progesterone** from its receptors in bone cells. That's why all people on cortisone are at high risk for **osteoporosis**. It blocks **progesterone** from doing its work. Cortisone's message to the cells is, "Stop whatever you're doing." If you have poison oak, your doctor can give you cortisone, and it will stop the poison oak. If you have inflammation in your joints like rheumatoid arthritis, he can inject cortisone, and it will stop the inflammation. Cortisone stops the cell from doing what it's doing because of inflammation. In the case of bone cells, it stops them from making new bone. This was the reason the woman's bone density measurement went down in the 23rd month.

When I explained this to her husband, they stopped the injections and the bone density increased again. After four years she had gained 37.9% new bone. There is no other treatment anywhere that comes close to this. In her case it was the only thing she needed. Her doctor told her that she would have to take estrogen. She replied, "Oh no, my sister took estrogen, and she died of breast cancer." You have to be stubborn, and this lady was stubborn. Her husband told her it couldn't work. Her son told her it couldn't work. Her doctor told her it couldn't work. Her orthopedist told her it couldn't work. Her radiologist told her it couldn't work. Now, one by one I've gotten letters from all these doctors – her radiologist, her orthopedist, her doctor, and her husband – all basically saying, "If we hadn't seen it with our own eyes, we would never have believed what you wrote in your

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at Osteoporosis

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book." I still haven't heard from the son, but he is using proges-ter-one in his practice, so we got them all changed in their thinking. And this is how it is going to happen – one by one, people are going to see that **progesterone** works.

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In a couple of my patients **progesterone** was not working. One lady was taking too much thyroid hormone which accelerates bone loss, and when we got that straight-ened out her bone density improved. Another lady was 75. She didn't make hydrochlo-ric acid. If you don't make hydrochloric acid you can't absorb calcium. It took great brains to discover that. You have to be very, very clever. She came in and said, "I don't think I'm absorbing the calcium." So I asked her why she thought that and she said, "Well, I can see the little calcium pills in my bowel movements." So, clever as I was, I said, "I think you're not absorbing the calcium! The reason is that you don't have enough hydrochloric acid." She disagreed and told me that the Ross Valley Clinic was giving her a medicine to suppress her acid because she'd had indigestion for years so she probably had too much acid. They gave her Tums, but that didn't help. Then they gave her Tagamet. Tagamet stops the stomach from making acid, but that didn't help her indigestion. I told her that she had indigestion because she didn't have the acid necessary to digest her food so the undigested food goes into the intestine where the bacteria that live there digest it, ferment it, and make all these things that cause gas and indigestion. I suggested that she try some hydrochloric acid. She was afraid of getting an ulcer, but I persuaded her to try some betaine hydrochloride from the health food store. Not only did her indigestion go away, but her bones immediately began to get stronger as well.

The doctor was treating a symptom. It didn't work, and he wasn't even curious enough to figure out why it didn't work. Approximately 50% of people over 70 don't make enough acid to absorb calcium. A large number of older people take antacids on a regular basis. Maalox, Mylanta, and all of the H 2 blockers stop the stomach from making its normal acid. And now these H 2 blockers such as Pepsid AC and Tagamet, are being sold over the counter. They knock out 85% to 90% of the stomach's acid production. These people will not be able to absorb nutrients like calcium. Antacids increase the **osteoporosis** problem and may be related to eventual deep bone deficiency and pernicious anemia. Gastric cancer could also be related. Mother Nature makes these stomach acids for a reason. Antacids stop the absorption of calcium, no matter how it is given.

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Winston Churchill once said, "Every once in a while it happens that people stumble over the truth. But most of the time they pick themselves up and go on as if nothing happened." That's what I don't want to do. I don't want to go on as if nothing hap-pened. Something happened to me. I fell into this, and I saw all these good things that were happening.

- **Anovulatory cycle** means that the ovaries didn't make the eggs that month, and if women don't make eggs, they don't make **progesterone**.
- **Apoptosis** means normal, programmed cell death. The only reason you can stay healthy and young is because the cells die on time, so the new cells coming along will have a place to work. The word means "a falling away".
- **National Osteoporosis Foundation**: A bogus organization at best, funded by the manufacturers of Premarin and Tums. They are a group of retired professors who go around the country charging \$300, \$400, \$500 for people to come and hear their

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talk. They know that I say that a little progesterone is very important. So when they were asked about Dr. Lee, a member from the National Osteoporosis Foundation in Boston said, "Oh, we know Dr. Lee. He's Chinese, and he owns all the progesterone companies." I've got the right surname for being Chinese, but my grandparents all came from Norway and Sweden, and I don't own a share in any company that makes progesterone cream. I don't own anything in any company that makes a progesterone cream. So when they were in New York they were asked, "What about Dr. Lee's ideas about progesterone?" And they replied, "Oh, we know Dr. Lee. We offered him as many millions as he needed to do a double blind study, but he refused." I've been retired from private practice for nine years, so maybe I missed it in the mail, but I haven't seen it.

There are things in life that do not need a double blind, placebo-controlled study. We have a pasture on our farm, and we pasture horses for people. There is one horse that likes to kick at you when you walk behind her. You don't need a double blind study to avoid getting kicked. You avoid the horse, and that's all you need to do. If someone says all sheep are white, all you have to do is bring in a couple black sheep. You don't have to do a double blind study. It's the same thing with natural progesterone cream. If they say that after age 65 osteoporosis cannot be reversed, and you reverse it in 62 women using just progesterone, you don't need a double blind study! I'm not against someone doing a double blind study, but they know that no one will pay for it. Progesterone is a real hormone and since it's not a patentable synthetic, there is no money to be made so no one is going to ante up the \$500,000 to \$1,000,000 to do a study.

**For more complete information on breast cancer and progesterone,
please refer to the John R. Lee, M.D. Medical letter.**

To subscribe call: (800) 528-0559

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DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents 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 by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the 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 the Respondents 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 Respondents have 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 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 Lawrence A. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with his principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with

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others, he formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs.

2. Respondent Stephanie L. Jordan is an individual trading and doing business as Springboard and Pro Health Labs with her principal office or place of business at 3115 Stoney Oak Drive, Spring Valley, California 91978. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Springboard and Pro Health Labs.

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 purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - a. Lawrence A. Johnson, individually and trading and doing business as Springboard and Pro Health Labs; and
 - b. Stephanie L. Jordan, individually and trading and doing business as Springboard and Pro Health Labs.
2. “Competent and reliable scientific evidence” shall mean 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.

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3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to ProBalance and ProBalance Plus.
4. “Food,” shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. “Drug” shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. “Device” shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and

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which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

7. "Covered product or service" shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. "Commerce" shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.
9. "Endorsement" shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

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- A. That such product or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

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

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in 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;
- B. 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
- C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice 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 Respondents 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. Respondents 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.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to Springboard or Pro Health Labs or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; 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

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change 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. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on November 13, 2027, 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

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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 Respondent 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 (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from Lawrence Jordan and Stephanie Jordan, individuals trading and doing business as Springboard and Pro Health Labs (together, “respondents”).

The proposed consent order has been placed on the public record for thirty (30) days for reception 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 the advertising and promotion of ProBalance and ProBalance Plus, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that ProBalance and ProBalance Plus: (1) are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) do not increase the user’s risk of developing breast cancer and/or are effective in preventing or reducing the user’s risk of developing breast cancer. The complaint alleges that respondents failed to have substantiation for these claims. The complaint also alleges that respondents misrepresented that clinical testing proved that ProBalance and ProBalance Plus are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer and breast cancer. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Analysis to Aid Public Comment

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. Part IX provides that the order will terminate after twenty (20) years under certain circumstances.

Analysis to Aid Public Comment

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 agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**THE GREEN WILLOW TREE, LLC,
AND
ROBERT BURNS**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4207; File No. 072 3144

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses the deceptive advertising and promotion of Progesta Care Plus, EST, and Restored Balance transdermal creams in violation of the FTC Act. According to their labels, the creams contained, among other ingredients, natural progesterone. The complaint alleged that the respondent had no substantiation for its claims that the creams were effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The consent order requires that respondents have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health related service or program is effective in preventing, treating, or curing any disease. The order also bars respondents from engaging in similar acts and practices in the future and prohibits the respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the *Commission*: Gregory A. Ashe, Laura DeMartino, Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the *Respondents*: Not represented by counsel.

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that The Green Willow Tree, LLC, a limited liability company, and Robert Burns, individually and as a manager and member of The Green Willow Tree, LLC (“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 The Green Willow Tree, LLC is a North Carolina limited liability company with its principal office or place of business at 34 Rocky Ridge Road, Asheville, North Carolina 28806.

2. Respondent Robert Burns is a manager and member of The Green Willow Tree, LLC. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of The Green Willow Tree, LLC, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of The Green Willow Tree, LLC.

3. 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.

4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell

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overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Progesta Care Plus, EST, and Restored Balance. Respondents advertise and offer the products for sale through the Internet site www.greenwillowtree.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Progesta Care Plus, EST, and Restored Balance are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Progesta Care Plus is a drug labeled as containing Natural Progesterone USP and other ingredients. A four ounce tube costs \$35 plus shipping and handling. EST is a drug labeled as containing 960 mg of USP natural progesterone extracted from wild yam and soybean per two ounce tube and other ingredients. A two ounce tube costs \$24.95 plus shipping and handling. Restored Balance is a drug labeled as containing Natural Progesterone USP (15-20 mg per 1/8 teaspoon dose) and other ingredients. A two ounce tube costs \$24 plus shipping and handling. Progesta Care Plus, EST, and Restored Balance are applied transdermally.

8. To induce consumers to purchase Progesta Care Plus, EST, and Restored Balance, respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondents' website:

A. A BRIEF LOOK AT THE MAJOR HORMONES

* * *

Complaint

Because progesterone is the hormone responsible for building bone, we may also start to lose bone during this period [perimenopause]. And whether or not we decide to use estrogen during or after menopause, we should continue to use progesterone indefinitely to protect our bones. This hormone is generally best absorbed through the skin in the form of a cream or liquid.

* * *

Benefits of progesterone

* * *

Prevents endometrial cancer
Helps prevent breast cancer
Stimulates bone building

* * *

Synthetic progestones, like Provera, have many side effects and can be dangerous as well. Natural progesterone is a “human-identical hormone in that it is an exact copy of the molecule produced by the ovaries.
(Exhibit A at 4-5.)

- B. We believe that natural progesterone is the safest and most beneficial form of supplemental progesterone.

U.S.P. bio-identical progesterone is very different from synthetic progestin. Bio-identical progesterone has the same molecular structure as the progesterone produced in the human body and the body recognizes it. Topical creams have been shown to be the most effective mode of administration. When bio-identical progesterone is applied topically, it is absorbed transdermally (through the skin)

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immediately into the bloodstream and then distributed and utilized in progesterone target tissues. Transdermally absorbed progesterone works within the body in essentially the same manner as the progesterone that is endogenously secreted (produced within the body) to enter the blood stream directly.

(Exhibit A at 8.)

C. THE BENEFITS OF NATURAL PROGESTERONE

* * *

An essential key, according to an increasing number of researchers and medical professionals, is the neglected substance known as natural progesterone. Their studies indicate that this hormone is beneficial for a wide range of symptoms related to PMS and menopause, and that progesterone may be the key factor in understanding, preventing, and even reversing osteoporosis.

First, let's clarify the difference between natural and synthetic progesterone--a distinction that even many doctors do not make. Natural progesterone is considered extremely safe. Dr. Joel T. Hargrove, director of the PMS and Menopause Clinics at Vanderbilt University in Nashville, says, "I have been prescribing (natural) progesterone for 12 years and I haven't seen any long-term side effects. It doesn't affect cholesterol levels; it doesn't affect Mother Nature--basically, it is a wonderful thing." In England, Dr. Katharina Dalton has been using natural progesterone for over 30 years and has seen no increases in cancer.

Synthetic progestones, such as Provera, are called progestins or progestogens, and are known to have a wide range of side effects. David Steinman, author of *Diet for a Poisoned Planet*, writes that "In addition to unpleasant

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side effects such as fluid retention and salt build-up, synthetic progesterone is known to cause some serious illnesses--blood clots and uterine and breast cancers.” The list of side effects, risks, and warning for Provera is a full page long. Synthetic progesterone causes side effects, says John R. Lee, MD (now deceased) of Sebastopol CA, because “it’s not progesterone. The pharmaceutical companies alter the molecular structure so it no longer fits into the bio-chemical machinery of the body.”

* * *

Effects of excess or unbalanced estrogen	Progesterone effects
* * *	* * *
causes endometrial cancer	prevents endometrial cancer
increased risk of breast cancer	helps prevent breast cancer
slightly restrains osteoclast function	stimulates osteoblast bone building

One of the most important actions of progesterone is that it has major implications for bone health, however, the use of natural progesterone for the prevention of osteoporosis in post-menopausal women is very controversial. In the International Clinical Nutrition Review, Dr. Lee reported on his treatment of 100 post menopausal women with natural progesterone. Many of the women had lost height or suffered one or more fractures; both indications of osteoporosis. Bone density tests were used to monitor the effects of the therapy. Although some women were treated with estrogen as well, Dr. Lee concluded that “the bone building benefits of the progesterone therapy were independent of the presence or absence of supplemental estrogen.” This is not surprising when we realize that the function of estrogen pertains to the osteoclast cells which

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dissolve old or imperfect bone, while progesterone mediates the osteoblast cells which build bone. Osteoporosis occurs when osteoclast activity exceeds osteoblast activity. Thus, estrogen can slow the loss of bone, but progesterone can help to build it. Dr. Lee insured adequate mineral intake for his patients; however, nutritional support cannot account for the impressive results he achieved. “It was common to see a 10% increase (in bone density) in the first 6 to 12 months and an annual increase of 3 to 5% until stabilizing at the levels of healthy 35-year olds,” Lee says. “Neither age nor time from menopause was an apparent factor. The faster increases occurred in those with the lowest initial bone densities. . . The occurrence of osteoporotic fractures dropped to zero.”

Dr. Lee describes the case of a 72 year old woman who was especially conscientious in following his therapeutic program. She suffered from back pains and kyphosis and had lost height; x-rays revealed an advanced case of osteoporosis. Dual-photon densitometry tests over a period of 22 years on Dr. Lee’s program revealed an average increase of over 29% in the bone density of the lumbar vertebrae. “The vertebrae of lowest mineral density increased over 39% in mineral density,” states Dr. Lee. His conclusion offered hope to countless menopausal women: “Osteoporosis would appear to be reversible.”

(Exhibit A at 12-14.)

- D. Natural progesterone is technically called “Progesterone USP” or sometimes “USP progesterone”. Because it is not cancer causing and because it is such a beneficial hormones, progesterone USP has been considered so safe that a “more is better” attitude has been adopted.

(Exhibit A at 18.)

- E. Since 1995, I have been writing about the positive benefits of natural estrogen and progesterone, as opposed to the

Complaint

dangers of synthetic hormones. . It is my firm belief that women do not have to choose between heart attacks or cancer on the one hand; and hot flashes, mood swings, premature aging, and other symptoms of low hormone levels on the other. Natural alternatives exist, and they go far beyond the commonly used remedies of using more soy products and herbs. These alternatives are just as effective as the synthetics. While nothing in this life is 100% safe, according to all the research and experience at my disposal, they are virtually free of both dangerous complications and uncomfortable side effects.

(Exhibit A at 22.)

- F. Osteoporosis is one of the most serious health concerns for mid-life and mature women, and can affect men as well. The use of natural hormones, such as progesterone, is essential for bone health.

(Exhibit A at 27.)

- G. However, all foremost authorities on this subject agree that progesterone is by far the more important hormone for osteoporosis. Progesterone helps to build new bone. It's [sic] like having a bank balance. Estrogen helps you to spend less, but progesterone puts new cash into your account. Therefore, using progesterone is essential for your bone health. Progesterone levels begin to fall 5-15 years before menopause. This corresponds with the fact that bone loss usually starts when women are in their forties, when estrogen levels are generally still high. Progesterone declines even further after menopause. If you want to keep your bones healthy, use some type of progesterone!

* * *

Complaint

Dr. John Lee's [sic] impressive study involved 100 post-menopausal women, many of whom showed osteoporosis symptoms. The women used a 3% natural progesterone cream for at least three years. Of the 63 women who had bone density tests, instead of the predicted bone loss that would be expected in this group, every single one had an increase in bone mass. Some women showed an increase of 10% after the first 6 to 12 months of therapy, and others showed a 20-25% increase in the first year. Dr. Lee found that the effects of the therapy were independent of whether the women were receiving estrogen. While Dr. Lee's [sic] results have not been replicated in the US, I have heard that progesterone is the standard treatment for osteoporosis in Europe.

(Exhibit A at 32-34.)

- H. This elegant white cream contains natural progesterone and natural phyto-estrogens, and provides an ideal hormone balance for menopausal and post-menopausal women. A rare find, EST is based on a phyto-estrogen equivalent of bi-estrogen with natural progesterone. It is formulated for quick absorption into the skin with superior bioavailability. This completely natural product can provide relief from menopausal and peri-menopausal symptoms including, hot flashes, night sweats, mood swings, vaginal dryness, and sleep disturbances. May also help improve new bone formation.

(Exhibit A at 37.)

9. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that:

A. Progesta Care Plus, EST, and Restored Balance are effective in preventing, treating, or curing osteoporosis;

Complaint

B. Progesta Care Plus, EST, and Restored Balance are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. Progesta Care Plus, EST, and Restored Balance do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 7 and 8, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. The acts and practices 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.


THEREFORE, the Federal Trade Commission, on this thirteenth day of November, 2007, has issued this complaint against respondents.

By the Commission.

Complaint

Exhibit A

AND OTHER HEALTH AND WELLNESS - AND OTHER HEALTH AND WELLNESS SUPPLEMENT FOR A HEALTHY LIFESTYLE



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We offer a wide array of natural supplements to assist you with thyroid health, PMS, menopause, andropause, and other changes in life. We offer phyto-estrogens, natural progesterone, thyroid support, Human Growth Hormone, testosterone precursors, homeopathics, and products for enhancing libido and sexual performance in both men and women.

As well as natural hormones, we also carry the finest supplements for enhancing bone and heart health, skin care, digestive health, detoxification, and more. Everything in our catalog has been selected to be as safe and effective as possible. None of our products have been tested on animals.

At The Green Willow Tree, we value our reputation for giving you personal attention. Your email inquiries and orders will receive a prompt response.

We have been researching natural hormones and related health products for over ten years, and continue to upgrade our product line at every opportunity. For those who enjoy reading more in-depth information, please consult the Articles section on this site. You may wish to begin by reading the selection called The Major Hormones, and/or consult our Product Selection Guide.

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THE GREEN WILLOW TREE, INC. (GWT) - THE GREEN WILLOW TREE, INC. - TRADEMARK SUPPLEMENTS FOR THERAPEUTIC PURPOSES Page 2 of 2

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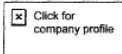
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LEARNING ACTIVITIES PROVIDED - LEARNERS - A BRIEF LOOK AT MAJOR MOVEMENTS

Page 1 of 1



For more information, email **The Green Willow Tree**.

by Elora Gabriel

ESTROGEN is the hormone that makes us women and that makes us feel like women. When estrogen levels begin to drop, usually in our late 40's, we may notice one or more of the symptoms in the table below. Or, we may simply experience a loss of well-being.

Hot flashes	Depression, moodiness	Joint/muscle pain	Vaginal atrophy
Night sweats	Anger/rage	Heart palpitations	Vaginal dryness
Fatigue	Memory loss	Dizziness	Bladder infections

Stabilizes moods	Improves memory and energy	Restores vaginal lubrication
Relieves hot flashes	Alleviates sleep disturbances	Improves vitality and energy
	Prevents vaginal/bladder	Improves skin & breast

Complaint

Slows bone loss	Infections	tone
-----------------	------------	------

But what about the dangers and side effects of estrogen? First of all, there are different types of estrogen. Some are much, much safer than others and have virtually no side effects. There are three major types of estrogen in our bodies: estradiol, estrone, and estriol. Estradiol and estrone are the highly potent estrogens that may stimulate cancer. Estriol is considered very safe, and clinical evidence indicates that it even protects against breast cancer. All standard estrogen prescriptions are either estradiol or estrone. Premarin, for example, is estrone, and is made of horse estrogens that are not natural for our bodies. For most women, the ideal balance of estrogens is 80% estriol, 10% estrone, and 10% estradiol. This blend, called tri-estrogen, has been found to rapidly alleviate the symptoms of menopause without increasing the danger of breast cancer. Tri-estrogen is the blend of estrogens naturally found in a healthy young woman's body. Please see **The Good News About Natural Estrogen**, for a complete discussion of the different types of estrogen.

Phyto-estrogens are estrogenic compounds found in plants. Research shows that phyto-estrogens can balance either high or low estrogen levels, and may reduce the risk of breast cancer. Phytoestrogens differ remarkably from synthetic estrogens in that they are easily broken down, are not stored in the tissues and spend very little time in the body, thus they are unlikely to cause cancer. And because humans have spent millions of years eating plants and herbs, our bodies easily accept plant estrogens and find them both effective and beneficial. We carry a product called Pro-Estron which is a phyto-estrogen blend based on the tri-estrogen ratio.

Please click [here](#) to view our estrogen products.

PROGESTERONE is a bit more subtle than estrogen, but just as important. It has its own unique benefits, and it balances estrogen. Progesterone might be likened to a healthful meal of protein and vegetables, while estrogen is like a great dessert. It is fine to use only progesterone. But, just as we wouldn't want to eat dessert without the main course, we should never use estrogen without the balancing effect of progesterone. This rule holds true even for women who have had a hysterectomy.

In fact, we should think about progesterone first when we want to balance our hormones. PMS, which is often caused by a lack of progesterone, can occur at any age prior to menopause. As we enter peri-menopause, usually during our 40's, falling progesterone levels can cause increased PMS and menstrual problems, growth of fibroids, insomnia, mood swings, etc. Because progesterone is the hormone responsible for building bone, we may also start to lose bone during this period. And whether or not we decide to use estrogen during or after menopause, we should continue to use progesterone indefinitely to protect our bones. This hormone is generally best absorbed through the skin in the form of a cream or liquid. For more complete information on progesterone, please see **The Benefits of Natural Progesterone**.

Complaint

Benefits of progesterone

Natural diuretic	Helps thyroid hormone action	Prevents endometrial cancer
Natural antidepressant	Normalizes blood sugar levels	Helps prevent breast cancer
Normalizes blood clotting	Protects against fibrocysts	Stimulates bone building

As with estrogen, progesterone comes in different types. Synthetic progesterones, like Provera, have many side effects and can be dangerous as well. Natural progesterone is a "human-identical hormone" in that it is an exact copy of the molecule produced by the ovaries. Wild yam extract is an herbal product with many progesterone effects and benefits. Wild yam might be described as a phyto-progesterone (a plant-derived progesterone like substance.)

Please click [here](#) to view our progesterone products.

DHEA is the most abundant hormone in the human body, and is produced by the adrenal glands. Levels drop with age, for both men and women, falling to a fraction of their peak value in the 20's. Most people over the age of 50 are deficient in DHEA and would benefit from supplementation. DHEA can be converted in the body into other sex hormones. Thus it may decrease hot flashes (estrogen) and increase libido (testosterone). DHEA cream is very effective for both of these purposes, and also helps to increase bone density (see **Hormonal and Lifestyle Factors for Bone Health**.) Perhaps the best thing about DHEA is that it just makes you feel better! Supplementation tends to increase energy, well-being, and sleep quality. Many people report reduced joint and muscle pain. Research indicates that DHEA has positive implications for breast cancer, heart disease, diabetes, MS, memory loss, CFS, Alzheimer's, and Parkinson's disease. 5-15 mg./day is the ideal dose for most women, while men can use 25 mg./day. These dosages are considered very safe by hormonal experts and should have no side effects. It is important to buy pure, good quality DHEA, as most DHEA on the market is of inferior quality and may be contaminated with various impurities. For more information on DHEA, please email **The Green Willow Tree**.

TESTOSTERONE is the major sex hormone for men, and is needed by women in smaller quantities. It is responsible for firm muscles and a healthy libido in both sexes, and has other important roles to play in the body as well. Please see **Testosterone, Hormone of Energy and Desire**, for more information. For women, levels of this hormone usually drop before or during menopause. Men also pass through "andropause" which is caused by a lessening of testosterone production, resulting in lowered virility and decreased muscle mass. Many men would benefit by supplementation with natural testosterone. While synthetic methyl testosterone (found in Estratest, for example) can cause liver toxicity and other side effects, natural testosterone is considered very safe.

Complaint

Numerous studies have shown, for example, that it actually has a positive effect upon cardiovascular health. Natural testosterone also protects against breast cancer, according to Dr. William Douglas, editor of Second Opinion health newsletter. Benefits of testosterone may be obtained either by using a prescription form of natural testosterone, or through one of the other hormones which convert into testosterone--DHEA and Androstenedione. For women specifically interested in increasing sex drive, please see **How to Have a Healthy Libido in Mid-Life and Beyond**. Please click [here](#) to view our testosterone enhancing products.

THYROID HORMONE is essential to proper metabolism and for the functioning of almost every organ and system in the body. Low thyroid symptoms include cold hands/feet, sluggish metabolism, low basal temperature, weight gain, slow pulse, depression, dry skin, dry/brittle/thinning hair, fatigue, feeling groggy in the morning but more alert at night, constipation, yellowish coloration on skin (particularly on the palms), slow speech, PMS and/or painful menstrual cramps, recurrent respiratory infections, fluid retention and puffiness in face, ankles, etc. Many doctors and practitioners believe that we are currently experiencing an epidemic in low thyroid function, particularly among women. A large majority of hypothyroid patients are not able to get help with their condition, due to the fact that doctors usually rely solely on the TSH for diagnosing thyroid problems. It is my belief that the TSH test is not always accurate, and that symptoms are an important guide. Please see **The Thyroid Connection** for more information. This article offers resources for getting help, either by prescription or using effective non-prescription alternatives. Please click [here](#) to view our thyroid products.

HUMAN GROWTH HORMONE. Holistic doctors have been excited about human growth hormone for years, but at \$1000/month, the injections have been available only to the rich. Normally produced in the pituitary, HGH is clinically proven to reverse many aspects of the aging process. Extensive studies with HGH have shown the following:

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Enhanced sexual performance	Greater cardiac output	Hair regrowth
Superior immune function	Improved cholesterol profile	Younger thicker skin
Return of natural hair color	Lowered blood pressure	Improved sleep
Elimination of cellulite	Regeneration of major organs	Better memory

Recently, effective and less expensive forms of HGH have become available. We now have secretagogues, or products which cause the pituitary to produce growth hormone. Even better, actual growth hormone is now available over the counter at very reasonable prices. Please see **Human Growth Hormone, Clinically Proven Rejuvenation**, for more information. Please click [here](#) to view our HGH

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"The overall deterioration of the body that comes with growing old is not inevitable. We now realize that some aspects of it can be reversed." -- Daniel Rudman, MD.

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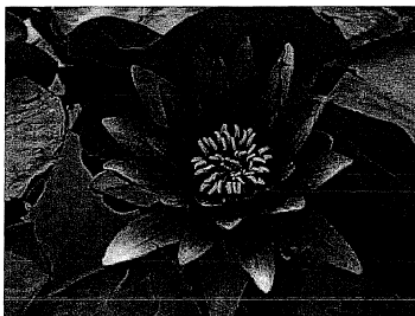
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Progesterone

In our opinion, progesterone is essential for any woman using estrogen.

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U.S.P. bio-identical progesterone is very different from synthetic progestin. Bio-identical progesterone has the same molecular structure as the progesterone produced in the human body and the body recognizes it. Topical creams have been shown to be the most effective mode of administration. When bio-identical progesterone is applied topically, it is absorbed transdermally (through the skin) immediately into the bloodstream and then distributed and utilized in progesterone target tissues (1). Transdermally absorbed progesterone works within the body in essentially the same manner as the progesterone that is endogenously secreted (produced within the body) to enter the blood stream directly.

1. Pearson GC, McCullough WL, Taylor PA et al. Topical natural progesterone cream effect on postmenopausal bone loss: a two-year double-blind, randomized, placebo-controlled trial. From IOF

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THE GREEN WILLOW TREE PROGESTERONE - THE GREEN WILLOW TREE - Natural Supplements for Natural Health Page 2 of 4

World Congress on Osteoporosis Osteoporosis International
2004; 15(suppl 1):abstract OC.

For one opinion on [natural progesterone](#), please click here. For a discussion the problem of [excess progesterone](#), please click here.

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Please click on the above link to learn about accurate home test kits for your hormone levels.

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**11. Restored Balance**

This high quality cream is on Dr. John Lee's approved list of progesterone creams. It is more concentrated than most natural progesterone creams, and comes with an easy to use dispenser. The result is that your tube will last longer. Restored Balance is also pure and chemical free, containing no chemical preservatives or stabilizers. Herbal extracts and Vitamins A and E added for enhanced benefits.* Unconditional money back guarantee if you are not satisfied. (2 oz. pump tube, about an 8 week supply.) [For more information please click on picture]

OUR PRICE: \$24.00 [\[Add to Cart\]](#)

1a. Progestacare Plus

[REPLACES FEMININE BALANCE PLUS] ProgestaCare Plus is a convenient way to supplement your estrogen and progesterone levels with one easy application. This pure, chemical-free cream combines bio-identical natural progesterone with the highest quality all natural phytoestrogens. A medium strength product, it should be adequate to support healthy hormonal balance for

Complaint



most menopausal or post-menopausal women. The convenient, reasonably priced pump tube dispenses an average dose with one press and contains four ounces of cream (twice that of similar products). Lasts about two months.* **[For more information please click on picture]**

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**38. Vitex**

Vitex is known as the supreme hormonal tonic for women. Traditionally known to be helpful for a wide range of symptoms associated with PMS, menopause, and the entire menstrual cycle. Also indispensable for women with uterine fibroids, fibrocystic breasts, or endometriosis; and **especially good for women experiencing hormonal upsets after coming off the birth control pill.*** (2 oz. bottle. Should last 3-4 weeks.) **[For more information please click on picture]**

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THE BENEFITS OF NATURAL PROGESTERONE
by Elora Gabriel

Women's lives are deeply affected by the ebb and flow of our hormones. Like dwellers on the seashore, our lives are patterned by the cycles of nature, whether it is the monthly rhythm of our menstrual cycle, or the greater divides of puberty and menopause. Our female hormones make possible our greatest gifts--for only we can bring forth life. But hormonal lack or imbalance can also be our most consistent enemy, causing the all-too-common miseries of PMS and menopause. Many women are still unaware of the fact that there is help for these problems without resorting to artificial hormones. An essential key, according to an increasing number of researchers and medical professionals, is the neglected substance known as natural progesterone. Their studies indicate that this hormone is beneficial for a wide range of symptoms related to PMS and menopause, and that progesterone may be the key factor in understanding, preventing, and even reversing osteoporosis.

First, let's clarify the difference between natural and synthetic progesterone--a distinction that even many doctors do not make. Natural progesterone is considered extremely safe. Dr. Joel T. Hargrove, director of the PMS and Menopause Clinics at Vanderbilt University in Nashville, says, "I have been prescribing (natural) progesterone for 12 years and I haven't seen any long-term side effects. It doesn't affect cholesterol levels; it doesn't affect Mother Nature--basically, it is a wonderful thing." In England, Dr. Katharina Dalton has been using natural progesterone for over 30 years and has seen no increases in cancer.

Synthetic progestones, such as Provera, are called progestins or progestogens, and are known to have a wide range of side effects. David Steinman, author of *Diet for a Poisoned Planet*, writes that "In addition to unpleasant side effects such as fluid retention and salt build-

Complaint

up, synthetic progesterone is known to cause some serious illnesses-- blood clots and uterine and breast cancers." The list of side effects, risks, and warning for Provera is a full page long. Synthetic progesterone causes side effects, says John R. Lee, MD (now deceased) of Sebastopol CA, because "it's not progesterone. The pharmaceutical companies alter the molecular structure so it no longer fits into the biochemical machinery of the body." As one woman said to me, "Since I've been using Provera, I scream at my kids, my husband can't stand me, and I've gained 20 pounds. Other than that, I've had no side effects!"

As the mass of baby boomers enters mid-life, increasing attention has been focused upon hormone replacement therapy. So far, the emphasis has largely been upon estrogen. While many women do need and benefit greatly from estrogen, several important points are often missed here. One is that--even for women who have had a hysterectomy--estrogen should always be used with some form of natural progesterone. Progesterone is the one hormone which has the ability to counterbalance the potentially harmful effects of unopposed estrogen. A second consideration for those who need estrogen is the fact that the female body actually produces three major kinds of estrogen--estradiol, estrone, and estriol. Of the three, estriol is by far the safest--in fact, evidence exists to show that it actually protects against breast cancer. For more information on estrogen, please see my article **The Good News About Natural Estrogen**.

What about progesterone? Is this less glamorous hormone a substance that we use only because we need it to balance estrogen? Not necessarily. Progesterone has its own unique spectrum of benefits, and is safer than estrogen. Many researchers now believe that, for many hormonal problems, natural progesterone is the place to start. While the power of estrogen is undeniable, its danger lies in its ability to promote growth, including cancerous growth, in body cells. Progesterone is more of an intermediate building block. At need, the body converts a certain amount of it into estrogen or other hormones. Therefore, using progesterone can help to balance the endocrine system and alleviate other hormonal deficiencies. Dr. Lee, who has done extensive research on the effects of estrogen and progesterone upon menopause, has summarized the effects of these two hormones in his paper "Slowing the Aging Process With Natural Progesterone". Please note that the negative effects of estrogen occur when it is in excess or not adequately balanced with progesterone. In proper balance, estrogen is highly beneficial.

Effects of excess or unbalanced estrogen	Progesterone effects
breast stimulation	protects against fibrocysts
salt and fluid retention	natural diuretic
increased fat in body	helps use fat for energy
decreases libido	restores libido
impairs blood sugar control	normalizes blood sugar levels
increased blood clotting	normalizes blood clotting
reduced oxygen levels in all cells	restores proper cell oxygen levels
causes endometrial cancer	prevents endometrial cancer

FEDERAL TRADE COMMISSION DECISIONS
VOLUME 144

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AMERICAN ANTI-DOPING AGENCIES - ALLEGATIONS - THE EFFECTS OF SYNTHETIC PROGESTERONE

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increased risk of breast cancer	helps prevent breast cancer
slightly restrains osteoclast function	stimulates osteoblast bone building

One of the most important actions of progesterone is that it has major implications for bone health, however, the use of natural progesterone for the prevention of osteoporosis in post-menopausal women is very controversial. In the International Clinical Nutrition Review, Dr. Lee reported on his treatment of 100 post menopausal women with natural progesterone. Many of the women had lost height or suffered one or more fractures; both indications of osteoporosis. Bone density tests were used to monitor the effects of the therapy. Although some women were treated with estrogen as well, Dr. Lee concluded that "the bone building benefits of the progesterone therapy were independent of the presence or absence of supplemental estrogen." This is not surprising when we realize that the function of estrogen pertains to the osteoclast cells which dissolve old or imperfect bone, while progesterone mediates the osteoblast cells which build bone. Osteoporosis occurs when osteoclast activity exceeds osteoblast activity. Thus, estrogen can slow the loss of bone, but progesterone can help to build it. Dr. Lee insured adequate mineral intake for his patients; however, nutritional support cannot account for the impressive results he achieved. "It was common to see a 10% increase (in bone density) in the first 6 to 12 months and an annual increase of 3 to 5% until stabilizing at the levels of healthy 35-year olds," Lee says. "Neither age nor time from menopause was an apparent factor. The faster increases occurred in those with the lowest initial bone densities. . . The occurrence of osteoporotic fractures dropped to zero."

Dr. Lee describes the case of a 72 year old woman who was especially conscientious in following his therapeutic program. She suffered from back pains and kyphosis and had lost height; x-rays revealed an advanced case of osteoporosis. Dual-photon densitometry tests over a period of 2 1/2 years on Dr. Lee's program revealed an average increase of over 29% in the bone density of the lumbar vertebrae. "The vertebrae of lowest mineral density increased over 39% in mineral density," states Dr. Lee. His conclusion offered hope to countless menopausal women: "Osteoporosis would appear to be reversible."

[Ed. Subsequently, clinical studies have shown that natural progesterone given transdermally enters the blood stream as progesterone, but does not show improvement in bone health at the levels that were studied. A study by Pearson GC, McCullough WL, Taylor PA et al. Topical natural progesterone cream effect on postmenopausal bone loss: a two-year double-blind, randomized, placebo-controlled trial. [From IOF World Congress on Osteoporosis Osteoporosis International 2004; 15(suppl 1):abstract OC.] reported:
The study involved 45 postmenopausal women, aged 49-70. For the first year, one group used a topical progesterone cream (1.5% USP) containing 40 mg progesterone twice daily, while the other group used placebo. Both groups showed a decrease in mean lumbar spine BMD (bone mass density) at 12 months, and there was no significant difference between the two.
During the second year, the trial became an open-label study. The first group doubled the dose and applied 80 mg progesterone twice daily, whereas the placebo group started using the cream, at 40 mg

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progesterone twice daily, and also took a vitamin and mineral supplement. Both groups again showed a decrease in BMD at 24 months.

Even though the progesterone cream was well absorbed, it did not prevent bone loss or increase bone mass in postmenopausal women, Pearson and colleagues concluded. She suggested that perhaps a different dose or formulation or delivery system would be effective, noting that animal studies have shown that progesterone stimulates bone formation.]

Less dangerous than osteoporosis, yet of monthly concern to millions of women, is the problem of PMS. The cause of this condition has long been a mystery, but it is now believed that a high proportion of PMS sufferers have too much estrogen in their bodies in relation to progesterone. Neils Lauenstein, M.D., co-author of *PMS: Pre-menstrual Syndrome and You* and professor of obstetrics and gynecology at New York Medical College, claims that more than 90% of patients in his practice who have tried natural progesterone have found relief. "When nothing else works, it is the treatment of choice--in my practice, hundreds of women who were severely handicapped by PMS have been completely symptom-free with (natural) progesterone," says Dr. Lauenstein. He adds that synthetic progestogens actually worsen the symptoms of PMS. Because these drugs inhibit a the concentration of natural progesterone in the blood, they exacerbate the imbalance of female hormones, thereby increasing pre-menstrual distress. David Steinman discusses the case of a 40-year old woman whose doctor prescribed Provera for her unpredictable menstrual cycle, which included irritability and wild mood swings. Provera caused nervousness and heart palpitations. When the patient switched to natural progesterone, her cycle became regular and PMS symptoms completely disappeared. Many women have also found that progesterone both relieves and prevents menstrual cramps, from mild to severe.

A great many women are now experiencing what is called the pre-menopausal or peri-menopausal period. This is a period of five to eight years preceding actual menopause when female hormones begin to fluctuate. Symptoms of PMS may worsen, or seem to last all month long. Some women suffer from insomnia and depression; others experience fluid retention, painful breasts and/or the rapid growth of uterine fibroids. These symptoms are often caused by what is termed "unopposed estrogen". During these years, estrogen production may continue unabated, while progesterone production begins to taper off. Thus, supplementing with natural progesterone can alleviate the imbalance and resulting symptoms. It's interesting to note that, even if both estrogen and progesterone are low, estrogen will dominate. Thus, it is crucially important to keep progesterone levels up. Dr. Lee writes, "Supplementation with natural progesterone during the peri-menopausal stage when estrogen dominance often prevails will prevent uterine fibroids. If a woman can prevent or reverse osteoporosis without estrogen (such as with progesterone) she need not risk estrogen-induced fibroids. This is not good news to surgeons."

The story doesn't end here. Researchers like Dr. Raymond F. Peat continue to find other benefits of this remarkable hormone. Peat states that progesterone protects against blood clotting caused by excess estrogen. He also says that progesterone "prevents stress-induced coronary blood vessel spasms in aged hearts", which is probably one

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LEAHN RELATED ARTICLES - MOVIES - THE DEBTS OF NATURAL PROGESTERONE

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reason that women have few heart attacks as long as their ovaries are functioning. Dr. Peat continues: "Other studies suggest that progesterone has a role in regeneration of damaged brain cells and prolonged growth of the brain. Delayed aging and longer life span have been very clearly related to extra progesterone. Many types of tumors have been prevented and helped with progesterone." Dr. Peat considers both progesterone and thyroid to be primary regulatory hormones which regulate metabolism directly and have a normalizing effect on the pituitary, the body's master gland. Progesterone can also protect against hypoglycemia as it increases the oxygenation and metabolic efficiency of the cells. And impressive studies have shown that supplemental natural progesterone during pregnancy produces children with higher IQ's (by about 35 points) and better adjusted personalities.

How should we obtain natural progesterone? Dr. Lee used an over-the-counter 3% topical cream in his study. And in fact, the moderate-strength creams (such as those containing 800-900 mg. of progesterone per 2 oz. jar) seem to produce the best results. Natural progesterone is also available in tablet form (oral micronized progesterone). However, according to Dr. Lee, the creams are far superior for supporting bone health. Saliva hormone assays should be used periodically to check progesterone levels. Some laboratories are not helpful in helping a woman determine whether she is actually using too much progesterone, or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams." Other testing facilities, such as North Bay Diagnostics, however, have collected enough data from women using both oral and transdermal hormones, so they can accurately determine whether a woman has developed as excess of progesterone. These will be found in our **Hormone Tests** section. Periodic testing is important, at least until your usage pattern is stabilized, since continuous use of progesterone creams can cause a build-up of excess progesterone, leading to undesirable side effects. See my article **The Problem of Excess Progesterone**, for a complete discussion of this topic and suggestions on how to avoid any possibility of progesterone build-up.

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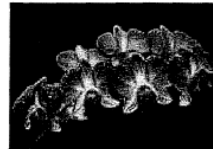
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THE PROBLEM OF EXCESS PROGESTERONE
by Elora Gabriel

In recent years, due to the research of Dr. John Lee and others, the importance of natural progesterone has been well established. Please see my article **The Benefits of Natural Progesterone** for more complete information on this essential hormone, and the difference between natural and synthetic progesterones.

Natural progesterone is technically called "Progesterone USP" or sometimes "USP progesterone". Because it is not cancer causing and because it is such a beneficial hormone, progesterone USP has been considered so safe that a "more is better" attitude has been adopted. Whereas the ovaries only produce 20-50 mg./day of progesterone, doctors routinely prescribe 200 mg./day. One of the rationales for using large amounts of progesterone is the belief that progesterone will convert into other hormones in the body, as needed. For example, progesterone is supposed to convert to estrogen and testosterone. And in fact, this is how the progesterone produced by our ovaries does work.

However, with the advent of the more accurate saliva hormone assays, we have learned that there is at least one important distinction between the way that ovarian progesterone and Progesterone USP work in the body. While ovarian progesterone does have the ability to "cascade", or convert into other hormones in the body, there is no evidence that Progesterone USP cascades in the body, beyond a possible slight conversion to testosterone. Upjohn, one of the manufacturers of Progesterone USP, has admitted that this is true, perhaps due to the laboratory processing. Therefore, if a woman takes in more than she needs, she can develop excessive amounts of progesterone. This fact is very often missed even by holistic doctors and health practitioners, and certainly by those selling and promoting natural progesterone.

What are the effects of excess progesterone? Symptoms can begin in a

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very subtle manner, and can mimic many other types of conditions. The first sign could be depression and/or lethargy. Women who are still menstruating may have anovulatory cycles, perhaps because too much progesterone can actually block estrogen. Memory loss, fluid retention, and protracted menstrual hemorrhaging have been observed in some cases. Joy Bucknell from Dr. Lynn August's office in New Fane, Vermont, has written about the problem of progesterone excess. To quote from her article:

"Initially, most women feel a calming effect when they use progesterone. However, after approximately eight months of high active progesterone levels a clinical depression may develop. Often times the cause of this depression is not attributed to the use of the progesterone cream. The second downside of high active progesterone is its effect on active cortisol levels in the body . . . High levels of active progesterone . . . cause a significant increase in free active cortisol . . . High active cortisol over the long term can result in hunger and sugar or carbohydrate cravings, weight gain around the waist, reduced muscle mass, bone thinning, food sensitivities and allergies, reduced athletic endurance, yeast overgrowth, reduced thyroid function, insomnia, PMS, and if not corrected, eventual exhaustion and chronic fatigue."

Strangely enough, the worst cases of this problem that I have personally encountered were two women who were both using a moderate strength non-prescription Progesterone USP cream. In both cases, they had felt so much better when they started on the progesterone, that when they began to feel worse, they assumed that more progesterone was needed. There has been a great deal of press in recent years about estrogen dominance, to the point where some women believe that this is the cause of all hormonal ills. Thinking that they were still estrogen dominant, therefore, these women kept increasing their dosages until they were using very large amounts of cream. Symptoms resolved when they stopped the progesterone and/or switched to wild yam cream. (Wild yam is a plant-derived, progesterone-like substance which provides many of the benefits of natural progesterone.)

For women using progesterone creams, saliva hormone assays will often show excessively high progesterone levels. Some laboratories are not helpful in helping a woman determine whether she is actually using too much progesterone or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams". Other testing facilities, however, have collected enough data from women using both oral and transdermal hormones, so that they can accurately determine whether a woman has developed an excess of progesterone. One such laboratory is North Bay Diagnostics. Saliva test kits for this lab can be found in our **Hormone Tests** section. We strongly recommend that women who are using progesterone avail themselves of such testing, on a periodic basis, until an ideal usage pattern has been determined.

Below are some further points which should be helpful.

1. When using progesterone creams, do not apply them on areas which are underlain by fatty tissue. It is the build-up of progesterone in the fatty tissue that seems to cause the problem. Instead, use thin-skinned

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areas underlain by venous circulation, so that the hormones will be absorbed directly into the blood stream. These areas include the sides of the throat, insides of the arms, wrists, palms and backs of hands, and tops of the feet.

2. When possible, select products which are not oil-based creams, but rather water or alcohol-based gels. Feminine Balance Plus, a combination natural progesterone/phyto-estrogen product carried by The Green Willow Tree, is one such product. The formulator, a nurse practitioner, states that she has seen no problems of progesterone excess with patients using Feminine Balance Plus.

3. Use a physiological dose. Pharmacies dispensing USP normally recommend 200 mg./day. However, we have noted that this is far more than the ovaries ever produce. If we are using estrogen, we certainly want to get enough progesterone to prevent endometrial hyperplasia (a precancerous condition of the uterus caused by using estrogen alone.) Dr. John Lee states that he found 30 mg./day of progesterone to be enough to prevent hyperplasia in women using estrogen. Using 1/4 tsp. of a moderate strength product such as NuGest 900 twice daily will give you approximately 60 mg./day. Given that nothing absorbs 100%, still this amount should be ample. Dr. Lee used a non-prescription cream (Pro-Gest) in his famous study of osteoporosis reversal in 100 women, rather than the high dosages favored by pharmacies. And Dr. Alan Gaby, author of *Preventing and Reversing Osteoporosis*, states that the "therapeutic window" for progesterone appears to be much less than 200 mg./day and that larger doses may be less effective against osteoporosis. Possible excesses of Progesterone USP will be much less likely if you use a moderate dosage. The 10% strength prescription creams from most compounding pharmacies are, in my opinion, at least three times stronger than necessary.

4. For those who find that they have developed excess progesterone, generally this problem resolves itself over a few months when the woman in question stops using her progesterone supplement. In the case of women needing progesterone to balance their estrogen replacement therapy, a good solution is to switch to a pure wild yam cream, such as Progestone Ten, for several months. Wild yam has been denigrated by many advocates of natural progesterone. While it is true that little clinical work has been done with wild yam, particularly in key areas such as bone health, it is undeniable that a good quality wild yam extract provides progesterone benefits. I have observed wild yam to be capable of acting in the same way that progesterone does in opposing (balancing) estrogen. And wild yam does not build up to excess in the body. However, small amounts may convert to estrogen, so wild yam may be contra-indicated for women who must avoid estrogen in any form.

5. There are a few women whose bodies do not tolerate progesterone in any form. This is not a situation of progesterone excess, but a simple intolerance of USP progesterone. These women generally do very well using wild yam creams.

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LAWRENCE ANDERSON - THE FUTURE OF EXCESS FLORESCE

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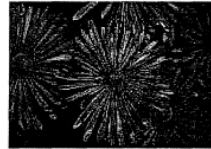
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THE GOOD NEWS ABOUT NATURAL ESTROGEN
by Elora Gabriel

Since 1995, I have been writing about the positive benefits of natural estrogen and progesterone, as opposed to the dangers of synthetic hormones. This article will recapitulate recent medical findings in this regard, and then go on to present several safe and highly effective choices for health conscious women. It is my firm belief that women do not have to choose between heart attacks or cancer on the one hand; and hot flashes, mood swings, premature aging, and other symptoms of low hormone levels on the other. Natural alternatives exist, and they go far beyond the commonly used remedies of using more soy products and herbs. These alternatives are just as effective as the synthetics. While nothing in this life is 100% safe, according to all the research and experience at my disposal, they are virtually free of both dangerous complications and uncomfortable side effects.

Millions of women are still reeling from the recent publicity regarding the dangers of commonly prescribed types of HRT. A long-term study by the National Institutes of Health, in which 16,600 women using PremPro were monitored over a period of years, had to be halted because so many of the participants suffered life-threatening side effects. An article by Loran Neergaard (Washington AP) stated that:

"Government scientists abruptly ended the nation's biggest study of a type of hormone replacement therapy, saying long-term use of estrogen and progestin significantly increased the women's risk of breast cancer, strokes and heart attacks. Six million American women use this hormone combination, either for short-term relief of hot flashes and other menopausal symptoms or because of doctors' longstanding assumptions that long-term use would prevent heart disease and brittle bones and generally keep women healthier longer. Two of those assumptions are wrong, the National Institutes of Health announced

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Tuesday. In fact, years-long use of estrogen and progestin **increased otherwise healthy women's risk of a stroke by 41 percent, a heart attack by 29 percent and breast cancer by 24 percent...** 'We recommend that clinicians stop prescribing this combination for long-term use,' wrote Dr. Suzanne Fletcher of Harvard Medical School in an editorial accompanying the study results posted on the Web site of the Journal of the American Medical Association. 'Risks from the drug add up over time.'

I was personally unsurprised at the results of this study. I am only relieved that, at last, the dangers of synthetic HRT have come out in the open. Why, indeed, should it be such a revelation to us that if women take hormones which are completely unnatural for our bodies, side effects will not only be unpleasant but dangerous? Hormones directly or indirectly control all of our body processes. It is surely of urgent importance to make sure that we get the very best and safest in hormonal support.

Let's take a moment to look at PremPro, the popular HRT combination used in the study. PremPro is a combination of Premarin and Provera. Premarin is composed of horse estrogens. It is also largely estrone, one of the more dangerous and cancer-causing types of estrogen. As Dr. Jonathan Wright (a leading holistic authority from Kent, WA) says, "The next time I see a menopausal horse, I will be happy to prescribe Premarin, a horse estrogen!" And let me add here that anyone who loves animals would never touch Premarin if she knew how this drug was obtained.

Provera is a synthetic, chemically altered form of progesterone which again, is highly unnatural to the body. Studies with primates using generic Provera resulted in greatly increased incidence of strokes and heart attacks. Researchers were shocked to find that this was such a dangerous drug, yet the study was buried and doctors have continued to prescribe Provera and its synthetic cousins. For more information on progesterone, and the difference between natural and synthetic progesterone, please click [here](#). Our natural progesterone products can be accessed at [this link](#).

Now let's return to the question of estrogen. As menopause approaches, estrogen deficiency makes itself known in the all too familiar symptoms of hot flashes, night sweats, sleep disorders, mood swings, and vaginal dryness. Other symptoms could include fatigue, rapid skin aging, joint pains, dizziness, bladder problems, crawling sensations on skin and scalp, or severe depression. The emotional changes that accompany hormonal deficiency can be particularly difficult.

Supplementing with estrogen turns all of these symptoms around. Hot flashes and night sweats disappear; moods return to normal; mental clarity increases; sleep quality improves; the skin becomes moist and more youthful; and so on. Estrogen also slows bone loss. And in my opinion, it probably does protect the cardiovascular system, if taken in a natural form and particularly when not taken with synthetic progesterones which are so dangerous to the heart and arteries.

Estrogen has had some bad press, but in my opinion this is almost entirely due either to the use of synthetic estrogens, or taking estrogen without progesterone. In fact, estrogen is so vital to the health and well-

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being of women that its absence not only accelerates aging, but can cause a malaise whose intensity is only believable to those who have experienced it. I have spoken to many women over the years who were literally suicidal, simply from lack of estrogen. These women were often prescribed anti-depressants when all they needed was a natural boost to their hormone levels. Too much estrogen is certainly no better than too much of anything else; but this hormone, in the right amount, is the juice of life for the female body. How, then, do we obtain the benefits of estrogen without its downsides? Based upon a decade of research and counseling women, I believe there are two major choices.

1) Phytoestrogens. These substances are estrogenic compounds which occur naturally in plants such as soy, black cohosh, dong quai, licorice root, etc. In countries where large amounts of phytoestrogens are consumed, women suffer very few menopausal symptoms. Phytoestrogens differ remarkably from synthetic estrogens in that they are easily broken down, are not stored in the tissues and spend very little time in the body, thus they are unlikely to cause cancer. And because humans have spent millions of years eating plants and herbs, our bodies easily accept plant estrogens and find them both effective and beneficial.

Phytoestrogens appear to exert a natural balancing action in the body. If estrogen is low, phytoestrogens will increase estrogen activity in the body. When estrogen levels are high, phytoestrogens will compete for estrogen receptor sites, causing a decrease in the estrogen effects. The result is a chemoprotecting action. Numerous studies have indicated that high intake of phytoestrogenic substances may reduce the risk of breast cancer.

Many women have turned to soy products as a source of phytoestrogens. Large amounts of soy may not be appropriate for every woman however, particularly those who are hypothyroid. Fortunately, we have numerous other sources of phytoestrogens. I personally like Feminine Balance Plus (no longer available...see our EST and Progestacare Plus products), a combination gel which contains phytoestrogens from black cohosh along with natural progesterone. Many women may have tried phytoestrogen products but found the results to be disappointing. These products vary greatly in their effectiveness and many are weak or poorly formulated. At The Green Willow Tree we have spent many years locating natural estrogen creams and tablets which really work, even for the woman who has had a total hysterectomy.

2) Tri and bi-estrogen. Other forms of natural, user-friendly estrogen are also available. In order to explain this next section, we need a short lesson on this hormone. There are actually three major forms of estrogen in the female body. They are called estradiol, estrone, and estriol. The commonly prescribed forms of estrogen are universally made of estradiol, estrone, or combinations of the two. For example, Premarin is largely estrone, Estrace and Estraderm are estradiol, and so on. Estradiol and estrone are very potent estrogens, and they both have a stimulating effect upon the cells of the breast and uterine lining. It is this effect which can eventually lead to cancer.

However, there is a third type of estrogen--called estriol--which is often called "the forgotten estrogen" because it has been overlooked in favor

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ESTRONE AND ESTRADIOL - ESTROGENS - THE GOOD NEWS ABOUT NATURAL ESTROGEN

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of its more dangerous cousins. Estriol is the estrogen which dominates during pregnancy, and it has a much less stimulating effect on the breast and uterine lining than estradiol and estrone. **In fact, estradiol is 1000 times more stimulating to the breast tissue than is estriol, according to leading authority Dr. John R. Lee of Sebastopol, CA. Estrone is considered even more risky, and is believed to be the estrogen most responsible for breast cancer.** Since PremPro contains mostly estrone (and horse estrone at that) we can now understand the frightening results of the study discussed at the beginning of this article.

The most exciting thing about estriol is the fact that not only does it not promote breast cancer, but considerable evidence exists to show that it protects against this disease. In 1978, Alvin H. Follingstad, M.D., wrote an article for the Journal of the American Medical Association calling for the use of estriol instead of estrone and estradiol. In support of his position, he cited a group of postmenopausal women with metastatic breast cancer. When given small doses of estriol, 37% of the women experienced either a remission or a complete arrest of the metastasized lesions! In 1966, H. M. Lemon, M.D. demonstrated that women with breast cancer have lowered estriol levels. Later, he showed that women without breast cancer had naturally higher estriol levels (compared to estrone and estradiol) than those with breast cancer.

Dr. Julian Whitaker, well known author and publisher of the *Health and Healing* newsletter, says that "estriol's anti-cancer effect is thought to be due to its anti-estrone characteristics. It apparently blocks the stimulatory effect of estrone on the breast." Estriol is weaker than other types of estrogen, appears to have very little effect on bone density. Therefore, for most women a blend of estriol with small amounts of the more potent estrogens seems to be ideal. Dr. Jonathan Wright, mentioned above, has been experimenting with the use of estriol since the early 1980's. He created a formula called "tri-estrogen" which contains 10% estradiol, 10% estrone, and 80% estriol. Dr. Wright determined that this is the ratio of estrogens naturally occurring in a young woman's body. This formula has been found by Dr. Wright to rapidly alleviate the symptoms of menopause without amplifying the danger of breast cancer. Women who have tried it find it gentle, effective, and free of unpleasant side effects. Tri-estrogen is also believed to be more effective against osteoporosis than pure estriol.

A new refinement on tri-estrogen is bi-estrogen, composed of 80% estriol and 20% estradiol. The rationale for bi-estrogen is that estradiol converts into estrone in the body, so there is no need to supplement with this type of estrogen at all. Opinions vary as to which is better. I like both products and believe that bi and tri-estrogen are infinitely superior to Premarin and virtually all other prescription estrogens.

If you would like a prescription for bi or tri-estrogen, you can ask your doctor to telephone a compounding pharmacy, such as the Women's International Pharmacy at 1-800-279-5708.

Saliva hormone assays should be used initially, and then periodically to check estrogen levels on supplementation. Some laboratories are not helpful in helping a woman determine whether she is actually using enough natural estrogen, or not. For example, the well-known Great Smokies Diagnostic Laboratory insists that women abstain from the use

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of any hormones before taking their saliva tests, as "there is no reference range for women using hormones, particularly the transdermal creams." Other testing facilities, such as North Bay Diagnostics, however, have collected enough data from women using both oral and transdermal hormones, so they can accurately determine whether a woman has initial low estrogen, then adequate level with supplementation. These will be found in our **Hormone Tests** section. Periodic testing is important, at least until your usage pattern is stabilized.

Women have been misinformed and mis-treated for decades with harmful, synthetic hormones, a chemical cocktail which has resulted in untold suffering for many. It has become something of a mission for me to educate my sisters to the fact that many wonderful alternatives do exist. With natural hormones, we really can have our cake and eat it too.

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Osteoporosis is one of the most serious health concerns for mid-life and mature women, and can affect men as well. The use of natural hormones, such as progesterone, is essential for bone health. In addition, the products below can greatly aid in preserving and even increasing bone density. A major cause of bone loss is an acid constitution; therefore alkalizing the body is essential. See also sections for Progesterone and Hormone Tests.

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Periodic saliva hormone testing for progesterone and cortisol	Magnesium, zinc, manganese, boron, and silica	Vitamin K, 3000 mcg./day	Eat plenty of dark green leafy vegetables

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THE GREEN WILLOW TREE BONE & JOINT THERAPY - THE GREEN WILLOW TREE - Natural Supplements for Natur... Page 2 of 2

Optional--DHEA cream	Trace mineral complex	An alkalizing product of some kind	Avoid coffee, sweets, and sodas
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"Osteoporosis is very common in women who are depressed and that is one in four women. It's because of higher cortisol levels than normal. That is the stress hormone. I think that is the predominant cause of osteoporosis - depression and unabated stress resulting in a hypercortisol state that dissolves the bones over time. Most women, the vast majority, will not get osteoporosis that will lead to a fracture if they take enough calcium and magnesium and also do regular weight bearing exercise." -- Christiane Northrup, M.D. For those concerned about cortisol levels, please see our Adrenals Section

**29. OsteOrganicCal**

An exceptional supplement for those who have lost bone mass. Increases in bone mass have been achieved faster than with drugs such as Fosamax, and with no side effects. This product contains a rare, highly bio-available form of calcium along with magnesium, iron, and manganese. Comes in a 2-bottle set: 60 capsules of the calcium/mineral supplement, and 30 capsules of Vitamin D3 from shark liver oil. Money back guarantee if bone scans do not improve after 6 months (click on photo for details). In many cases adequate levels of bone mass are achieved after 12-24 months of treatment.* (30 day supply.) **[For more information please click on picture]**

OUR PRICE: \$69.00 [Add to Cart](#)**30. Vitamin D-3**

Vitamin D-3 is essential if you're serious about bone health. More active in this regard than regular Vitamin D, the major function of D-3 is to increase calcium absorption from the intestine and promote bone formation and mineralization. A general recommendation is 800 IU per day with whatever form of calcium you are taking.* (A bottle of 90 400 IU capsules. Will last 6 weeks at 2/day.) **[For more information please click on picture]**

OUR PRICE: \$9.95 [Add to Cart](#)**36. Bio-K-Mulsion (Liquid Vitamin K)**

Vitamin K is a critically important nutrient for bone density and for the prevention of heart disease. It is the biological "glue" that plugs calcium into your

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THE GREEN WILLOW TREE DONE & JOINT HEALTH - THE GREEN WILLOW TREE - Natural Supplements for Natur... Page 3 of 3



bone matrix, thus helping to prevent and even reverse osteoporosis. It also assists in the prevention of heart failure and coronary artery disease. Most Americans do not get enough Vitamin K, and most supplements provide much less than the doctor-recommended 3000 mcg, per day. 1 oz. bottle will last 5 months. Drops have no taste.*[For more information please click on picture]

OUR PRICE: \$16.00 [Add to Cart](#)



Acid Redux

Acid Redux is a unique formulation of acid buffering agents that can be helpful in the alleviation of occasional acid indigestion. This product not only comforts the digestive system, but assists in maintaining proper body pH. It has a pH of 9.5 and is up to 11 times more effective than name brand alternatives. Acid Redux increases the pH of the blood, which reduces overall body acidity. Alkalizing the body is believed by many health professionals to be essential for maintaining health, and is particularly important for bone density.* 90 mint-flavored lozenges; take 1 lozenge 2-3 times daily or as needed. [For more information please click on picture]

OUR PRICE: \$10.00 [Add to Cart](#)



Boswellin Cream

Try this wonderful cream for the temporary relief of minor aches and pains of muscles and joints associated with arthritis. Boswellin Cream provides warm, penetrating pain relief. In addition, it has a pleasant aroma and is both greaseless and stainless. It offers two herbal extracts, Capsaicin and Wintergreen, for fast, effective pain relief--in a soothing base of Boswellia serrata, standardized for Boswellic acids and Vitamin E. Four ounce tube.* [For more information please click on picture]

OUR PRICE: \$15.00 [Add to Cart](#)

High Absorption Magnesium

Magnesium (Mg) is a trace mineral that is known to be required for several hundred different functions in the body. A significant portion of the symptoms of many chronic disorders are identical to

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symptoms of magnesium deficiency. Studies show many people in the U.S. today do not consume the daily-recommended amounts of Mg (or are not absorbing it properly). A lack of this important nutrient may be a major factor in many common health problems in industrialized countries. Common conditions such as migraines, mitral valve prolapse, attention deficit disorder, fibromyalgia, asthma and allergies have all been linked to a Mg deficiency. Perhaps not coincidentally, these conditions also tend to occur in clusters together within the same individual. A magnesium deficiency as a root cause would provide a logical explanation of why some people suffer from a constellation of these types of problems.

Among the several conditions linked to magnesium deficiency, THE GREEN WILLOW TREE would like to single out **migraine headaches**. Recent clinical findings reconfirmed the ability of magnesium to alleviate the symptoms of an acute migraine attack, and other studies have shown the daily intake of magnesium to prevent recurring attacks.

240 tablets suitable for vegetarians; take 2 twice a day between meals. **[For more information please click on picture]**
OUR PRICE: \$26.36 [\[Add to Cart\]](#)



Osteo-Nutrients II - 240 capsules
This product is not available for shipment to Canada!

OSTEO-NUTRIENTS II is a comprehensive bone support formula which contains high amounts of elemental calcium and magnesium, as well as the other essential nutrients for healthy teeth and bones. Calcium and magnesium are also essential to many physiological functions such as helping to maintain and build bone mass and strength before and during menopause. Boron, which also plays a role in bone health, has been added to this formula* Bottle of 240 capsules. Take 4 capsules daily for a total of 1000 mg of calcium (as carbonate/citrate-malate) per day; post menopausal women may need one additional capsule/day.

[For more information please click on picture]
OUR PRICE: \$25.50 [\[Add to Cart\]](#)

Rebuild Osteoporosis Formula
This product is not available for shipment to Canada!

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Our new Osteoporosis product, Rebuild® is formulated to reflect the positive results of research performed by Paul Saltman, Ph.D. at UCSD. By combining the most bioavailable form of Calcium (citrate/malate) with balanced levels of Magnesium Citrate and the exact minerals, Zinc, Copper, Manganese, Boron, Vitamin D3 and Vitamin K, used in university studies, Rebuild® provides the finest Osteopenia and Osteoporosis formula available today.*
180 vegetable cellulose capsules. Preservative and Excipient free. Thirty-day (30) supply..
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HORMONAL AND LIFESTYLE FACTORS FOR BONE HEALTH

by Elora Gabriel

HOW THE DIFFERENT HORMONES AFFECT OSTEOPOROSIS

If you have osteoporosis, or if you are at risk for osteoporosis, what hormones should you be taking? What other factors should you consider? Bone loss is a serious and disabling condition. It is important for all of us to make informed choices this subject.

First of all, let's look briefly at the action of the different hormones on bone density. For years, estrogen has been prescribed to protect against osteoporosis, because it is known that it helps to slow bone loss. Little research has been done on the effect of the safer estrogens (estriol and tri-estrogen) upon bone health. It is known, however, that very large amounts of estriol are needed to prevent osteoporosis. Therefore tri-estrogen would be recommended for most women in preference to estriol. While we do not have any studies on tri-estrogen and bone health, Dr. Alan Gaby (author of the highly recommended *Preventing and Reversing Osteoporosis*) states that the information we have on tri-estrogen "suggests that it would also be effective for osteoporosis." Phyto-estrogens found in the isoflavone complex (derived from soybeans) also have a positive effect upon bone density, according to the *Alternative Medicine Digest*.

However, all foremost authorities on this subject agree that progesterone is by far the more important hormone for osteoporosis. Progesterone helps to build new bone. It's like having a bank balance. Estrogen helps you to spend less, but progesterone puts new cash into your account. Therefore, using progesterone is essential for your bone health. Progesterone levels begin to fall 5-15 years before menopause. This

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corresponds with the fact that bone loss usually starts when women are in their forties, when estrogen levels are generally still high. Progesterone declines even further after menopause. If you want to keep your bones healthy, use some type of progesterone! After a brief look at the other hormones, we will return to discuss progesterone in greater depth.

DHEA is a hormone which is produced by the adrenal glands in both sexes; levels peak in our 20's and decline thereafter. Most people over the age of 50 are deficient in DHEA. Researchers are becoming increasingly aware that this hormone has positive implications for osteoporosis. DHEA directly increases levels of estrogen and testosterone (another bone-building hormone) and indirectly increases progesterone levels. Dr. Gaby describes the case of a woman with osteoporosis who was using progesterone and "doing everything right" in terms of lifestyle. Nothing helped her until she began using DHEA. DHEA creams are recommended as the best source of DHEA for this purpose. Dr. Julian Whitaker, editor of *Health and Healing* newsletter, reported very good increases in bone density for post-menopausal women using DHEA cream.

Natural testosterone, as opposed to synthetic methyl testosterone, can also be used by those of us who are especially conscious of bone health. High testosterone levels in men act as a prevention against osteoporosis. Natural testosterone (2% gel) may be obtained from Clark's Pharmacy, 1-800-480-3432.

Human Growth Hormone (HGH) has increasingly come into the limelight for its properties of rejuvenating the body. Its effects on bone density are less recognized, but certainly worthy of note. Dr. Whitaker states that: "The hormone that beats all other agents hands down for reversing osteoporosis is HGH. In a 1993 study of 24 postmenopausal women with osteoporosis, markers for bone remodeling increased by an incredible 30% to 40%, after 12 weeks of using HGH." We do not have any information about the results of over-the-counter HGH precursors or sublingual tablets and sprays for bone health, however. These products may be very helpful, but are probably not the first line of defense.

Women are understandably concerned about taking thyroid hormone since it is reported that using thyroid increases bone loss. Dr. Gaby thoroughly addresses this belief in *Preventing and Reversing Osteoporosis*. He explains that the studies indicating this connection were seriously flawed, and goes on to cite a recent study in *Lancet* which refutes the connection between thyroid and osteoporosis. This long-term study of women who were using thyroid hormone, compared to a control group, showed no difference in bone density. "These findings, combined with earlier reports that the incidence of fractures is not increased in people taking thyroid hormone, indicate that treatment with thyroid hormone does not cause osteoporosis and does not increase the risk of developing fractures," says Dr. Gaby (emphasis added). It is worth noting, however, that the non-prescription product **Thyodine** has been very helpful in normalizing thyroid function without the need for medication.

Now let's return for a more in-depth look at natural progesterone. Dr. John Lee's impressive study involved 100 post-menopausal women, many of whom showed osteoporosis symptoms. The women used a 3%

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LAWRENCE ROSENBERG, FOUNDER - CHESTNUT BONE DENSITY CENTER - LIFESTYLE AND NUTRITIONAL TIPS

Page 3 of 4

natural progesterone remain for at least three years. Of the 63 women who had bone density tests, instead of the predicted bone loss that would be expected in this group, every single one had an increase in bone mass. Some women showed an increase of 10% after the first 6 to 12 months of therapy, and others showed a 20-25% increase in the first year. Dr. Lee found that the effects of the therapy were independent of whether the women were receiving estrogen. While Dr. Lee's results have not been replicated in the US, I have heard that progesterone is the standard treatment for osteoporosis in Europe.

Regarding dosage for progesterone: Dr. Lee used a moderate strength of progesterone, and we do not know the effect of high-dosage Progesterone USP upon bone density. Dr. Gaby speaks of the important concept of the "therapeutic window" for each hormone, i.e. the amount that is most effective. In other words, if the therapeutic window for progesterone is 30-50 mg./day, giving 4 times that amount may be less effective. While a few women may need larger amounts of progesterone, in general the moderate dosages (about 60 mg./day) would appear to be best. Also, continued use of progesterone has led, in many cases, to excess build-up of progesterone in the body. Periodic screening of progesterone levels is strongly recommended for all women over the age of 40. Saliva hormone assays are recommended over standard blood tests, and they are available without a prescription from Great Smokies Medical Labs, at 1-888-891-3061. Please see my article **The Problem of Excess Progesterone** for a complete discussion of this topic.

Osteoporosis is not just a matter of hormones. Diet and exercise play a very important role. Please read Dr. Gaby's *Preventing and Reversing Osteoporosis* and also Betty Kamen's *Hormone Replacement Therapy, Yes or No?* (Note: Betty Kamen's book is very anti-estrogen, perhaps because tri-estrogen and estriol were not available when she wrote it. However, her section on osteoporosis is excellent.) The notes below are mostly condensed from Dr. Kamen's book.

NUTRITION AND LIFESTYLE TIPS FOR BONE HEALTH

1. Exercise regularly! The best exercise for bone health is weight-bearing, aerobic, and ideally outdoors. Natural light is important for health, as is fresh air. Fast walking is an excellent choice. Walking is recommended for at least 20 minutes 5 times/week.
2. Eat dark green leafy vegetables, especially kale, collards, mustard and turnip greens. These are all very high in bioavailable calcium. Cooked cabbage and green beans are reasonably good sources, as is tahini made from unhulled sesame seeds.
3. Avoid dairy products. Dairy products are very acid forming in the body. This acidic condition must be buffered with large amounts of calcium. If necessary, the body will even rob calcium out of the bones to balance blood pH. Because of its high level of animal protein, milk consumption may cause a greater loss than gain of calcium. Homogenization makes it worse. Women in countries with a high consumption of dairy, like the US, have much more osteoporosis than countries where small amounts of dairy products are consumed.
4. Also avoid sweets and excess carbohydrates. Eating sweets and high-glycemic carbohydrates such as bread, pasta, and potatoes; causes a

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surge in blood sugar and insulin levels. This in turn causes a massive excretion of calcium which again, may be robbed from your bones. You can exercise, use the right hormones, and take the best type of calcium in the world; but all of these good health habits may be in vain if you eat a high glycemic diet. Even fruits and fruit juices should be used in moderation.

5. Reduce phosphorus intake. Too much phosphorus blocks calcium assimilation. Some high phosphorus foods are processed and canned meats (hot dogs, ham, bacon), processed cheese, most baked products, sodas, and meats. Sodas are devastating to bone health.

6. Avoid not only milk, but coffee, which acidifies the blood. In addition, ALL forms of caffeine, whether from coffee, tea, or cola soft drinks, stimulate the release of calcium from the bone.

7. Avoid fluoride in any form. While it can increase bone mass, it also makes bone more brittle. "Nonvertebral fractures increase 300 to 600% in patients undergoing fluoride therapy." If your city water is fluoridated, use filtered or bottled water.

8. Avoid chlorinated water. It reduces calcium absorption.

9. Avoid canned foods, which may contain high levels of tin.

10. Avoid aluminum (found in aluminum cookware, antacids, processed cheeses, many deodorants, some baking powders, etc.) Read labels! There is a correlation between aluminum poisoning and spontaneous bone fractures.

11. Regarding supplements for bone health:

*Two types of calcium which have shown impressive clinical results for increasing bone density are OsteOrganicAL and 3A Calcium. Please see the **Bone & Joint Health** section for further information. We also offer Vitamin D-3 in this section. Vitamin D-3 is slightly different from regular Vitamin D and is more active for bone health.

*Supplemental hydrochloric acid can help with calcium absorption. Taking trace minerals, such as liquid colloidal minerals, is also essential! Our foods today are seriously depleted of minerals.

*Be sure to supplement your calcium with magnesium as well. Most Americans are magnesium deficient.

The information in this article is for educational purposes only, and is not intended as medical advice.

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1. EST
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This product may be used as a replacement for Feminine Balance Plus.

This elegant white cream contains natural progesterone and natural phyto-estrogens, and provides an ideal hormone balance for menopausal and post-menopausal women. A rare find, EST is based on a phyto-estrogen equivalent of bi-estrogen with natural progesterone. It is formulated for quick absorption into the skin with superior bioavailability. This completely natural product can provide relief from menopausal and peri-menopausal symptoms including, hot flashes, night sweats, mood swings, vaginal dryness, and sleep disturbances. May also help improve new bone formation. Two ounce tube should last about one month.*

Phyto-estrogens are found in many plant sources, primarily soy, wild yam, licorice, black cohosh, and chamomile. In this formulation, the manufacturers have selected phytoestrogens which replicate, as closely as possible, the same molecular structure found in human estrogens. Therefore it is closer to a bio-identical estrogen than most of the phytoestrogen products available. EST is also one of the only over-the-counter creams containing an approximation of bi-estrogen. Bi-estrogen is considered to be the ideal balance of estrogens, containing 80% estriol (the safest but weakest form of estrogen) and 20% of the more potent estradiol. The inclusion of natural progesterone, with its many benefits, makes this a well balanced and convenient product.*

EST contains approximately 1 mg of natural estrogen and 20 mg of natural progesterone per 1/4 tsp dose. Suggested usage: ¼ teaspoon twice daily, rubbed into soft-skin areas of the body such as the throat, insides of the arms, wrists, backs of hands, and tops of feet. Generally this product is used for about 25 days with a break of 5 days, which is taken during the time of menstruation for women who are still having periods.*

Ingredients per 2 ounce tube:

960 mg of USP natural progesterone extracted from wild yam and soybean, with natural phyto-estrogens extracted from Soya, Dong Quai, Black Cohosh, Red Clover Blossom, Licorice Root and Wild Yam, in a 2 ounce base of: deionized water, aloe vera gel,

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caprylic/capric triglycerides, polyacrylamide/c13-14,
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Two ounce tube for \$24.95; 6 or more for \$22.46 each.

OUR PRICE: \$24.95 (6+ \$22.46)

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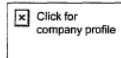
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11. Restored Balance
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Restored Balance is on Dr. John Lee's approved list of progesterone creams. It is more concentrated than most natural progesterone creams, and comes with an easy to use dispenser. The result is that your tube will last longer. Restored Balance is also pure and chemical free, containing absolutely no chemical preservatives or stabilizers. Herbal extracts and Vitamins A and E added for enhanced benefits.* Unconditional money back guarantee if you are not satisfied.

2 oz. pump tube, about an 8 week supply, for \$24.00; 6 or more for \$21.60 each. Pump tube automatically dispenses correct dosage. 1/8 tsp. of cream contains 15-20 mg. of natural progesterone; used twice daily this equals about 30-35 mg./day.

INGREDIENTS:
Purified Water, Natural Glycerin, Stearyl Konium Chloride, Tocopherol (Vitamin E), Avocado Oil, Natural Progesterone [(USP) 15-20 mg per 1/8 teaspoon dose], Aloe Vera Oil, Rosemary Extract, Vitamin A Palmitate, Saw Palmetto, Cramp Bark, Sarsaparilla, Carrot Oil, Lemon Grass Oil.

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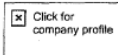


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Mind-Body Response R...



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1a. Progestacare Plus

SKU: proplus

This product may be used as a replacement for Feminine Balance Plus.

ProgestaCare Plus is a convenient way to supplement your estrogen and progesterone levels with one easy application. This pure, chemical-free cream combines bio-identical natural progesterone with the highest quality all natural phytoestrogens (plant-derived estrogenic substances). A medium strength product, it should be adequate to support healthy hormonal balance for most menopausal or post-menopausal women. The convenient, reasonably priced pump tube dispenses an average dose with one press and contains four ounces of cream (twice that of similar products). Lasts about two months.*

Estrogens work in harmony with progesterone, and the appropriate balance between the two is significant for health and well-being. This product may be helpful for hot flashes, mood swings, fatigue and sleep disturbances caused by falling hormone levels.*

KEY INGREDIENTS:

Natural Progesterone (USP)

-Helps balance hormone levels*
-Reduces estrogen dominance*

Tocotrienols (Natural Super Vitamin E)

-Powerful anti-oxidant*

Primrose Oil

-Helps reduce PMS symptoms*

Aloe Vera

-Soothing skin softener*

MSM (Methyl Sulfonyl Methane)

-Stimulates the immune system*

Grape Seed Extract

-Powerful anti-oxidant*

Complaint

THE GREAT THING ABOUT PROGESTACARE PLUS - THE GREAT THING ABOUT - Natural Supplements for Natu... Page 2 of 2

Relora
Allergies: a Foundat...
Allergies: Desert U...
Allergies: Great Lak...
Allergies: Northeast...
Allergies: Pacific U...
Allergies: Plains U...
Allergies: Rocky Mou...
Allergies: Southern ...
Allergies: Southwest...
Allergies: Total Mol...
Climate Comfort: Col...
Climate Comfort: Col...
Climate Comfort: Hot...
Climate Comfort: Hot...
Climate Comfort: Wea...
NetiPot
*SP-Zyme - Natural A...
Borage Oil
Boswellin Cream
29. OsteOrganicCal
30. Vitamin D-3
36. Bio-K-Mulsion (L...
Acid Redux
High Absorption Magn...
Osteo-Nutrients II ~...
Rebuild Osteoporosis...
35a. Ultra One, Ultr...
5d. Enteric Coated O...
Sympathical's Homeop...
* SP-Zyme
30. Pressure Control
34. Healthy Cholesterol
Water Retention Cont...
Cosmic Essence Catalog
* OxyPowder
*Uriflow™
3C. DIM Plus
Healthy Additions C...
Healthy Smoking Cont...
Heavy Metal Test Kit
Floraderm
Super Enzymes (NOW
F...
1. EST
15. DHEA/Pregnenolon...

PhytoPro, Red Clover Tops, Dong Quai Extract
-Phyto-estrogens, or natural compounds derived from various
plant sources which exert estrogenic effects in the human body*

COMPLETE FORMULA:
Deionized Water, Aloe Vera Gel, Sunflower Seed Oil,
Caprylic/Capric Triglycerides, Natural Glycerin, Shea Butter,
Stearic Acid, Natural Progesterone USP, Cetearyl Alcohol and
Ceteareth-20, Isopropyl Palmitate, Stearyl Alcohol, Flavonoids
(Extract of Artichoke, Extract of Sarsaparilla),
Methylsulfonylmethane, Lecithin, Carbomer, Disodium EDTA,
PhytoPro™ (Natural Super Phytoestrogen), Red Clover Tops
Extract, Chasteberry Extract, Dong Quai Root Extract, Saw
Palmetto, Tocotrienols (Natural Super Vitamin E), Xanthan Gum,
Hydroxypropyl Methylcellulose, Allantoin, Potassium Sorbate, Oil of
Rosemary, Triethanolamine, Tea Tree Oil, Sorbic Acid, Grape Seed
Extract.

SUGGESTED USE:
Each full pump of ProgestaCare Plus dispenses 20 mg. of natural,
bio-identical progesterone combined with 25 mg of highly effective
phytoestrogens. Rotate the area of application between chest,
abdomen, inner arms, and thighs.*

Menstruating Women: Apply once a day at bedtime on days 12
through 27 of your cycle, or as recommended by your physician.*

Menopausal and Post-Menopausal Women: Apply twice daily for 25
consecutive days followed by a five-day break, or as recommended
by your physician.*

Four ounce pump tube for \$35.00; 6 or more for \$31.50 each.

OUR PRICE: \$35.00 (6+ \$31.50)

Quantity

[Add To Shopping Cart](#)

YOUR ACCOUNT



[Email a friend about this item.](#)

[Return to catalog](#)

Complaint

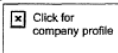
THE GREEN WILLOW TREE, LLC - THE GREEN WILLOW TREE - Natural Supplements for Health... Page 3 of 3

All products come with instructions for use.
For further information or personal questions, please **email us**.
You may order online, or place your order by phone at 877-968-4337 (toll free) or 828-665-3095.
Please hit "**Reload**" or "**Refresh**" to make sure you are seeing the most current version of this page.

*These statements have not been evaluated by the Food and Drug Administration.
Our products are not intended to diagnose, treat, cure, or prevent disease.

[Home](#) : [About Us](#) : [Order Information](#) : [FAQ](#) : [Contact Us](#) : [Privacy](#) : [Policies](#)

The Green Willow Tree
34 Rocky Ridge Rd
Asheville, NC 28806
Phone: 877-968-4337 or 828-665-3095
Fax: 208-330-2445
info@greenwillowtree.com (product questions)
customerservice@greenwillowtree.com (order questions)



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Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents 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 by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the 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 the Respondents 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 Respondents have 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 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 The Green Willow Tree, LLC is a North Carolina limited liability company with its principal office or place of business is at 34 Rocky Ridge Road, Asheville, North Carolina 28806.

Decision and Order

2. Respondent Robert Burns is a manager and member of The Green Willow Tree, LLC. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of The Green Willow Tree, LLC, including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of The Green Willow Tree, LLC.

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 purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - a. The Green Willow Tree, LLC, a limited liability company, its successors and assigns and its managers; and
 - b. Robert Burns, individually and as a member and manager of The Green Willow Tree, LLC.
2. “Competent and reliable scientific evidence” shall mean 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.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or

Decision and Order

synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Progesta Care Plus, EST, and Restored Balance.

4. “Food,” shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. “Drug” shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. “Device” shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and

Decision and Order

which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.
9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

Decision and Order

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner,

Decision and Order

expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in 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;
- B. 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
- C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice make available to the Federal Trade Commission for inspection and copying:

- A. All advertisements and promotional materials containing the representation;

Decision and Order

- 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 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. Respondents 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.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to The Green Willow Tree, LLC or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; 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

Decision and Order

or address. *Provided, however*, that, with respect to any proposed change 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. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on November 13, 2027, 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

Decision and Order

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 Respondent 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 (“FTC” or “Commission”) has accepted, subject to final approval, an agreement containing a consent order from The Green Willow Tree LLC, a limited liability company, and Robert Burns, individually and as a member and manager of The Green Willow Tree (together, “respondents”).

The proposed consent order has been placed on the public record for thirty (30) days for reception 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 the advertising and promotion of Progesta Care Plus, EST, and Restored Balance, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that Progesta Care Plus, EST, and Restored Balance: (1) are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) do not increase the user’s risk of developing breast cancer and/or are effective in preventing or reducing the user’s risk of developing breast cancer. The complaint alleges that respondents failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or

Analysis to Aid Public Comment

reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. 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 agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**HEALTH SCIENCE INTERNATIONAL, INC.,
AND
DAVID MARTIN**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4205; File No. 072 3145

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order relates to the deceptive advertising and promotion of respondents' transdermal cream, Serenity for Women Natural Progesterone Cream. The complaint alleged that respondents violated the FTC Act by falsely advertising that its cream was effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The complaint alleged that respondents had no substantiation for these claims. The consent order requires that respondents have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing any disease. The order further bars respondents from engaging in similar acts and practices in the future and prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the Commission: *Gregory A. Ashe, Laura DeMartino,
Janice P. Frankle, James A. Kohm, and Michael Ostheimer.*

For the Respondents: *Not represented by counsel.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International, Inc. ("Respondents"), have violated the provisions of the Federal Trade

Complaint

Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Health Science International, Inc. is a Florida corporation with its principal office or place of business at 1648 Taylor Road, Suite 118, Port Orange, Florida 32128.

2. Respondent David Martin is an officer of Health Science International, Inc. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Health Science International, Inc., including the acts and practices alleged in this complaint. His principal office or place of business is the same as that of Health Science International, Inc.

3. 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.

4. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman’s risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman’s risk of developing breast cancer.

Complaint

5. Respondents have advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Serenity for Women Natural Progesterone Cream. Respondents advertise and offer the products for sale through the Internet sites www.health-science.com and www.progesterone.com.

6. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Serenity for Women Natural Progesterone Cream is a “drug” as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

7. Serenity for Women Natural Progesterone Cream is a drug labeled as containing Natural Progesterone USP (2.25%) and other ingredients. A 60 gram jar costs \$32 plus shipping and handling. Serenity for Women Natural Progesterone Cream is applied transdermally.

8. To induce consumers to purchase Serenity for Women Natural Progesterone Cream, Respondents have disseminated or have caused to be disseminated advertisements, including but not necessarily limited to the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on Respondents’ website:

A. Does Progesterone or Estrogen increase or decrease my risk for cancer?

Molecular biologist, Dr. Ben Formby of Copenhagen, Denmark and Dr. T.S. Wiley at the University of California in Santa Barbara have researched two genes, BCL2 and P53, and their effect on female-specific cancers and prostate cancer.

Cells of breast, endometrium, ovary and prostate, were grown in the laboratory. Estrogen (estradiol) was added to the cells. This hormone turned on the BCL2 gene, causing the cells to grow rapidly and not die. Then, progesterone

Complaint

was added to the cell cultures. Cell reproduction stopped and the cells died on time (apoptosis).

This methodology was applied to all the above types of cancer. The BCL2 gene, therefore, stimulates the growth of these cells and the risk of cancer. On the other hand, the P53 gene promotes apoptosis or programmed cell death and thereby, reduces the risk of cancer. Estradiol upregulates or stimulates the production of the BCL2 gene, while progesterone upregulates or stimulates the production of the P53 gene.

Therefore natural progesterone decreases the risk for several types of cancer, while unopposed estradiol causes these same types of cancer. Since Breast cancer is considered to be a hormone dependent cancer it is critically important to maintain optimal levels of natural progesterone and avoid the factors that would promote too much estradiol.

* * *

Clearly the underlying causes of breast cancer are too much estrogen relative to too little natural progesterone, especially in the presence of trans fatty acids (hydrogenated fats).

“When faced with decisions on critically important health issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility & osteoporosis, Informed Women demand and deserve the finest natural progesterone cream formula available anywhere in the world “Serenity for Women Certified Potency Progesterone Cream.”

(Exhibit A at 2.)

Complaint

- B. Natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.
(Exhibit A at 4.)
- C. Because the female body uses natural progesterone to make natural estrogen, a properly formulated natural progesterone cream is the natural safe choice for menstruating women and for post-menopausal women seeking to establish the correct balance of their two primary female hormones.

This balance of Natural Progesterone and Natural Estrogens will protect them from the effects of the condition known as “Estrogen Dominance”.*

The resultant Benefits of natural progesterone include

* * *

Helps Protect Epithelial cells against Breast Cancer
Helps Prevent Endometrial Cancer
Helps prevent Ovarian Cysts and Ovarian Cancer

* * *

Stimulates Osteoblast Cells (Osteoporosis Reversal)

As you can see, natural progesterone counterbalances the effects of too much estrogen discussed here.

(Exhibit A at 5.)

- D. Bone tissue should be broken down and rebuilt continuously, just like all of the cells in our body. This process takes place when Osteoclasts help to dissolve old bone tissue, while osteoblasts stimulate new bone growth. Because estrogen has a rate limiting effect on Osteoclasts,

Complaint

Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function).

Natural progesterone, on the other hand, stimulates osteoblast production which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis.**

Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density per year!!!

These results have not been found with any other form of hormone replacement therapy, prescription medication or dietary supplement!

Conclusion

Maintaining proper levels of natural progesterone, giving due attention to dietary choices, dietary calcium, managing stress and regular exercise are all vital components of strong, healthy bones.

(Exhibit A at 6.)

- E. Side Effects: There are no reports of any significant side effects or health problems associated with natural progesterone.

(Exhibit A at 8.)

Complaint

F. Dear Health & Science

I am 54 and have been using Serenity for Women for over 3 years now.

Recently, I had my first bone density test. I was very scared because I had a number of risk factors for osteoporosis. The results of my test?

Bones of a 25 year old!

My Doctor had never seen such a high rating for someone my age.

I am amazed!

(Exhibit A at 10.)

- G. Because estrogen has a rate limiting effect on Osteoclasts, Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function). Natural progesterone, on the other hand, stimulates osteoblast bone cell activity which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis. **** Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!**

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density per year!!! These results have not been found with any other form of hormone replacement therapy or dietary supplementation!...

Complaint

Vital, necessary factors for the maintenance of strong, healthy bones are:

§ Maintaining proper levels of natural progesterone;

* * *

(Exhibit A at 11-12.)

- H. It is also important that we distinguish Natural Progesterone from Yam extract and from its counterparts in the drug industry - PROGESTINS. Although these drugs are commonly referred to as progesterone, this is a misnomer. In some ways they mimic the effects of progesterone in the body, but in other important ways they gravely interfere with natural progesterone and can create and exacerbate hormone related health problems, and be a primary contributor to the condition referred to as Estrogen Dominance:

* * *

Increased Risk of Breast Cancer

* * *

Increased Risk of Endometrial Cancer

Increased Risk of Uterine Cancer

* * *

When the above list of ill-effects is compared to the benefits of Natural Progesterone, we see a nearly one-to-one correlation.

(Exhibit A at 13.)

- I. Dr. John Lee, of California, U.S.A., used natural progesterone creams in his practice for 19 years. He states

Complaint

in his books that natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.

(Exhibit A at 15.)

- J. The more natural method of raising progesterone levels is free from side-effects. This has been well documented by the high rate of success reported by Dr. John R. Lee, M.D., using Transdermal Natural Progesterone in his practice for approximately 19 years and the success reported to the *Health & Science Research Institute* from thousands of women around the world.

Finally, oral progesterone will produce a sharp rise in serum progesterone levels followed by a rapid drop within about an hour. Progesterone administered via a properly formulated progesterone cream will raise systemic progesterone levels for eleven or twelve hours. This offers informed women continual and stable progesterone levels which may play a critical role in the prevention of female specific cancers, the amelioration of the symptoms of PMS & Menopause, the ability to get and stay pregnant, and the reversal of Osteoporosis. (Bone loss in women who live in industrialized countries begins, on average, at age 35).

In thirty years of clinical practice, seventeen recommending transdermal natural progesterone, Dr. Lee has observed the **consistent benefits** and safety of natural progesterone therapy.

(Exhibit A at 19.)

- K. Natural Transdermal Progesterone Cream, applied topically to the face, neck, arms, chest and fatty tissue areas of the body such as the breasts, the abdominal area, the buttocks, the inner thighs, etc., is stored in these fatty tissues for use as required by the body and has been shown to reverse the effects of Estrogen Dominance listed below:

Complaint

* * *

Increased Risk of Breast Cancer
Increased Risk of Ovarian Cancer
Increased Risk of Endometrial Cancer
Restraint of Osteoclast Function (bone loss)

* * *

It is also important that we distinguish Natural Progesterone from its counterparts in the drug industry - PROGESTINS. Although these drugs are commonly referred to as Progesterone, this is a misnomer.

In some ways they mimic the effects of Natural Progesterone in the body, but in other important ways they gravely interfere with Natural Progesterone and can create and exacerbate hormone related health problems, and be a primary contributor to Estrogen Dominance.

(Exhibit A at 20.)

- L. Serenity for Women has been carefully formulated for women who suffer with the unpleasant symptoms of Menopause & PMS, and who are experiencing the conditions of Infertility and Osteoporosis.

(Exhibit A at 23.)

- M. When faced with decisions on critically important issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility and osteoporosis, informed women demand and deserve the finest cream available anywhere in the world.

Serenity for Women, Certified Potency, Natural Progesterone Cream

(Exhibit A at 24.)

Complaint

N. Dear Health & Science,

I used the Serenity cream for over four months after I was diagnosed with abnormal Endometrial cells.

My Doctor insisted I get a hysterectomy. His reasoning that I was 48 years old, had three children, no plans for more and the cells could end up cancerous. I told him I wanted to use the cream for a few months and then have another biopsy. He became quite angry with me saying "Why don't you just do what I say?!" and he went on to say that the cream could not be regulated and would not help me.

Before the biopsy this first doctor had recommended HRT for me.

Needless to say, I switched to another doctor. When I investigated on the internet I found out about Serenity. I used it for over 4 months and then my new doctor did a D&C. She said we will try it but 95% of the cases are the same - but maybe we will have a miracle.

Well, we did - **my cells were all 100% normal.**

So I am very grateful to Serenity for Women.

* * *

(Exhibit A at 25.)

- O. Estrogens (estradiol, estrone, estriol) are predominately female hormones, and in adults, they are important for maintaining the health of the reproductive tissues, breasts, skin and brain. Excessive estrogens can cause fluid retention, weight gain, migraines and over stimulation of the breasts, ovaries and uterus, leading to cancer, endometriosis, polycystic ovaries, uterine fibroid tumors.

Complaint

* * *

Most scientists now agree that by-products of estrogen metabolism are the cause of breast cancer, ovarian cancer and prostate cancer.

Progesterone is a hormonal balancer, particularly of estrogens. It enhances the beneficial effect of estrogens while preventing the problems associated with estrogen excess. . .

* * *

All of the research we have reviewed, the many years of clinical experience of Dr. John Lee (California, USA) and the six years clinical experience we have with tens of thousands of women worldwide cause us to conclude that natural progesterone is safe and free of side effects (when administered topically) and addresses the underlying causes of many hormone related health problems that plague women, including infertility, polycystic Ovaries and ovarian cancer.

(Exhibit A at 26-27.)

- P. A commonality of the worlds' industrialized societies is the prevalence of uterine fibroids, fibrocystic breast disease, breast and/or uterine cancer, PMS, pre-menopausal bone loss as well as a high incidence of post-menopausal osteoporosis.

* * *

Because natural progesterone is the biological precursor for the production of natural estrogen, it is the natural choice for menopausal women as well as for pre-menopausal women to enjoy optimal health, free of the

Complaint

risks and side effects associated with synthetic hormones. Additionally, natural progesterone will stimulate the body's natural bone building cells (osteoblasts), offer significant protection against stroke and heart disease and benefit virtually every cell and organ of the body.

* * *

Natural Progesterone has been found to be safe and effective when applied topically, in a cream formula free from petrochemicals and animal by-products.

(Exhibit A at 28.)

Q. There are no reports of any significant side effects or health problems associated with natural progesterone when it is administered in a properly formulated Natural Progesterone Cream.

(Exhibit A at 30.)

R. According to Dr. Stanley West, Chief Endocrinologist at St. Vincent's Hospital in New York, U.S, 90% of the hysterectomies performed in the United States each year are unnecessary surgery. According to Dr. John Lee those women who are told that they have "pre-cancerous" cells after a gynecological exam, need only supplement with a properly formulated natural progesterone cream and implement the known dietary/lifestyle modifications, and the so called "pre-cancerous" cells will diminish along with the need for surgery.

(Exhibit A at 32.)

9. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that:

A. Serenity for Women Natural Progesterone Cream is effective in preventing, treating, or curing osteoporosis;

Complaint

B. Serenity for Women Natural Progesterone Cream is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. Serenity for Women Natural Progesterone Cream does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, Respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. Through the means described in Paragraphs 7 and 8, Respondents have represented, expressly or by implication, that clinical testing proves that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis.

13. In truth and in fact, clinical testing does not prove that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

14. The acts and practices 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.

Complaint

THEREFORE, the Federal Trade Commission, on this thirteenth day of November, 2007, has issued this complaint against respondents.

By the Commission.

Complaint

Exhibit A

NATURAL PROGESTERONE AND WOMEN'S HEALTH :: HEALTH-SCIENCE.COM ::

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Estrogen, Progesterone And Breast Cancer

Does Progesterone or Estrogen increase or decrease my risk for cancer?
Molecular biologist, Dr. Ben Formby of Copenhagen, Denmark and Dr. T.S. Wiley at the University of California in Santa Barbara have researched two genes, BCL2 and P53, and their effect on female-specific cancers and prostate cancer.

Cells of breast, endometrium, ovary and prostate, were grown in the laboratory. Estrogen (estradiol) was added to the cells. This hormone turned on the BCL2 gene, causing the cells to grow rapidly and not die. Then, progesterone was added to the cell cultures. Cell reproduction stopped and the cells died on time (apoptosis).

This methodology was applied to all the above types of cancer. The BCL2 gene, therefore, stimulates the growth of these cells and the risk of cancer. On the other hand, the P53 gene promotes apoptosis or programmed cell death and thereby, reduces the risk of cancer. Estradiol upregulates or stimulates the production of the BCL2 gene, while progesterone upregulates or stimulates the production of the P53 gene.

Therefore natural progesterone decreases the risk for several types of cancer, while unopposed estradiol causes these same types of cancer. Since Breast cancer is considered to be a hormone dependent cancer it is critically important to maintain optimal levels of natural progesterone and avoid the factors that would promote too much estradiol.


Are Birth Control Pills Safe?
In order for natural progesterone to stimulate the production of the P53 gene it must attach itself to progesterone receptors found in abundance in breast, ovarian, and endometrial cells. If a woman is taking birth control pills or any other form of synthetic progesterones (progestins, progesterone acetate, medroxy-progesterone acetate) these synthetic progesterones will occupy progesterone receptors and prevent natural progesterone from occupying the receptor site. Synthetic progesterones not only fail to produce the P53 gene but prevent it's production by blocking natural progesterone from occupying the progesterone receptor and in the presence of excess estradiol, dramatically increase a woman's risk for female-specific cancers.

There are 12 references to tests on BCL2 and P53, and how they are affected by progesterone & estrogen. This information has been published, in part, in the following journals:


- The American Cancer Society Journal
- The Journal of Clinical Endocrinology
- The American Journal of Pathology
- International Journal of Cancer
- The Journal of the American Medical Association (JAMA)
- Fertility and Sterility - Journal of the American Society For Reproductive Medicine

Clearly the underlying causes of breast cancer are too much estrogen relative to too little natural progesterone, especially in the presence of trans fatty acids (hydrogenated fats).


"When faced with decisions on critically important health issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility & osteoporosis, Informed Women demand and deserve the finest natural progesterone cream formula available anywhere in the world "Serenity for Women Certified Potency Progesterone Cream."



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Osteoporosis



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LAWSON, KUGLER AND DICKSON :: HEALTH-SCIENCE.COM ::

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What Is Progesterone?

Progesterone is the single most important hormone made by the female body. It is critically important for the health of virtually every cell and organ of the body.


Because progesterone is a master hormone, it is used as a precursor for the production of other important hormones, such as estrogen and cortisone.

Progesterone production, however, can be suppressed by environmental antagonists, such as the hormones found in most commercially grown meats & dairy products, pesticides, petro-chemicals, prescription hormones and stress.

Informed women have restored progesterone levels by removing these environmental antagonists, successfully managing stress, implementing a high fiber diet and consistent use of a properly formulated natural progesterone cream.


Some of the other benefits of Natural Progesterone can be accessed from the Natural Progesterone Page!

The molecule for Natural Progesterone looks like this:




Natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.

SAFE PROGESTERONE



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Natural Progesterone

Natural progesterone is made by the ovaries prior to menopause and by the adrenal glands and fat cells after menopause and is the precursor for natural estrogen. It is the single most important hormone in the female body. [\[+\] More](#)

When the female body fails to produce enough progesterone between ovulation and menstruation and during menopause, natural transdermal progesterone cream can address the underlying cause of most symptoms.


Because the female body uses natural progesterone to make natural estrogen, a properly formulated natural progesterone cream is the natural safe choice for menstruating women and for post-menopausal women seeking to establish the correct balance of their two primary female hormones.

This balance of Natural Progesterone and Natural Estrogens will protect them from the effects of the condition known as "Estrogen Dominance".*


The resultant benefits of natural progesterone include

- Helps Use Fat for Energy
- Facilitates Thyroid Hormone Action
- Natural Anti-depressant
- Natural Diuretic
- Normalizes Blood Sugar Levels
- Restores Proper Cell Oxygen Levels
- Restores Libido
- Normalizes Menstrual Cycles
- Normalizes Zinc & Copper Levels
- Normalizes Blood Clotting
- Protects Against Breast Fibrocysts
- Helps Protect Epithelial cells against Breast Cancer
- Helps Prevent Endometrial Cancer
- Helps prevent Ovarian Cysts and Ovarian Cancer
- Precursor for Cortisone Production (Arthritis)
- Stimulates Osteoblast Cells (Osteoporosis Reversal)


As you can see, natural progesterone counterbalances the effects of too much estrogen discussed here.



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Osteoporosis & Natural Progesterone

Osteoporosis is a disorder in which progressive bone mass loss and demineralization increase ones risk of fracture. This condition permits us to observe how prescription progestins and estrogens compare to Natural Progesterone.

The standard medical protocol for osteoporosis is to use estrogen, (commonly synthesized from pregnant mare's urine), in spite of the fact that the most authoritative medical textbooks do not support it.

The following article illustrates:

"Estrogens decrease bone resorption" but "associated with the decrease in bone resorption is a decrease in bone formation. Therefore, estrogens should not be expected to increase bone mass."**

Scientific American's Updated Medicine Text, 1991.

Bone tissue should be broken down and rebuilt continuously, just like all of the cells in our body. This process takes place when Osteoclasts help to dissolve old bone tissue, while osteoblasts stimulate new bone growth. Because estrogen has a rate limiting effect on Osteoclasts, Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function).

Natural progesterone, on the other hand, stimulates osteoblast production which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis.**

Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density per year!!!

These results have not been found with any other form of hormone replacement therapy, prescription medication or dietary supplement!

Conclusion

Maintaining proper levels of natural progesterone, giving due attention to dietary choices, dietary calcium, managing stress and regular exercise are all vital components of strong, healthy bones.

- Osteoporosis & Calcium
- Read what some of our visitors have written
- Some Observations from Medical Doctors



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Suggested Use Of Natural Progesterone Cream

Progesterone is very well absorbed transdermally (through the skin) where it is stored in the fatty tissues for use as needed and unlike progesterone taken orally, it is not subject to being intercepted by the liver. For those women who are especially deficient in progesterone, it may take three to twelve months to restore optimal levels. For men with prostate disorders results may be felt within one or two days, but long term benefits may require six months.

In the morning and at bedtime, the cream should be gently massaged by the palms of the hands to areas of the body where one blushes: the face, neck, chest, upper arms and other areas of the body that may benefit from progesterone, e.g. breasts, abdomen, back of neck.

Serenity for Women is a Certified Potency Cream that contains not less than 1,260 mg. of Natural Progesterone per (60 grams) 2.1 ounces. Informed women have chosen a procedure that is in the following paragraph.

PMS & Infertility

Begin using crème 12 days from the first day of menstruation. Use approximately 1/8 teaspoon twice per day (morning and at bedtime). Stop using the cream on day 26. Women with more severe PMS or endometriosis have chosen to initially use twice the suggested amount of cream (1/4 teaspoon twice daily) for the first one or two months. In addition, women who experience uterine cramping have chosen to apply the cream just above the pubic area at the onset of cramps. Women who experience hormone related headaches have applied the cream to the sides of the neck and just behind the earlobe, at the onset of headaches.

Menopause or Post Hysterectomy

The crème should be applied 24 days out of the month and then discontinued for 6-7 days. Apply 1/8 teaspoon twice per day morning and at bedtime for all 24 days. Women who have severe menopausal symptoms have chosen to initially apply twice as much cream (1/4 teaspoon twice daily) for the first one or two months. In addition, women who are experiencing hot flashes have chosen to apply a small dab of the cream to the inside of the wrist at the onset of a hot flash. For those few women who still experience hot flashes, night sweats and/or vaginal dryness a natural estriol cream can be safely used for several months.

Osteoporosis

The cream should be applied 24 days of the month and then discontinued for 6-7 days. Apply 1/8 teaspoon twice per day morning and at bedtime for all 24 days.

Informed Men have used Serenity 1/16th of a teaspoon at bedtime, 24 days per month.

Side Effects: There are no reports of any significant side effects or health problems associated with natural progesterone.

A few women may experience temporarily experience an increase in the symptoms caused by too much estrogen such as incidental spotting and/or swelling of the breasts. This is normally alleviated within a few days or weeks with the normalizing of hormone levels.

Any persistent problems should always be checked by a qualified physician.



Premature Birth



Osteoporosis



Infertility

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Osteoporosis Prevention

Dear Health & Science

I am 54 and have been using Serenity for Women for over 3 years now.

Recently, I had my first bone density test. I was very scared because I had a number of risk factors for osteoporosis. The results of my test?

Bones of a 25 year old!

My Doctor had never seen such a high rating for someone my age.

I am amazed!

Barbara McCrady
 Maine, U.S.



Premature Birth



Osteoporosis



Infertility

Fibrocystic Breast Disease

Dear Health & Science,

I want to congratulate you on the production of Serenity for Women, Natural Progesterone Cream.

Although I had tried other "natural progesterone" creams in the past, Serenity for Women has been, by far, the most effective, consistent, and reliable one for the symptoms I was experiencing.

It has virtually stopped my hot flashes, eliminated the pain and swelling I had from cystic breasts, and even stabilized my moods!

Truly, this one product has made this time of my life much smoother and easier. I wish I had it 20 years ago!

On behalf of my husband and myself, a hearty, Thank You!

Yours Truly,
 Sandra Thomas,
 Registered Nurse
 Naturopathic Doctor
 New Hampshire, U.S.

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Calcium And Osteoporosis

Bone Architecture

Bone structure is made up of calcium and phosphorous crystals embedded in a framework of interlocking protein fibers. Hydroxyapatite (Bone-Up™) is the form of calcium found in human bone tissue and is the predominant structural form of calcium. It is responsible for 67% of the total bone weight, the remaining 33% being composed by collagen fibers (Rheumatol Forte™).

The mineral crystals give the bone hardness, strength and rigidity. The collagen fibers impart flexibility. Magnesium, fluoride, sodium, potassium, citrate and other trace elements act as a "mortar" that bonds the calcium phosphorous crystals.

The hormone calcitonin from the thyroid gland triggers the deposition of calcium by the osteoblast (bone building) cells while parathyroid hormone (parathormone) releases calcium from the osteoclast bone cells.

Vitamins compose 1% of our total body weight, minerals 4% and calcium and phosphorous account for 75% of mineral weight. 99% of all calcium is in the bone and teeth with the remaining 1% in the blood and soft tissues. The average adult contains 1,000-1,200 grams of calcium or 2.2-2.6 pounds.

Osteoporosis Defined

Although the percent of circulating calcium is relatively minute, the body's homeostatic mechanism will continuously cause the bones to release calcium into the bloodstream in order to maintain proper blood levels. So, while serum levels of calcium can test normal, in the absence of sufficient available dietary calcium, bone loss can be significant, this process being a primary cause of osteoporosis.

Between 2-4% of a person's skeleton is dissolved and rebuilt annually. This process is implemented by the osteoclast and osteoblast bone cells. Poor nutrition and a suppression of progesterone levels due to stress and other environmental antagonists result in a suppression of the osteoblast bone cell function, in spite of the fact that osteoclast cells continue to dissolve old bone tissue. This condition, especially when there is a loss of collagen, also results in osteoporosis.

In the U.S. more than one million fractures occur annually in women 45 years or older, 70% of whom are diagnosed with osteoporosis. Hip fractures carry a mortality rate of 12-15% and are the second leading cause of death in people 47-74 years of age. Of the 190,000 hip fractures that occur annually, 2/3 are due to osteoporosis which costs the U.S. \$5 billion each year. Post-menopausal women lose 0.7% to 2.0% of their bone per year; men lose 0.3%-0.7%. Between the ages of 45 to 70, women lose 30% of their skeletal structure and men lose 15%. Calcium supplementation of 1,000-1,500 mg. per day for persons who consume a high protein diet and 500-750 mg. per day for vegetarians can reduce fracture rates by 50%.

Hormonal Influences

Because estrogen has a rate limiting effect on Osteoclasts, Estrogen Dominance delays the breakdown of bone tissue but does not support bone building (osteoblast function). Natural progesterone, on the other hand, stimulates osteoblast bone cell activity which results in new bone tissue growth. Consequently, estrogens only slow down bone loss, not promote the formation of new bone tissue.

Osteoporosis Research

The efficacy of natural progesterone is verified by a three year study of 63 post-menopausal women with osteoporosis. **** Women using transdermal progesterone cream experienced an average 7-8% bone mass density increase the first year, 4-5% the second year and 3-4% the third year!**

Untreated women in this age category typically lose 0.7% to 2.0% bone mineral density

Weight Loss

Dietary Consideration

Hot Flashes

Complaint

Calcium and Osteoporosis .. HUGOBONIC.COM ..

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per year!!! These results have not been found with any other form of hormone replacement therapy or dietary supplementation! Conclusion

Vital, necessary factors for the maintenance of strong, healthy bones are:

1. Maintaining proper levels of natural progesterone;
2. Giving due attention to dietary choices;
3. Maintaining Optimal Levels of Friendly Bacteria (Vitamin K), Vitamin D and Calcium;
4. Learn to successfully manage stress.
5. Regular exercise (30-45 minutes four or five days per week).

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Estrogen Dominance


Natural progesterone is produced by the corpus luteum after ovulation and balances the side effects of otherwise unopposed estrogen.

Under influences of anovulatory cycles, menopause, stress and dietary antagonists, progesterone production ceases or is suppressed and the effects of Estrogen Dominance, can be observed. Many women experience otherwise unexplained weight gain from the lack of progesterone that is required for proper thyroid function.*


It is also important that we distinguish Natural Progesterone from Yam extract and from its counterparts in the drug industry - PROGESTINS. Although these drugs are commonly referred to as progesterone, this is a misnomer. In some ways they mimic the effects of progesterone in the body, but in other important ways they gravely interfere with natural progesterone and can create and exacerbate hormone related health problems, and be a primary contributor to the condition referred to as Estrogen Dominance:

- Increased Body Fat
- Interference with Thyroid Hormone Activity (hypo-thyroid)
- Depression & Headaches
- Salt and Water Retention
- Blood Sugar Irregularities (Food Cravings)
- Reduced Oxygen In All Cells
- Decreased Libido (Sex Drive)
- Loss of Zinc and Retention of Copper
- Excessive Blood Clotting
- Increased Risk of Breast Cancer
- Reduced Vascular Tone
- Increased Risk of Endometrial Cancer
- Endometriosis
- Uterine Cramping
- Infertility
- Increased Risk of Uterine Cancer


When the above list of ill-effects is compared to the benefits of Natural Progesterone, we see a nearly one-to-one correlation.




Weight Loss



Hot Flashes



Osteoporosis



Premature Birth

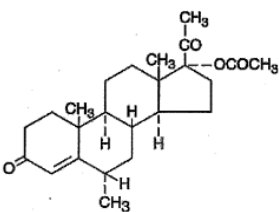
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PROVERA (medroxyprogesterone acetate) ... 1061061061.COM

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The Informed Woman Overview Breast Cancer Depression Estrogen Dominance Fertility Hot Flashes Insomnia Libido Menopause Migraines Osteoporosis Ovarian Cancer PMS Learn More Brain Function & Aging Diet/Lifestyle Fluoride Toxicity And Osteoporosis Infertility Intestinal Health Microwave Hazards Synthetic-Progesterone Tissue Cleansing	<p>Following are Contraindications, Warnings, Precautions, and Adverse Reactions published by the manufacturer of</p> <p>"Synthetic Progesterone" (medroxy-progesterone acetate)</p> <p>Provera (Medroxyprogesterone Acetate, Progestins)</p> <p>Warning: The use of Medroxyprogesterone Acetate during the first four months of pregnancy is NOT recommended. Progestational agents have been used beginning with the first trimester of pregnancy in an attempt to prevent habitual abortion. There is no adequate evidence that such use is effective when such drugs are given during the first four months of pregnancy. Furthermore, in the vast majority of women, the cause of abortion is a defective ovum, which progestational agents could not be expected to influence. In addition, the use of progestational agents, with their uterine-relaxant properties, in patients with fertilized defective ova may cause a delay in spontaneous abortion. Therefore, the use of such drugs during the first four months of pregnancy is not recommended.</p> <p>Several reports suggest an association between intrauterine exposure to progestational drugs in the first trimester of pregnancy and genital abnormalities in male and female fetuses. The risk of hypospadias, 5 to 8 per 1,000 male births in the general population, may be approximately doubled with exposure to these drugs. There are insufficient data to quantify the risk to exposed female fetuses, but insofar as some of these drugs induce mild virilization of the external genitalia of the female fetus, and because of the increased association of hypospadias in the male fetus, it is prudent to avoid the use of these drugs during the first trimester of pregnancy.</p> <p>If the patient is exposed to PROVERA Tablets (medroxyprogesterone acetate) during the first four months of pregnancy or if she becomes pregnant while taking this drug, she should be apprised of the potential risks to the fetus.</p> <p>Description PROVERA Tablets contain medroxyprogesterone acetate, which is a derivative of progesterone. It is a white to off-white, odorless crystalline powder, stable in air, melting between 200 and 210 C. It is freely soluble in chloroform, soluble in acetone and in dioxane, sparingly soluble in alcohol and in methanol, slightly soluble in ether, and insoluble in water.</p> <p>The chemical name for medroxyprogesterone acetate is Pregn-4-ene-3,20-dione, 17-(acetyloxy)-6-methyl-, (6a)-. The structural formula is:</p>  <p>Each PROVERA tablet for oral administration contains 2.5 mg, 5 mg or 10 mg of medroxy-progesterone acetate. Inactive ingredients: calcium stearate, corn starch, lactose, mineral oil, sorbic acid, sucrose, talc. The 2.5 mg tablet contains FD&C Yellow</p>

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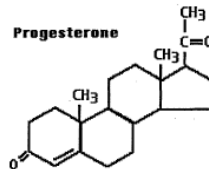
A 10106 (PROGESTERONE) PROGESTERONE ACETATE/... AUGUST 1980/COM ...

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no. 6.

The information contained in the box only is not from the manufacturer of synthetic progesterone

Contrastingly, the molecule for Natural Progesterone looks like this:



This is the molecule made by the female body and the exact same molecule found in a properly formulated natural progesterone cream. Dr. John Lee, of California, U.S.A., used natural progesterone creams in his practice for 19 years. He states in his books that natural progesterone is remarkably safe and free of side-effects when administered in a proper cream formulation.

Actions

Medroxyprogesterone acetate, administered orally or parenterally in the recommended doses to women with adequate endogenous estrogen, transforms proliferative into secretory endometrium. Androgenic and anabolic effects have been noted, but the drug is apparently devoid of significant estrogenic activity. While parenterally administered medroxyprogesterone acetate inhibits gonadotropin production, which in turn prevents follicular maturation and ovulation, available data indicate that this does not occur when the usually recommended oral dosage is given as single daily doses.

Indications and usage

Secondary amenorrhea; abnormal uterine bleeding due to hormonal imbalance in the absence of organic pathology, such as fibroids or uterine cancer.

Contraindications for Medroxyprogesterone Acetate

1. Thrombophlebitis, thromboembolic disorders, cerebral apoplexy or patients with a past history of these conditions.
2. Liver dysfunction or disease.
3. Known or suspected malignancy of breast or genital organs.
4. Undiagnosed vaginal bleeding. 5. Missed abortion.
5. As a diagnostic test for pregnancy.
6. Known sensitivity to PROVERA Tablets.

Warnings for Medroxyprogesterone Acetate

1. The physician should be alert to the earliest manifestations of thrombotic disorders (thrombophlebitis, cerebrovascular disorders, pulmonary embolism, and retinal thrombosis). Should any of these occur or be suspected, the drug should be discontinued immediately.
2. Beagle dogs treated with medroxyprogesterone acetate developed mammary nodules some of which were malignant. Although nodules occasionally appeared in control animals, they were intermittent in nature, whereas the nodules in the drug-treated animals were larger, more numerous, persistent, and there were some breast malignancies with metastases. Their significance with respect to humans has not been established.
3. Discontinue medication pending examination if there is sudden partial or complete loss of vision, or if there is a sudden onset of proptosis, diplopia or migraine. If examination reveals papilledema or retinal vascular lesions, medication should be withdrawn.
4. Detectable amounts of progestin have been identified in the milk of mothers

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receiving the drug. The effect of this on the nursing infant has not been determined.

5. Usage in pregnancy is not recommended (See WARNING Box).
6. Retrospective studies of morbidity and mortality in Great Britain and studies of morbidity in the United States have shown a statistically significant association between thrombophlebitis, pulmonary embolism, and cerebral thrombosis and embolism and the use of oral contraceptives.¹⁻⁴ The estimate of the relative risk of thromboembolism in the study by Vessey and Doll³ was about sevenfold, while Sartwell and associates⁴ in the United States found a relative risk of 4.4, meaning that the users are several times as likely to undergo thromboembolic disease without evident cause as nonusers. The American study also indicated that the risk did not persist after discontinuation of administration, and that it was not enhanced by long continued administration. The American study was not designed to evaluate a difference between products.

Precautions for Medroxyprogesterone Acetate

1. The pretreatment physical examination should include special reference to breast and pelvic organs, as well as Papanicolaou smear.
2. Because progestogens may cause some degree of fluid retention, conditions which might be influenced by this factor, such as epilepsy, migraine, asthma, cardiac or renal dysfunction, require careful observation.
3. In cases of breakthrough bleeding, as in all cases of irregular bleeding per vaginum, nonfunctional causes should be borne in mind. In cases of undiagnosed vaginal bleeding, adequate diagnostic measures are indicated.
4. Patients who have a history of psychic depression should be carefully observed and the drug discontinued if the depression recurs to a serious degree.
5. Any possible influence of prolonged progestin therapy on pituitary, ovarian, adrenal, hepatic or uterine functions awaits further study.
6. A decrease in glucose tolerance has been observed in a small percentage of patients on estrogen-progestin combination drugs. The mechanism of this decrease is obscure. For this reason, diabetic patients should be carefully observed while receiving progestin therapy.
7. The age of the patient constitutes no absolute limiting factor although treatment with progestins may mask the onset of the climacteric.
8. The pathologist should be advised of progestin therapy when relevant specimens are submitted.
9. Because of the occasional occurrence of thrombotic disorders, (thrombophlebitis, pulmonary embolism, retinal thrombosis, and cerebrovascular disorders) in patients taking estrogen-progestin combinations and since the mechanism is obscure, the physician should be alert to the earliest manifestation of these disorders.
10. Studies of the addition of a progestin product to an estrogen replacement regimen for seven or more days of a cycle of estrogen administration have reported a lowered incidence of endometrial hyperplasia. Morphological and biochemical studies of endometrium suggest that 10-13 days of a progestin are needed to provide maximal maturation of the endometrium and to eliminate any hyperplastic changes. Whether this will provide protection from endometrial carcinoma has not been clearly established. There are possible additional risks which may be associated with the inclusion of progestin in estrogen replacement regimen. The potential risks include adverse effects on carbohydrate and lipid metabolism. The dosage used may be important in minimizing these adverse effects.
11. Aminoglutethimide administered concomitantly with PROVERA may significantly depress the bioavailability of PROVERA.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term intramuscular administration of PROVERA has been shown to produce mammary tumors in beagle dogs (see WARNINGS). There was no evidence of a carcinogenic effect associated with the oral administration of PROVERA to rats and mice. Medroxyprogesterone acetate was not mutagenic in a battery of in vitro or in vivo genetic toxicity assays.

Medroxyprogesterone acetate at high doses is an antifertility drug and high doses would be expected to impair fertility until the cessation of treatment.

Adverse reactions to Medroxyprogesterone Acetate

Pregnancy-(See WARNING Box for possible adverse effects on the fetus).

Breast-Breast tenderness or galactorrhea has been reported rarely. Skin-Sensitivity reactions consisting of urticaria, pruritus, edema and generalized rash have occurred in an occasional patient. Acne, alopecia and hirsutism have been reported in a few cases.

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... PROVERA Tablets ...

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Thromboembolic Phenomena-Thromboembolic phenomena including thrombophlebitis and pulmonary embolism have been reported.

The following adverse reactions have been observed in women taking progestins including PROVERA Tablets: breakthrough bleeding, spotting, change in menstrual flow, amenorrhea, edema, change in weight (increase or decrease), changes in cervical erosion and cervical secretions, cholestatic jaundice, anaphylactoid reactions and anaphylaxis, rash (allergic) with and without pruritus, mental depression, pyrexia, insomnia, nausea, somnolence.

A statistically significant association has been demonstrated between use of estrogen-progestin combination drugs and the following serious adverse reactions: thrombophlebitis; pulmonary embolism and cerebral thrombosis and embolism. For this reason patients on progestin therapy should be carefully observed.

Although available evidence is suggestive of an association, such a relationship has been neither confirmed nor refuted for the following serious adverse reactions: neuro-ocular lesions, eg, retinal thrombosis and optic neuritis.

The following adverse reactions have been observed in patients receiving estrogen-progestin combination drugs: rise in blood pressure in susceptible individuals, fatigue, backache, hirsutism, premenstrual-like syndrome, loss of scalp hair, erythema multiforme, changes in libido, erythema nodosum, changes in appetite, hemorrhagic eruption, cystitis-like syndrome, headache, itching, nervousness, dizziness.

In view of these observations, patients on progestin therapy should be carefully observed.

The following laboratory results may be altered by the use of estrogen-progestin combination drugs: Increased sulfobromophthalein retention and other hepatic function tests. Coagulation tests: Increase in prothrombin factors VII, VIII, IX and X. Metyrapone test. Pregnanediol determination. Thyroid function: Increase in FBI, and butanol extractable protein bound iodine and decrease in T3 uptake values.

Dosage and administration for Medroxyprogesterone Acetate

Secondary Amenorrhea-PROVERA Tablets may be given in dosages of 5 to 10 mg daily for from 5 to 10 days. A dose for inducing an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen is 10 mg of PROVERA daily for 10 days. In cases of secondary amenorrhea, therapy may be started at any time. Progestin withdrawal bleeding usually occurs within three to seven days after discontinuing PROVERA therapy.

Abnormal Uterine Bleeding Due to Hormonal Imbalance in the Absence of Organic Pathology-Beginning on the calculated 16th or 21st day of the menstrual cycle, 5 to 10 mg of medroxyprogesterone acetate may be given daily for from 5 to 10 days. To produce an optimum secretory transformation of an endometrium that has been adequately primed with either endogenous or exogenous estrogen, 10 mg of medroxyprogesterone acetate daily for 10 days beginning on the 16th day of the cycle is suggested. Progestin withdrawal bleeding usually occurs within three to seven days after discontinuing therapy with PROVERA. Patients with a past history of recurrent episodes of abnormal uterine bleeding may benefit from planned menstrual cycling with PROVERA.

How supplied

PROVERA Tablets are available in the following strengths and package sizes:

- 2.5 mg (scored, round, orange)
- Bottles of 30 NDC 0009-0064-06
- Bottles of 100 NDC 0009-0064-04
- 5 mg (scored, hexagonal, white)
- Bottles of 30 NDC 0009-0286-32
- Bottles of 100 NDC 0009-0286-03
- 10 mg (scored, round, white)
- Bottles of 30 NDC 0009-0050-09
- Bottles of 100 NDC 0009-0050-02
- Bottles of 500 NDC 0009-0050-11
- DOSEPAK-3 Unit of Use (10) NDC 0009-0050-12

Store at controlled room temperature 15-30 C (59-86 F).

References

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2. Inman WHW, Vessey MP: Investigation of deaths from pulmonary, coronary, and cerebral thrombosis and embolism in women of child-bearing age. Br Med J 2:193-199, 1968.
3. Vessey MP, Doll R: Investigation of relation between use of oral contraceptives and thromboembolic disease. A further report. Br Med J 2:651-657, 1969.
4. Sartwell PE, Masi AT, Arthes FG, et al: Thromboembolism and oral contraceptives: An epidemiological case-control study. Am J Epidemiol 90:365-380, 1969.

Patient Information

PROVERA Tablets contain medroxyprogesterone acetate a synthetic progesterone.

The information below is that which the U.S. Food and Drug Administration requires be provided for all patients taking medroxyprogesterone acetates. The information below relates only to the risk to the unborn child associated with use of medroxyprogesterone acetate during pregnancy. For further information on the use, side effects and other risks associated with this product, ask your doctor or read the information.

WARNING FOR WOMEN

Medroxyprogesterone acetate or progesterone-like drugs have been used to prevent miscarriage in the first few months of pregnancy. No adequate evidence is available to show that they are effective for this purpose. Furthermore, most cases of early miscarriage are due to causes which could not be helped by these drugs.

There is an increased risk of minor birth defects in children whose mothers take this drug during the first 4 months of pregnancy. Several reports suggest an association between mothers who take these drugs in the first trimester of pregnancy and genital abnormalities in male and female babies. The risk to the male baby is the possibility of being born with a condition in which the opening of the penis is on the underside rather than the tip of the penis (hypospadias). Hypospadias occurs in about 5 to 8 per 1,000 male births and is about doubled with exposure to these drugs. There is not enough information to quantify the risk to exposed female fetuses, but enlargement of the clitoris and fusion of the labia may occur, although rarely.

Therefore, since drugs of this type may induce mild masculinization of the external genitalia of the female fetus, as well as hypospadias in the male fetus, it is wise to avoid using the drug during the first trimester of pregnancy.

These drugs have been used as a test for pregnancy but such use is no longer considered safe because of possible damage to a developing baby. Also, more rapid methods for testing for pregnancy are now available.

If you take PROVERA and later find you were pregnant when you took it, be sure to discuss this with your doctor as soon as possible.

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A TRADITIONAL AND SUCCESSFUL TREATMENT FOR PMS - PROGESTERONE.COM

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PMS - Traditional & Successful Treatments

Traditional PMS Treatments

Traditional treatments have included tranquilizers, diuretics, dietary changes, thyroid supplements, herbs, vitamins, exercise, acupuncture and psychiatric counseling. While these may provide some easing of **symptoms**, the underlying **causes** remain.

Successful Treatments


Dr. Joel T. Hargrove of Vanderbilt University Medical Center has seen some success in treating PMS with oral doses of natural progesterone.* The problem with oral progesterone administration, however, is that the liver intercepts approximately 90% of the hormone. So, in order to achieve a net dose of 20 mg. the typical dose prescribed is 200 mg. per day. The liver thus converts progesterone to progesterone metabolites, which work against natural hormone function.

The more natural method of raising progesterone levels is free from side-effects. This has been well documented by the high rate of success reported by Dr. John R. Lee, M.D., using Transdermal Natural Progesterone in his practice for approximately 19 years and the success reported to the *Health & Science Research Institute* from thousands of women around the world.


Finally, oral progesterone will produce a sharp rise in serum progesterone levels followed by a rapid drop within about an hour. Progesterone administered via a properly formulated progesterone cream will raise systemic progesterone levels for eleven or twelve hours. This offers informed women continual and stable progesterone levels which may play a critical role in the prevention of female specific cancers, the amelioration of the symptoms of PMS & Menopause, the ability to get and stay pregnant, and the reversal of Osteoporosis. (Bone loss in women who live in industrialized countries begins, on average, at age 35).

In thirty years of clinical practice, seventeen recommending transdermal natural progesterone, Dr. Lee has observed the **consistent benefits** and safety of natural progesterone therapy. He makes this statement:

"Though not completely understood, PMS most commonly represents an individual reaction to estrogen dominance, secondary to relative progesterone deficiency. Appropriate treatment requires correction of this hormone imbalance in conjunction with known dietary lifestyle modifications and the most effective technique, at present, for achieving this is supplemental Transdermal Natural Progesterone."**



Premature Birth



Hot Flashes



Weight Loss

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Libido & Natural Progesterone

The Female Body manufactures many types of Estrogen but only one Progesterone and Natural Progesterone is the Source of Libido or Sex Drive in Women!

Sources of Natural Progesterone

Natural Progesterone is normally produced by the female ovaries right after ovulation and balances the side effects of otherwise unopposed estrogen.

Under the Influences of dietary estrogens, petrochemicals, stress, and menopause, Progesterone production ceases or is suppressed and the effects of Estrogen Dominance, can be observed.

Most women experience Loss of Libido, mood swings, irritability, anger, depression, headaches and weight gain from the lack of Progesterone that is required for proper thyroid function.

Natural Transdermal Progesterone Cream, applied topically to the face, neck, arms, chest and fatty tissue areas of the body such as the breasts, the abdominal area, the buttocks, the inner thighs, etc., is stored in these fatty tissues for use as required by the body and has been shown to reverse the effects of Estrogen Dominance listed below:

<ul style="list-style-type: none"> • Increased Body Fat • Depression • Migraine Headaches • Blood Sugar Irregularities • Excessive Blood Clotting • Reduced Vascular Tone • Endometriosis • Infertility • Interference with Thyroid Function • Loss of Libido (Sex Drive) 	<ul style="list-style-type: none"> • Anger, Rage • Uterine Cramping • Water Retention • Loss of Zinc, Retention of Copper • Increased Risk of Breast Cancer • Increased Risk of Ovarian Cancer • Increased Risk of Endometrial Cancer • Restraint of Osteoclast Function (bone loss) • Reduced Oxygen in All Cells (Foggy Brain)
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It is also important that we distinguish Natural Progesterone from its counterparts in the drug industry - PROGESTINS. Although these drugs are commonly referred to as Progesterone, this is a misnomer.

In some ways they mimic the effects of Natural Progesterone in the body, but in other important ways they gravely interfere with Natural Progesterone and can create and exacerbate hormone related health problems, and be a primary contributor to Estrogen Dominance.


Traditional Treatments

Traditional treatments have included tranquilizers, diuretics, dietary changes, thyroid supplements, herbs, vitamins, exercise, acupuncture and psychiatric counseling. While these may provide some easing of symptoms, the underlying causes remain.


- Successful Treatments




Hot Flashes



Heart Health



Premature Birth



Dietary Consideration

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Are All "Progesterone" Creams The Same?

The task of selecting an effective "progesterone" cream can be a challenging one.

Women are bombarded by a constant supply of new companies selling "progesterone" creams, often times started by those who have no nutritional or health care experience. In a desperate attempt to generate income many of these companies will use marketing techniques that emphasize fantastic commission checks to their distributors, who, in their heightened state of about to be realized "financial independence", will tell the consumer almost anything.

Further, Many "popular creams" sold today contain little or no Progesterone USP, or contain inconsistent levels:

- Each 2 oz (57 g) pot of Pro-Gest® Cream (Emerita™) contains 200 mg of progesterone..
- This assay was done on tubes of Pro-Gest® cream purchased by mail over a period of 5 months! *The Lancet Medical Journal, (Volume 351, Number 9111, 25 April 1998)

Complicating matters is the fact that, at one time, one of the components of Yam (*Dioscorea villosa*), diosgenin, was believed to be converted in the female body to progesterone. In fact, in his first book, Dr. John Lee of California, U.S.A., states that diosgenin is probably converted to Progesterone. However, that has since been proven to be unsubstantiated and, in fact, in his current book, "What Your Dr. May Not Tell You About Menopause" on page 270, Dr. Lee states "...there is no evidence that the human body converts diosgenin to hormones."

Dr. David Zava, (PhD in Bio Endocrinology whose focus has been progesterone and estrogen receptor activity) is the laboratory director of Aeron Life Cycles, one of the foremost hormone testing facilities in the world. Dr. Zava has tested progesterone levels for many thousands of women and responded with the following: "In response to your question about wild yam steroids - do they convert into progesterone? The answer is no, there are no enzymes in the human body that will convert diosgenin, the active component of wild yams, into progesterone. This does not mean diosgenin is without activity in the body as it has been used by phytotherapists for centuries as an adaptogen."




So, when selecting a progesterone cream for the purpose of raising bio-available progesterone levels, the first criteria that must be met is that the cream must contain sufficient levels of USP Natural Progesterone and be a Certified Potency Cream! The cream must also be properly formulated. Second and equally as important, the consumer benefits by the selection of a company that is adequately staffed or owned by Health Care Consultants who are trained in natural, side-effect free approaches to optimal health.

Considering the normal healthy monthly female cycle, we observe, in response to ovulation, that progesterone levels increase from 2-3 mg. per day to 22-25 mg. per day for 12 to 14 days just prior to menstruation. Because there are many cream companies promoting a product that contains only a few milligrams of progesterone per ounce or none, those formulations are unable to have a positive effect on biologically available levels of progesterone.

Consequently, the typical response from women using a "yam cream" or a cream that does not have a certified potency has been:

- It seems to have helped a little, but it is not what I really need."

Conversely, women who use a properly formulated certified potency progesterone cream

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[REDACTED]

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and have applied the supplemental suggestions from a qualified Health Care Consultant, have stated:

- I have finally achieved relief from the symptoms I have endured for many years and I now experience a sense of well-being that I have not enjoyed since

Serenity for Women has been carefully formulated for women who suffer with the unpleasant symptoms of Menopause & PMS, and who are experiencing the conditions of Infertility and Osteoporosis. Used in conjunction with known Dietary-Lifestyle modifications, many thousands of women around the world (114 countries) have regained their health and control of their lives.




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Learn More Brain Function & Aging Diet/Lifestyle Fluoride Toxicity And Osteoporosis Infertility Intestinal Health Microwave Hazards Synthetic-Progesterone Tissue Cleansing	<p>Many "popular creams" sold today contain little or no Progesterone USP, or at best, have inconsistent levels of progesterone.</p> <p>"Each 2 oz (57 g) pot of Pro-Gest® cream (Emerita™) contains 200 mg of progesterone..." *</p> <p>(This assay was done on tubes of Pro-Gest® cream purchased by mail over a period of 5 months)</p> <p>*The Lancet Medical Journal, (Volume 351, Number 9111, 25 April 1998).</p> <p>Additionally, most creams, including those that claim to be "progesterone" creams are formulated with petrochemicals.</p> <p>When faced with decisions on critically important issues such as breast cancer, ovarian cancer, endometriosis, fibrocystic breast disease, migraine headaches, infertility and osteoporosis, informed women demand and deserve the finest cream available anywhere in the world.</p> <p>Serenity for Women, Certified Potency, Natural Progesterone Cream Other Products</p>
  	
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Ovarian,Cancer

Typically, lower fertilization rates are found in women who have polycystic ovaries rather than those with tubal disease or endometriosis. Increased levels of estrogen stimulate increased levels of testosterone and androgen (increased body hair). Increased androgen (hyper-androgenism) has been shown to be critical in the pathogenesis or development of polycystic ovaries and ovarian cancer.

Mechanisms by which androgens induce cyst formation, however, have not yet been elucidated. It has been hypothesized that ovarian androgen excess produces larger follicles and increased apoptosis, resulting in cyst formation and follicular atresia (death and regression of an ovarian follicle).

Hyper-androgenism, therefore, produces larger follicles and increased apoptosis. Apoptosis is the process by which a cell runs its life course and actively "commits suicide".

It is now well recognized that apoptosis is essential in many aspects of normal development and is required for maintaining tissue homeostasis. Failure to properly regulate apoptosis can have catastrophic consequences. Cancer and many diseases (AIDS, Alzheimer's disease, Parkinson's disease, heart attack, stroke, etc.) are thought to arise from deregulation of apoptosis.

The basic roles, therefore, performed by estrogen and progesterone are

Estrogens (estradiol, estrone, estriol) are predominately female hormones, and in adults, they are important for maintaining the health of the reproductive tissues, breasts, skin and brain. Excessive estrogens can cause fluid retention, weight gain, migraines and over stimulation of the breasts, ovaries and uterus, leading to cancer, endometriosis, polycystic ovaries, uterine fibroid tumors. Insufficient estrogen levels or fluctuations of estrogen can lead to hot flushes, vaginal dryness, rapid skin aging, urinary problems, excessive bone loss and possible acceleration of dementia. An excess of estrogen, relative to testosterone, is thought to play a role in the development of prostate problems in men. Most scientists now agree that by-products of estrogen metabolism are the cause of breast cancer, ovarian cancer and prostate cancer.

Progesterone is a hormonal balancer, particularly of estrogens. It enhances the beneficial effect of estrogens while preventing the problems associated with estrogen excess, which includes Polycystic Ovaries. Natural Progesterone also helps regulate apoptosis. Progesterone also helps create a balance of all other steroids. It also has intrinsic calming and diuretic properties. Progesterone is the "Pro-Gestational" hormone and is the single most important hormone for conception and full-term pregnancy. It is important in women, but it's importance in men for the maintenance of prostate health is only now being appreciated.

So, whether a woman conceives through traditional "natural pregnancy" or IVF Fertility Treatment, it is critically important that she maintain optimal levels of progesterone throughout pregnancy. A drop in progesterone levels or a blockade of progesterone receptors during the first 11 or 12 weeks of pregnancy will often result in loss of the embryo.

Dr. Catherine Dalton has suggested that pregnant women use a properly formulated natural progesterone cream until the start of the third tri-mester when the placenta takes over progesterone production. She further states that women who maintain high progesterone levels during pregnancy produce healthier and more intelligent children.

Polycystic Ovaries

A 29 year old woman in the United States presented with excessive facial/body

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hair growth, acne, and weight gain about the waist. She had suffered with these problems since puberty and had been on several of the popular low fat/high carbohydrate diets, which helped with weight temporarily, but resulted in rebound weight gain. Menstrual periods were also irregular. Saliva testing during the second half of the menstrual cycle (luteal phase) indicated high-normal estradiol, low progesterone, and high androgens-both DHEAS and testosterone. Further examination by her doctor revealed cystic ovaries. Dietary modification (removal of simple, refined carbohydrates-pastas, chips, pastries, sodas etc.) and use of natural progesterone has helped restore normal menstrual cycles, resolve the cystic ovaries and reduce the risk for ovarian cancer.

All of the research we have reviewed, the many years of clinical experience of Dr. John Lee (California, USA) and the six years clinical experience we have with tens of thousands of women worldwide cause us to conclude that natural progesterone is safe and free of side effects (when administered topically) and addresses the underlying causes of many hormone related health problems that plague women, including infertility, polycystic Ovaries and ovarian cancer.

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Menopause, Estrogen & Your Health**Menopause Overview**

A commonality of the worlds' industrialized societies is the prevalence of uterine fibroids, fibrocystic breast disease, breast and/or uterine cancer, PMS, pre-menopausal bone loss as well as a high incidence of post-menopausal osteoporosis.

Significantly, the common thread weaving its way through all of these conditions is estrogen dominance, secondary to an insufficiency of progesterone. However, after menopause or a hysterectomy, estrogen production decreases by about 40% to 60%. In other words the female body still produces estrogen at about 40% to 60% of pre-menopause levels.

Because natural progesterone is the biological precursor for the production of natural estrogen, it is the natural choice for menopausal women as well as for pre-menopausal women to enjoy optimal health, free of the risks and side effects associated with synthetic hormones. Additionally, natural progesterone will stimulate the body's natural bone building cells (osteoblasts), offer significant protection against stroke and heart disease and benefit virtually every cell and organ of the body.

By establishing a balance of these hormones through proper Diet, Stress Management and Natural Progesterone supplementation, fluctuations of estrogen and progesterone, the resultant hot flashes, night sweats and other symptoms of menopause are either significantly alleviated or completely eliminated.

Persistent Symptoms

For those women for whom hot flashes, night sweats and/or vaginal dryness still persist they have found that 400 I.U. of natural vitamin E three times per day (1200 I.U./day), essential oil supplementation (primrose oil, omega III) and four to six tablespoons of whole psyllium seed husks in juice daily has been effective in ameliorating these persistent symptoms.

In cases where Estrogen Replacement Therapy is elected to control hot flashes, vaginal dryness or night sweats, natural estriol cream is recommended usually for several months or, in some cases a year. This is a safe, non-cancer promoting form of phyto-estrogen available here.

In most cases, however, estriol is not needed when a sufficient amount of Natural Progesterone is available, as it is the precursor (raw material) for other adrenal hormones, including all three forms of natural estrogen and cortisone.

Safety of Natural Hormones

Natural Progesterone has been found to be safe and effective when applied topically, in a cream formula free from petrochemicals and animal by-products.

Risks of HRT

This is in contrast to the standard medical protocol of HRT.

Studies have shown that women taking replacement estrogen have a 2 to 8 times higher risk of developing breast cancer, ovarian cancer and endometrial cancer than women who do not take estrogen. The risk increases after 2 to 4 years of estrogen use and seems to be greatest when large doses (>1 mg./day) are taken or when the estrogens are used for long periods of time (>4 years). This risk factor increases sharply in women who smoke cigarettes.

Sleuthing a Thyroid Mystery
by Dr. Stephen Langer



Premature Birth



Osteoporosis



Infertility

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Serenity For Women Info

Product Description

Serenity for Women is The Finest Quality Moisturizing Cream that contains not less than 1,260 mg. of USP Natural Progesterone (converted from plant sources) per 2.1 ounce (60 gram) jar (Why a Jar? Isn't a tube better) This is the optimal progesterone level for a proper cream formulation. (Fragrance Free & HYPO-ALLERGENIC)

Ingredients

Purified Water, Organic Aloe Vera Gel 200:1 Concentrate (Aloe Barbadensis), Vegetable Glycerin, Natural Progesterone USP (2.1%), Vespene (Complex, Stabilized Vegetable Oil), Natural Vitamin E, Glyceryl Stearate (from plant), Stearic Acid (from plant), Cetyl Alcohol (from plant), PEG-20 Methyl Glucose Sesquistearate (from plant), Methyl Glucose Sesquistearate (from plant), Hyaluronic Acid (Natural Skin Moisturizer), NaPCA (Natural Skin Humectant), Xanthan Gum, Citrus Seed Extract (a natural preservative).

- Serenity for Women is formulated with the most advanced delivery system for maximum absorption (97-100% assimilated) and is light & non-oily.
- The process involves No Animal Testing, No Animal Cruelty and No Animal by-products.
- A 60-gram jar normally lasts six to twelve weeks, depending on the severity of symptoms and beginning progesterone levels.
- No Petroleum Derivatives or by-products are used in the manufacturing of Serenity for Women.
- Serenity for Women does not contain Keratin!

Suggested Use

Please see the Suggested Use Page

Precautions

There are no reports of any significant side effects or health problems associated with natural progesterone when it is administered in a properly formulated Natural Progesterone Cream.

A few women may temporarily experience an increase in the symptoms caused by too much estrogen. This is not an adverse reaction to progesterone or to the cream, but an increase in the activity of estrogen. This is often referred to as the "healing crisis" and can be alleviated by strict adherence to the dietary/lifestyle pages.

Note: If you are using thyroid medication your health care professional should monitor thyroid function as progesterone may support normal thyroid function and thyroid medication may over stimulate the thyroid gland.

Any persistent problems should always be checked by a qualified health care professional.

Related Links

Free Dr. Lee book with purchase of three Serenity!



Premature Birth



Osteoporosis



Infertility

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Hysterectomy

A hysterectomy causes the female body to become immediately menopausal.

According to Dr. Stanley West, Chief Endocrinologists at St. Vincent's Hospital in New York, U.S., 90% of the hysterectomies performed in the United States each year are unnecessary surgery. According to Dr. John Lee those women who are told that they have "pre-cancerous" cells after a gynecological exam, need only supplement with a properly formulated natural progesterone cream and implement the known dietary/lifestyle modifications, and the so called "pre-cancerous" cells will diminish along with the need for surgery.

The standard medical decision, however, is to perform a hysterectomy and to give women estrogen replacement therapy, in spite of the fact that 75% of patients still make sufficient amounts of estrogen. This can be verified by a saliva hormone test which measures available levels of estrogen and is more meaningful than a blood test.





After surgery hormone production does not cease, as estrogen and progesterone should still be made by the adrenals & fat cells. The importance of proper balance of these two hormones is more critical at this time due to the fact that progesterone plays a critical supportive role in bone building (Osteoblast Cells), stroke prevention and a health heart.

Since the female body makes natural estrogen from natural progesterone, most women need only supplement with a properly formulated natural progesterone cream. Some women, however, do not readily make this conversion and may temporarily need supplemental estrogen or may implement a diet that is rich in phyto-estrogens and contains sufficient amounts of fiber.

For the women who need supplemental estrogen due to continued hot flashes, night sweats, and vaginal dryness, a natural estriol cream is a safe and effective treatment.

So, for menopause, whether surgically induced or not, Dr. Lee states in his book, "Adding progesterone will actively increase bone mass and density and can reverse osteoporosis."

Natural progesterone offers many other benefits for women who have had a hysterectomy and they are listed Here.


Heart Health

Weight Loss

Premature Birth

Dietary Consideration

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Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondents named in the caption hereof, and the Respondents 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 by the Commission, would charge the Respondents with violation of the Federal Trade Commission Act; and

The Respondents and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the 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 the Respondents 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 Respondents have 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 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 Health Science International, Inc. is a Florida corporation with its principal office or place of business is at 1648 Taylor Road, Suite 118, Port Orange, Florida 32128.

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2. Respondent David Martin is an officer of Health Science International, Inc. Individually, or in concert with others, he formulates, directs, controls, or participates in the policies, acts, or practices of Health Science International, Inc. His principal office or place of business is the same as that of Health Science International, Inc.

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 purposes of this order, the following definitions shall apply:

1. Unless otherwise specified, “Respondents” shall mean:
 - a. Health Science International, Inc., a corporation, and its successors and assigns and its officers; and
 - b. David Martin, individually and as an officer of Health Science International, Inc.
2. “Competent and reliable scientific evidence” shall mean 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.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside

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the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Serenity for Women Natural Progesterone Cream.

4. "Food," shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.
5. "Drug" shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. "Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

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7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.
9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;

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- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;
- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondents, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

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IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondents from making any representation for any drug that is permitted in 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;
- B. 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
- C. Nothing in this order shall prohibit Respondents from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

IV.

IT IS FURTHER ORDERED that Respondents shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon reasonable notice 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,

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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 shall delivery 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. Respondents 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.

VI.

IT IS FURTHER ORDERED that Respondents shall notify the Commission at least thirty (30) days prior to any change with regard to Health Science International, Inc. or any business entity that any Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; 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 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. All notices required by this Part shall be sent by

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certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondents, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of their current business or employment; or of their affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondents shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

IX.

This order will terminate on November 13, 2027, 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:

Analysis to Aid Public Comment

- 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 Respondent 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 OF PROPOSED 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 Health Science International, Inc., a corporation, and David Martin, individually and as an officer of Health Science International (together, "respondents").

The proposed consent order has been placed on the public record for thirty (30) days for reception of comments by interested persons.

Analysis to Aid Public Comment

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 the advertising and promotion of Serenity for Women Natural Progesterone Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondents represented that Serenity for Women Natural Progesterone Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The complaint alleges that respondents failed to have substantiation for these claims. The complaint also alleges that respondents misrepresented that clinical testing proved that Serenity for Women Natural Progesterone is effective in preventing, treating, or curing osteoporosis. The proposed consent order contains provisions designed to prevent respondents from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Analysis to Aid Public Comment

Part II of the proposed order prevents respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondents from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration (“FDA”) standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondents to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of their personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. 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 agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**SHELLY BLACK,
TRADING AND DOING BUSINESS AS
PROGESTERONE ADVOCATES NETWORK**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4206; File No. 072 3146

Complaint, November 13, 2007 – Decision, November 13, 2007

This consent order addresses Progesterone Advocates Network's advertising and promotion of Nature's Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. The complaint alleges that the respondents represented that Nature's Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The consent order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Participants

For the *Commission*: Gregory A. Ashe, Laura DeMartino, Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the *Respondents*: Not represented by counsel.

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COMPLAINT

The Federal Trade Commission, having reason to believe that Shelly Black, an individual trading and doing business as Progesterone Advocate Network (“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 Shelly Black is an individual trading and doing business as Progesterone Advocates Network with her principal office or place of business at Post Office Box 1004, Trabuco Canyon, California 92678. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Progesterone Advocates Network, including the acts and practices alleged in this complaint.

2. 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.

3. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While progestagens decrease a woman’s risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman’s risk of developing breast cancer.

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4. Respondent has advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Nature's Precise Cream. Respondent primarily advertises and offers the products for sale through the Internet site www.progestnet.com.

5. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Nature's Precise Cream is a "drug" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

6. Nature's Precise Cream is a drug labeled as containing USP Natural Progesterone (960 mg per 2 ounce tube) and other ingredients. A two fluid ounce tube costs \$19.95 plus shipping and handling. Nature's Precise Cream is applied transdermally.

7. To induce consumers to purchase Nature's Precise Cream, respondent has disseminated or has caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on respondent's website:

A. NPC-Nature's Precise Cream (Formally known as Natural Progesterone) Product Information

* * *

A topical dietary supplement, designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis. This completely natural product provides a safe and effective alternative to synthetic Hormone Replacement Therapies (also known as HRT or estrogen replacement) and their undesirable side effects. Menopausal and pre-menopausal women may experience hot flashes due to hormonal imbalance and in some cases, more severe symptoms including

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Endometriosis, Fibroid Tumors, Fibrocystic Breast Disease and Breast Cancer. Awareness of women's health concerns and the demand for natural treatments is at an all time high. Dr. John R. Lee's best selling book: "What your doctor may not tell you about Menopause", outlines the remarkable benefits provided by natural progesterone.

Who Needs Natural Progesterone?

Women who have symptoms of hormone imbalances:

* * *

Osteoporosis

* * *

(Exhibit A at 3.)

- B. Ovarian, uterine, and cervical cancers are all known to be a result of hormonal imbalances. Specifically they are a result of excess estrogen or estrogen dominance.

* * *

Uterine cancer, also known as endometrial cancer, is not as common as ovarian cancer. The usual time in a woman's life when endometrial cancer develops is during the premenopausal years when high levels of estrogen and low levels of progesterone are present. The only known cause of endometrial cancer is unopposed estrogen. Progesterone opposes the estrogen thereby decreasing the risk of endometrial cancer.

* * *

Estrogen is the hormone that stimulates cell growth. Cancer is the abnormal growth of cells and comes about

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from an imbalance in the body. Correct the balance and the cancer may go away. One of progesterone's most important roles in the body is to balance or oppose estrogen.

(Exhibit A at 5.)

- C. In the United States there are 175,000 cases of breast cancer reported a year, accounting for over 44,000 deaths. The risk of breast cancer rises with age, but has become more prevalent in younger, pre-menopausal women. For many cancers, the cause is still unknown. However, the cause of breast and endometrial cancers can be directly linked to hormonal factors. The carcinogenic effects of unopposed estrogen and the anticancer benefits of progesterone are well documented for these two cancers.

From the time that the first breast cancer cell emerges, it may be 8-10 years before the growth is large enough to be diagnosed with palpation. A mammogram may detect the growth, at most, 2 years earlier. What this implies is that many breast cancers start during the 10 to 15 years before menopause, when it is common for estrogen to be dominant and progesterone to be deficient. Estrogen stimulates cell growth. Progesterone regulates cell growth by telling it when to stop. Cancer is a result of abnormal cell growth and arises from an imbalance in the body. Correct the imbalance and you've corrected the problem.

After 25 years of using chemicals, radiation, and surgery we are still losing the war on cancer. Because of its many benefits and its great safety, natural progesterone deserves far more attention than is generally given in the prevention and care of women's health problems today.

(Exhibit A at 7.)

- D. **Should estrogen be taken without progesterone?**

Complaint

Definitely not! It is very important that natural progesterone be used with any form of estrogen. Estrogen without progesterone can cause endometrial and vaginal carcinomas.

* * *

I'm already on hormone replacement therapy from my doctor. Why should I switch to natural progesterone?

Natural progesterone is simply a NATURAL ALTERNATIVE to hormone replacement therapy. Synthetic progestins have many side effects.

* * *

(Exhibit A at 9.)

- E. With menopause, bone loss accelerates to 3 to 5 percent per year for about 5 years, after which bone loss continues at the rate of about 1.5 percent per year. The indication here is that a lack of progesterone causes a decrease in new bone formation, not a lack of estrogen, which is still at adequate levels prior to menopause. In fact, both during and after menopause, women may still maintain 40% to 60% of their estrogen levels (in fat cells) which is sufficient for maintaining proper health, yet they will have NO progesterone.

(Exhibit A at 11.)

- F. Natural progesterone is safe that is what makes it so great.

. .

* * *

Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

* * *

Complaint

Research indicates that this loss of bone is due to increased levels of progesterone, not estrogen. Adding natural progesterone supplementation will increase bone density and can reverse osteoporosis.

* * *

(Exhibit A at 12.)

- G. “Estrogen dominance” is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects. Signs and symptoms of estrogen dominance include:

* * *

Breast cancer

* * *

Uterine cancer

* * *

Pre-menopausal bone loss

* * *

Estrogen “deficiency” that is quite often used as an explanation of menopausal symptoms or health problems is not supported by sound research. When a woman’s menstrual cycle is functioning normally, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. After menopause, estrogen is still present and continues to be manufactured in fat cells. Most menopausal women have too little estrogen to support

Complaint

pregnancy, but sufficient amounts for other normal body functions. Few women are truly deficient in estrogen; most become progesterone deficient. If estrogen becomes the dominant hormone and progesterone is deficient, excess estrogen becomes toxic to the body. Progesterone has a balancing effect on estrogen.

(Exhibit A at 14-15.)

- H. Breast and endometrial are both hormone related cancers, and tend to surface in women at the time in their lives when estrogen is dominant and progesterone is deficient. Estrogen stimulates cell growth in the body, while progesterone regulates cell growth. Excess estrogen or estrogen dominance is the only known cause of endometrial cancer.

(Exhibit A at 16.)

- I. Because the safety of natural progesterone is so great, it's harmless to use a little more than you strictly need.

(Exhibit A at 18.)

- J. One of progesterone's most important and powerful roles in the body is to balance or oppose estrogen. Under the normal healthy circumstances of a woman's monthly cycle, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. When our progesterone levels are in balance, the body better handles excess estrogen.

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Benefits of Natural Progesterone include:

* * *

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Helps protect against endometrial, breast, ovarian, and prostate cancer

* * *

Increases new bone formation

* * *

Synthetic Progestins are not the same as Natural Progesterone

Medical literature tends to equate natural progesterone/progesterone with synthetic progestins. This assumption is altogether incorrect. Progesterone is a specific molecule made by the adrenal glands and by the ovary during of ovulation. Synthetic progestins are drugs that are manufactured by pharmaceutical companies and are normally available by prescription only. Synthetic progestins are not natural to the body and are known to cause undesirable side effects. . . .

(Exhibit A at 19.)

- K. Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

* * *

If you choose to continue using synthetic estrogen, it is imperative that you also use progesterone in conjunction with estrogen. Many physicians prescribe synthetic progestins along with estrogen. Avoid synthetic progestins and instead use natural progesterone. It is not only safer, it has MANY beneficial factors that cannot be seen with the use of progestins.

(Exhibit A at 21.)

- L. **Physiological effects of Progesterone versus Estrogen**

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Progesterone effects

* * *

Prevents endometrial
cancer
Helps prevent breast
cancer
Stimulates osteoblast bone
building

* * *

Estrogen effects

* * *

Increases risk of endometrial
cancer
Increases risk of breast
cancer
Slightly restrains osteoclast
function

* * *

(Exhibit A at 22.)

M. Medical literature tends to equate progesterone with synthetic progestins. This assumption is altogether incorrect.

Synthetic progestins are drugs that are manufactured by drug companies and are normally available by prescription only. Synthetic progestins are not natural to the body and can cause undesirable side effects. Some of the side effects from synthetic progestins include; cardiovascular complications, suspected links to uterine and breast cancer, blood clots, insomnia, menstrual irregularities, depression, masculinizing effects, breast tenderness, fluid retention and edema.

* * *

Progesterone is a specific molecule made by the adrenal glands or by the ovary during ovulation. Natural progesterone cream is derived from organic compounds found in nature and is molecularly identical to

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progesterone manufactured by the human body. Synthetic progestins are molecularly altered and have negative side effects when placed in the human body. For example: Progesterone is essential through out pregnancy, whereas synthetic progestins carry a warning that their use in early pregnancy may increase the risk of miscarriage.

Natural Progesterone Cream contains the natural hormone, which has been accurately synthesized from wild yams. Supplementing with natural progesterone has NO side effects - even during pregnancy.

Compare Effects - Natural Progesterone to Synthetic

Conditions * * *	Natural Proges- terone (real)	Progestins (synthetic)
Protects against endometrial cancer		
Protects against ovarian cancer	X	X
Protects against breast cancer	X	
* * *	X	
Improves new bone formation	X	
* * *		

(Exhibit A at 25-26.)

8. Through the means described in Paragraphs 6 and 7, respondent has represented, expressly or by implication, that:

A. Nature's Precise Cream is effective in preventing, treating, or curing osteoporosis;

Complaint

B. Nature's Precise Cream is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. Nature's Precise Cream does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer.

9. Through the means described in Paragraphs 6 and 7, respondent has represented, expressly or by implication, that she possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 8, at the time the representations were made.

10. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 8 at the time the representations were made. Therefore, the representation set forth in Paragraph 9 was, and is, false or misleading.

11. The acts and practices 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.

THEREFORE, the Federal Trade Commission, on this thirteenth day of November, 2007, has issued this complaint against respondent.


By the Commission.

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Exhibit A

Providing products for Quality of Life! We provide customers with quality products,

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Progesterone
Advocates
Network

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Natural Hormone Balance

Transdermal Creams

From PMS to Menopause and Beyond

Your source for promoting hormone balance naturally! We offer the complete line of Sarati's transdermal re-balancing creams,



including their most popular NPC - Nature's Precise Cream and EST - Essential Support Treatment Cream.

NPC - Nature's Precise Cream (FKA Natural Progesterone Cream) - Help symptoms that may occur with menstruation and menopause.

EST - Essential Support Treatment (FKA Estro-All) - Hard to find combination progesterone/phyto-estrogen formulation designed for menopausal women.

EMP - Essential Moisture Plus Cream (FKA Feminine Moisture Plus) - Advanced formulation provides soothing relief for vaginal dryness.

D-35 Complex (Formerly known as DHEA Plus) - Androstenedione works best in our formulation to boost DHEA levels and increase testosterone.

Improve Sexual Response

Our transdermal cream product, topically applied, is designed to safely increase sexual responsiveness. Fempower for women.


[Click here for more](#)

Essential Oils

Eucalyptus Oil is the most versatile essential oil found in nature.

[Click here for more](#)

EstroLogic



EstroLogic is a Herbal Supplement for Natural Estrogen Balance.

[More](#)

Nationwide Doctor Referral Service

In addition to the product and information available here at www.ProgestNet.com, we offer a nationwide referral service with healthcare practitioners who advocate obtaining optimum health naturally through nutrition and hormonal balance.

Hormone Balance Test Kit

By providing you with information, quality products, and the availability of [finding a doctor](#) in your area, we intend to positively

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Natural Progesterone and Natural Supplements at Affordable Pricing

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Influence current mainstream standards of healthcare in our country. Together we can make a difference.

A primary source for books by John R. Lee, M.D.

What Your Doctor May Not Tell You About Breast Cancer - Breakthrough book by John R. Lee, M.D., David Zava, M.D., and Virginia Hopkins.

What Your Doctor May Not Tell You About Menopause - The Breakthrough Book On Natural Progesterone by John R. Lee, M.D. with Virginia Hopkins.

What Your Doctor May Not Tell You About Premenopause - Balance Your Hormones and Your Life From Thirty to Fifty by John R. Lee, M.D., Jesse Hanley, M.D., and Virginia Hopkins.

is falling hormone levels, which is largely responsible for disorders in hormone balance.

Saliva testing can be used to determine your current hormonal state as well as monitor your supplementation with our natural hormone products.

The optimum hormone levels to have tested are: **progesterone, estradiol, DHEA, testosterone and cortisol**. If you only wish to test the minimum hormones then you would test for: **estradiol and progesterone**.

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

Natural Progesterone - Formulation: 960 mg USP natural progesterone in a 2 ounce base of: deionized water, caprylic/capric triglycerides, polyacrylamide/c13-14, isoparaffin/laureth 7, aloe vera gel, vitamin E acetate, grapefruit seed extract.

A topical dietary supplement, designed for women of all ages who experience symptoms relating to PMS, Menopause and Osteoporosis. This completely natural product provides a safe and effective alternative to synthetic Hormone Replacement Therapies (also known as HRT or estrogen replacement) and their undesirable side effects. Menopausal and pre-menopausal women may experience hot flashes due to hormonal imbalance and in some cases, more severe symptoms including Endometriosis, Fibroid Tumors, Fibrocystic Breast Disease and Breast Cancer. Awareness of women's health concerns and the demand for natural treatments is at an all time high. Dr. John R. Lee's best selling book: "What your doctor may not tell you about Menopause", outlines the remarkable benefits provided by natural progesterone.

Who Needs Natural Progesterone?

Women who have symptoms of hormone imbalances:

- PMS
- Premenopause
- Endometriosis
- Osteoporosis
- Weight Gain
- Low Sex Drive
- Heart Disease

NPC-Nature's Precise Cream (FKA Natural Progesterone) 1 Tube Retail \$19.95

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NPC-Nature's Precise Cream (Formerly known as Natural Progesterone) Product Information

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NPC-Nature's Precise Cream (FKA Natural Progesterone) 3 Tube Purchase \$56.00

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NPC-Nature's Precise Cream (FKA Natural Progesterone) 12 Tube Purchase \$130.00

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Complaint

Ovarian/Cervical/Uterine Cancer

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Ovarian/Cervical/Uterine Cancer

Ovarian, uterine, and cervical cancers are all known to be a result of hormonal imbalances. Specifically they are a result of excess estrogen or estrogen dominance. Most women in western civilization are estrogen dominant, due to environmental exposures such as: pollution, solvents, pesticides, herbicides, fungicides, car exhaust, emulsifiers found in soaps and cosmetics, industrial waste, meat and dairy products from animals fed estrogen, birth control pills, and synthetic estrogens & progestins frequently prescribed to millions of women.

Most ovarian cancer occurs in menopausal women around the age of fifty. Ovarian cancer is particularly scary because by the time it's diagnosed it is likely to have already spread to other parts of the body and increased the likelihood of mortality. Nearly 20 percent of gynecologic cancers are ovarian, and it is fifth in cancer fatalities in women. A 1995 study by C. Rodriguez and Associates published in the American Journal of Epidemiology, showed that in 240,073 women studied, the relative risk of fatal ovarian cancer was 72 percent greater among those women who were given unopposed estrogen for six years or more. The authors concluded; "long-term use of estrogen replacement therapy may increase the risk of fatal ovarian cancer." Fertility drugs may also play a role in the increasing rate of ovarian cancer. One study found that using fertility drugs increased ovarian cancer risk three times, but in women who had never been pregnant the risk was increased to 27 times. Other studies have shown that women who have children later in life, or are infertile, also have a higher risk of ovarian cancer. Since many women are "waiting" to have their children, and so many others have resorted to the use of infertility drugs, we may see ovarian cancer reach epidemic levels in the near future.

Uterine cancer, also known as endometrial cancer, is not as common as ovarian cancer. The usual time in a woman's life when endometrial cancer develops is during the pre-menopausal years when high levels of estrogen and low levels of progesterone are present. The only known cause of endometrial cancer is unopposed estrogen. Progesterone opposes the estrogen thereby decreasing the risk of endometrial cancer. This information has been an available part of medical education for years, but it seems to have been forgotten by doctors who prescribe Hormone Replacement Therapy. The use of HRT is based on drug company advertising rather than sound research data.

Oral contraceptives have been linked to both endometrial and cervical cancers. In the 1960s a Dr. Helen Grant was hired to work in a London clinic to test varying combinations and dosages of birth control pills. After 10 years of working with oral contraceptives, Dr. Grant found that they were very dangerous. Dr. Grant noticed that 'the pill' had many side effects, and that the risk of death from cervical, breast, and endometrial cancer was doubled with the use of oral contraceptives.

When a pre-menopausal women complains to her doctor about PMS, she is likely to leave with a prescription for estrogen or a birth control pill, which is probably the last thing in the world that she needs. Many pre-menopausal women prescribed unopposed estrogen will have an abnormal Pap test within a year, and her risk of breast cancer is significantly increased. If she has an abnormal Pap smear, it is routine for the doctor to suggest removing her uterus. Thus begins a dangerous cycle of HRT and undesirable hormone related symptoms and conditions

Estrogen is the hormone that stimulates cell growth. Cancer is the abnormal growth of cells and comes about from an imbalance in the body. Correct the balance and the cancer may go away. One of progesterone's most important roles in the body is to balance or oppose estrogen.

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U.S. DEPARTMENT OF JUSTICE

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Direct Cancer

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Breast Cancer

In the United States there are 175,000 cases of breast cancer reported a year, accounting for over 44,000 deaths. The risk of breast cancer rises with age, but has become more prevalent in younger, pre-menopausal women. For many cancers, the cause is still unknown. However, the cause of breast and endometrial cancers can be directly linked to hormonal factors. The carcinogenic effects of unopposed estrogen and the anticancer benefits of progesterone are well documented for these two cancers.

From the time that the first breast cancer cell emerges, it may be 8-10 years before the growth is large enough to be diagnosed with palpation. A mammogram may detect the growth, at most, 2 years earlier. What this implies is that many breast cancers start during the 10 to 15 years before menopause, when it is common for estrogen to be dominant and progesterone to be deficient. Estrogen stimulates cell growth. Progesterone regulates cell growth by telling it when to stop. Cancer is a result of abnormal cell growth and arises from an imbalance in the body. Correct the imbalance and you've corrected the problem.

After 25 years of using chemicals, radiation, and surgery we are still losing the war on cancer. Because of its many benefits and its great safety, natural progesterone deserves far more attention than is generally given in the prevention and care of women's health problems today.

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Frequently Asked Questions

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Frequently Asked Questions

1. What exactly is natural progesterone and how does it differ from a synthetic progesterone?

Natural progesterone, a cholesterol derivative, comes from a wild Mexican yam plant. It matches exactly the chemical composition of our body's own progesterone. Products that list yam extract among their ingredients may or may not include the saponin, a rich portion of the yam root. In other words, not all natural progesterone creams are created equal. Our progesterone cream contains the pharmaceutical grade natural progesterone created specifically to Dr. John Lee's specifications - at least 400 mg. per ounce! Our progesterone cream is the only cream on the market today with a high potency grape seed extract, which is proven to be a powerful antioxidant and a free radical scavenger. (Estrogen dominance causes free radical damage.)

2. Who should use natural progesterone cream?

Those women who suffer from PMS with: mood swings, cramping, weight gain, bloating, acne, insomnia, decreased sex drive, decreased energy, depression, water retention, heavy and/or irregular periods found relief according to Dr. Lee, by using a natural progesterone cream.

3. Are there any side effects from using natural progesterone?

Most frequently, any side effects from natural progesterone are associated with usage, and can be easily alleviated by changing the amount and frequency of the dosage. In the PMS age group, using too much natural progesterone (over one to four months) can delay the period a day or two. Discontinuing the natural progesterone will cause the period to start, and natural progesterone can be resumed after 7 days, but at a lower dose.

Women with irregular periods might notice some spotting at ovulation upon beginning natural progesterone treatment. What's indicated here is that the period is trying to regulate on a 28-day cycle. With continued use, periods will become regular and the spotting will be alleviated. Menopausal women might also notice some spotting when they begin using natural progesterone. This too should be alleviated with continued use. The postmenopausal and osteoporosis age group should not have any side effects at all.

4. Do I need a prescription for natural progesterone?

No. Natural progesterone in a cream or oil base comes from a wild Mexican yam plant, which is technically a food product, and all of the other ingredients, aside from a trace of some cosmetic ingredients, are natural.

5. Can natural progesterone help with endometriosis or fibrocystic breasts?

There are many factors that affect both of these conditions, one common factor being a higher level of circulating estrogen, indicating a hormonal imbalance. Progesterone is the precursor hormone and it helps to normalize all other endocrine and hormonal activity in the body. It will make or block estrogen as necessary. In the case of endometriosis, or fibrocystic breasts, it assists in lowering the level of estrogen in the body and thus, possibly helps to clear these conditions.

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Frequently Asked Questions

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6. Should estrogen be taken without progesterone?

Definitely not! It is very important that natural progesterone be used with any form of estrogen. Estrogen without progesterone can cause endometrial and vaginal carcinomas. Estrogen alone blocks thyroid and causes water retention, and it can cause fibrocystic breast disease and even fibroid tumors and cysts.

7. I'm already on hormone replacement therapy from my doctor. Why should I switch to natural progesterone?

Natural progesterone is simply a NATURAL ALTERNATIVE to hormone replacement therapy. Synthetic progestins have many side effects. Women with a history of hypertension, diabetes, weight problems, and/or varicose veins should not be on chemical estrogen and progestins.

8. How do I get off synthetics and on the natural?

If someone is taking both synthetic estrogen and progestins, a gradual step might be to at least substitute natural progesterone for the synthetic progestin. Do not go off synthetic estrogen suddenly. You need to wean off slowly; otherwise the symptoms will return (hot flashes, night sweats, mood swings, etc.).

9. I am post menopausal. Will I start menstruating again if I use natural progesterone? What if I have some breakthrough bleeding?

Occasionally, upon beginning use of natural progesterone, a post menopausal woman could experience some breakthrough bleeding, or a "period." This rarely happens, but if it should, it is a perfectly normal response and is nothing to cause alarm. The progesterone is simply causing the body to rid itself of excess stored estrogen which can sometimes stimulate uterine shedding - thus breakthrough bleeding. If this continues for longer than several months, one should consult a physician.

10. Why is transdermal absorption so good?

Natural progesterone being small, fat-soluble molecules, are much better absorbed through the skin than given orally. It goes across the skin to subcutaneous fat layers, then to blood circulation. So first it goes into body fats and then the blood, avoiding first pass loss through the liver.

11. How long before I notice maximum benefits?

It may require 2-3 months of use before maximum benefits are experienced. Some women report immediate improvement.

12. Where is the best place to apply the natural progesterone cream?

Natural progesterone cream can be applied to any area of the body; however, it is best to apply it to thinner, softer skin such as the chest, breasts, neck, or anywhere that you blush. It is recommended that you periodically rotate the area of the body where natural progesterone cream is applied. Natural progesterone is a very effective skin moisturizer and has been used in skin creams in lesser concentrations for years.

13. What do I say to my physician who thinks this is silly?

There is nothing new under the sun. This formula is the same base as 400 FDA drugs, just without chemicals. Also, as an informed individual you have the right to choose ... and the choice should be yours. Remember, physicians only recommend what they know best. Possibly your physician will want to study this further if he or she sees positive results with you. A good starting point will be a careful reading of Dr. John R. Lee's books; "What Your Doctor May

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[Frequently Asked Questions](#)

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Not Tell You About Menopause" and "What Your Doctor May Not Tell You About Pre-Menopause".

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Osteoporosis

Osteoporosis is the loss of normal bone density with thinning bone tissue and the growth of small holes in the bone. Symptoms include pain, especially in the low back, frequent broken bones, and loss of body height. It is identified most often in women who have gone through menopause. In the United States over 45 percent of women age 50 or more have bone mineral density deficiencies and there are 1,500,000 osteoporosis related fractures reported every year.

Unfortunately, proper treatment of this dangerous and easily preventable disease has been overlooked by mainstream medicine. The makers of Premarin and other estrogen manufacturers would like for our doctors and us to believe that lack of estrogen is the leading cause of osteoporosis. Yet significant bone loss occurs during the 10 to 15 years before menopause, when estrogen levels are still normal. Women's bone mass peaks in their mid-thirties and begins declining shortly thereafter at a rate of about 1 to 1.5 percent per year. This is when many women are experiencing irregular ovulation cycles. It is during these anovulatory cycles that progesterone levels fall while estrogen levels remain the same resulting in estrogen dominance.

By the time menopause is reached, osteoporosis is well under way, some women may have already lost as much as 25 percent of their bone density! With menopause, bone loss accelerates to 3 to 5 percent per year for about 5 years, after which bone loss continues at the rate of about 1.5 percent per year. The indication here is that a lack of progesterone causes a decrease in new bone formation, not a lack of estrogen, which is still at adequate levels prior to menopause. In fact, both during and after menopause, women may still maintain 40% to 60% of their estrogen levels (in fat cells) which is sufficient for maintaining proper health, yet they will have NO progesterone.

Estrogen slows the rate of osteoporosis, but not without serious risks. The bone benefits of estrogen replacement after menopause decrease after three to five years. Yet, mainstream medicine persists in the belief that estrogen is the "best" treatment for osteoporosis in women. Information gathered from Dr. John Lee's book "What Your Doctor May Not Tell You About Menopause".

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PROGESTERONE AND ESTROGEN INDEX

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Progesterone and Estrogen Index

About Estrogen

Estrogen dominance is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects.

Estrogen and Cancer

Cancer cells usually invade and destroy normal tissue cells and is born of an imbalance in the body.

Estrone, Estradiol, and Estriol

Estrone, estradiol, and estriol are all estrogens that are natural to the human body. They belong to the steroid hormones, and are primarily responsible for the growth of female characteristics in puberty and regulating the menstrual cycle.

How To Use Progesterone

Natural progesterone is safe that is what makes it so great... But, we are striving for balance, so avoid the "more is better" mentality when it comes to using progesterone cream.

What is Progesterone

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Who Should Use Natural Progesterone

Reports of well being with the use of transdermal natural progesterone are impressive. Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen.

Why Transdermal Application?

Transdermal progesterone is absorbed through the skin and into the layer of fat that lies beneath the surface. Natural progesterone is biologically active and when taken transdermally has an immediate effect on the body.

Wild Yam Extract

Although wild yams do have some effect on the body, it's just not known exactly what it is. Whatever its effects are it does not have the same benefits as progesterone.

Progesterone vs Estrogen

A listing of the physiological effects of Progesterone versus Estrogen.

Estrogen and Osteoporosis

Research indicates that this loss of bone is due to decreased levels of progesterone, not estrogen. Adding natural progesterone supplementation will increase bone density and can reverse osteoporosis.

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progesterone and estrogen index

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Synthetic vs Natural Progesterone

Synthetic progestins are not natural to the body and can cause undesirable side effects.

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About Estrogen

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About Estrogen

Estrogen is not a single hormone. It is a class of hormones and hormone like compounds that have estrogenic properties. There are human estrogens, animal estrogens, synthetic estrogens, phytoestrogens, and xenoestrogens. The three human estrogens are estradiol, estrone, and estrinol, and belong to the steroid hormone family.

"Estrogen dominance" is a term coined by Dr. John R. Lee. It describes a condition where a woman can have deficient, normal, or excessive estrogen but the body has little or no progesterone to balance its effects. Signs and symptoms of estrogen dominance include:

- Speeds up the aging process
- Allergies
- Autoimmune disorders
- Breast cancer
- Breast tenderness
- Cold hands and feet as a symptom of thyroid dysfunction
- Decreased sex drive
- Depression
- Dry eyes
- Early onset of menstruation
- Uterine cancer
- Fat gain in abdomen, hips, and thighs
- Fatigue
- Fibrocystic breasts
- Foggy thinking
- Hair loss
- Headaches
- Hypoglycemia
- Increased blood clotting
- Infertility
- Irregular menstrual periods
- Insomnia
- Memory loss
- Mood swings
- PMS
- Ovarian cysts
- Pre-menopausal bone loss
- Prostate cancer
- Sluggish metabolism
- Thyroid dysfunction
- Uterine cancer
- Uterine fibroids
- Water retention and bloating

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ABOUT US/US/0001

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In industrialized countries such as the United States, diets rich in animal fats, sugar, refined starches, and processed foods can lead to estrogen levels in women twice that of women of third-world countries. We are constantly exposed to xenobiotics (petrochemicals), xeno-hormone-laden meats and dairy products, forms of pollution, and prescriptions for synthetic hormones (such as the 'The Pill' and Premarin). It isn't too surprising that estrogen dominance has become an epidemic in industrialized countries. Over exposure to these potentially dangerous substances has significant consequences, one of which is passing on reproductive abnormalities to offspring.

Estrogen "deficiency" that is quite often used as an explanation of menopausal symptoms or health problems is not supported by sound research. When a woman's menstrual cycle is functioning normally, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. After menopause, estrogen is still present and continues to be manufactured in fat cells. Most menopausal women have too little estrogen to support pregnancy, but sufficient amounts for other normal body functions. Few women are truly deficient in estrogen; most become progesterone deficient. If estrogen becomes the dominant hormone and progesterone is deficient, excess estrogen becomes toxic to the body. Progesterone has a balancing effect on estrogen.

Supplemental estrogen, even in the slightest amounts, in a woman who doesn't need it, or who has no progesterone to balance it, can lead to many serious side effects. When a woman complains of even the slightest menopausal type symptoms, conventional medical doctors will recommend a prescription of estrogen. It is irresponsible and dangerous for doctors to be routinely prescribing estrogen for any type of pre-menopausal or menopausal symptom, and this practice can have tragic consequences. Progesterone should be the first choice. For severe menopausal symptoms not controlled by progesterone supplementation alone, natural phytoestrogens can be added. Please read our additional information regarding Natural Progesterone Cream and Estro-All cream, a safer form of supplemental estrogen.

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ESTROGEN AND CANCER

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Estrogen and Cancer

Cancer is the abnormal growth of cells in our bodies that can lead to death. Cancer cells usually invade and destroy normal tissue cells and is born of an imbalance in the body. Correct the imbalance and the cancer may go away. Billions of dollars have been spent on cancer research and yet we still don't understand exactly what cancer is.

Breast and endometrial are both hormone related cancers, and tend to surface in women at the time in their lives when estrogen is dominant and progesterone is deficient. Estrogen stimulates cell growth in the body, while progesterone regulates cell growth. Excess estrogen or estrogen dominance is the only known cause of endometrial cancer.

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Estrone, Estradiol, and Estriol

Estrone, estradiol, and estriol are all estrogens that are natural to the human body. They belong to the steroid hormones, and are primarily responsible for the growth of female characteristics in puberty and regulating the menstrual cycle. They are made primarily in the ovaries but are also manufactured from androstenedione in fat cells, muscle cells, and skin even after menopause. Progesterone is a precursor or building block to these hormones.

To date, all the available evidence available indicates that estriol is the safest estrogen to use to control menopausal symptoms, and that it may even be protective against breast cancer.

Despite sound marketing by the pharmaceutical industry, **synthetic estrogens are not equivalent to natural hormones**. Harmony and balance, the standard of a healthy body, are lost when biologically active synthetic compounds are thrown into the hormonal equation of a woman's body. They are disruptive, to say the least, to the steroid hormones and are likely responsible for a great deal of hormonal imbalance.

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HOW TO USE PROGESTERONE

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How To Use Progesterone

People differ in almost every aspect of their physiology. We're not all built the same, and there's wide variation in physiologic and metabolic processes from person to person. It's not rational to order the same dose of any given medicine for everybody, and the same is true of natural progesterone.

Although medical professionals can give you guidelines to work within, it's up to you to find the best dose for your body. Ideally, you should be able to find the minimum amount you can use to gain and sustain relief from your symptoms. Because the safety of natural progesterone is so great, it's harmless to use a little more than you strictly need. That gives you plenty of room for experimentation.

We are striving for balance, please avoid the 'more is better' mentality when it comes to using progesterone cream. Use too much and you could cause of a hormonal imbalance. If you are using a physiologic dose (an amount approximating what your body would make itself under normal circumstances) and your symptoms don't go away after four to six months, or if they return, it's best to work in partnership with a competent health care professional to find out why.

At the recommended dosage, (see the brochure that comes with your order of cream) a progesterone-deficient women who starts using the cream will find that in three to four months, the progesterone in her body fat will reach physiologic equilibrium and the amount in the saliva will be consistent with what would be produced normally during an ovulatory cycle.

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What is Progesterone

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What is Progesterone

One of progesterone's most important and powerful roles in the body is to balance or oppose estrogen. Under the normal healthy circumstances of a woman's monthly cycle, estrogen is the dominant hormone for the first two weeks and is balanced by progesterone, which is the dominant hormone for the latter two weeks. When our progesterone levels are in balance, the body better handles excess estrogen.

Natural Progesterone Cream is a topical dietary supplement designed for women of all ages who experience symptoms relating to PMS & Menopause.

Benefits of Natural Progesterone include:

- Protects against breast fibrocysts
- Helps protect against endometrial, breast, ovarian, and prostate cancer
- Normalizes blood clotting
- Helps prevent hypertension
- Acts as a natural diuretic
- Acts as a natural antidepressant
- Helps relieve anxiety
- Helps normalize blood sugar levels
- Helps thyroid hormone function
- Helps use fat for energy
- Is thermogenic (raises body temperature)
- Increases new bone formation
- Maintains normal cell membrane functions
- Has beneficial anti-inflammatory effects
- Reduces incidence of autoimmune disorders
- Prevents yeast (candida) infections
- Maintains the lining of the uterus for nurturing a fertilized ovum
- Makes the cervical mucus accessible by sperm
- Stops ovulation by the other ovary
- Prevents rejection of the developing baby
- Allows for full development of the fetus throughout pregnancy
- Increases libido at time of ovulation

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Synthetic Progestins are not the same as Natural Progesterone

Medical literature tends to equate natural progesterone/progesterone with synthetic progestins. This assumption is altogether incorrect. Progesterone is a specific molecule made by the adrenal glands and by the ovary during of ovulation. Synthetic progestins are drugs that are manufactured by pharmaceutical companies and are normally available by prescription only. Synthetic progestins are not natural to the body and are known to cause undesirable side effects. See [table](#) for more details.

The pharmaceutical companies who manufacture and market synthetic progestins, do not market natural progesterone

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because they cannot patent a natural product. As a result these companies do not provide funding for further clinical research nor promote it to healthcare professionals. This dynamic has hindered western medicine from becoming more informed of the benefits of natural progesterone.

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WHO SHOULD USE NATURAL PROGESTERONE

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Who Should Use Natural Progesterone

Likely nearly all of us! Reports of well being with the use of transdermal natural progesterone are impressive. Less anxiety and depression, increased vitality and reduced sleep disturbances, not to mention enhanced libido, are all benefits of a product with a track record of total safety.

Progesterone protects against the undesirable side effects of hormonal imbalance caused by unopposed estrogen. Most people who live in industrialized countries have a hormonal imbalance due to such factor as; stress, constant exposure to xenohormones, anovulatory cycles, or as a consequence of synthetic hormone prescriptions. Restoring proper progesterone levels is what is known as restoring hormone balance.

If you are currently using synthetic hormones, you will want to wean off of them slowly. If you choose to continue using synthetic estrogen, it is imperative that you also use progesterone in conjunction with estrogen. Many physicians prescribe synthetic progestins along with estrogen. Avoid synthetic progestins and instead use natural progesterone. It is not only safer, it has MANY beneficial factors that cannot be seen with the use of progestins.

Progesterone cream can be used without the guidance of a health care provider, yet one may be able to attain a better hormonal balance with the help of a physician who is experienced in balancing hormones - naturally. Some people will find immediate relief from symptoms, others find that it may take from one to four months to turn things around. This is a natural product, not a drug. Healing will take place naturally, on your body's own schedule.

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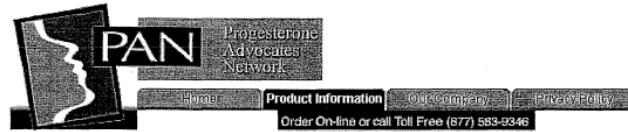
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PROGESTERONE VS. ESTROGEN

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Progesterone Vs. Estrogen

Physiological effects of Progesterone versus Estrogen

Progesterone effects

Maintains secretory endometrium
 Protects against fibrocystic breast
 Helps use fat for energy
 Natural diuretic
 Natural antidepressant
 Facilitates thyroid hormone action
 Normalizes blood clotting
 Restores sex drive
 Normalizes blood sugar levels
 Normalizes zinc and copper levels
 Restores proper cell oxygen levels
 Prevents endometrial cancer
 Helps prevent breast cancer
 Stimulates osteoblast bone building
 Restores normal vascular tone
 Necessary for survival of embryo
 Precursor of corticosteroids

Estrogen effects

Creates proliferative endometrium
 Causes breast stimulation
 Increases body fat
 Salt and fluid retention
 Depression and headaches
 Interferes with thyroid hormone
 Increases blood clotting
 Decreases sex drive
 Impairs blood sugar control
 Loss of zinc and retention of copper
 Reduces oxygen levels in all cells
 Increases risk of endometrial cancer
 Increases risk of breast cancer
 Slightly restrains osteoclast function
 Reduces vascular tone
 Increases risk of gall bladder
 Increases risk of autoimmune disorders

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PROGESTERONE VS. ESTROGEN

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Estrogen and Osteoporosis

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Estrogen and Osteoporosis

Bone mass in women peaks around their mid-thirties, after which a gradual decline of about 1 to 1.5 percent a year occurs. During the approximate five year period of menopause, bone density decrease rises to about 3 to 5 percent a year, after which it returns to the previous 1 to 1.5 percent loss.

The makers of Premarin would have us all believing that estrogen loss is the major cause of osteoporosis. If this is true, why is there a bone density decrease in the years prior to menopause when estrogen levels are still within the 'normal' range? Research indicates that this loss of bone is due to decreased levels of progesterone, not estrogen.

Supplementation of synthetic estrogen cannot reverse osteoporosis, but instead only reduce the rate of bone density loss and not without the risks of serious side effects. Any benefits osteoporosis benefits from estrogen are lost after the first 3 to 5 years of menopause onset. Mainstream medicine still persists in the misguided belief that estrogen is the mainstay of osteoporosis treatment for women. Even the most authoritative medical textbooks do not support this notion.

Could it be that the makers of Premarin are promoting the usage just to make a profit?

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SYNTHETIC VS NATURAL PROGESTERONE

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Synthetic vs Natural Progesterone

Medical literature tends to equate progesterone with synthetic progestins. This assumption is altogether incorrect.

Synthetic progestins are drugs that are manufactured by drug companies and are normally available by prescription only. Synthetic progestins are not natural to the body and can cause undesirable side effects. Some of the side effects from synthetic progestins include; cardiovascular complications, suspected links to uterine and breast cancer, blood clots, insomnia, menstrual irregularities, depression, masculinizing effects, breast tenderness, fluid retention and edema.

Pharmaceutical companies (who manufacture and market synthetic progestins) do not market natural progesterone because they cannot patent compounds that occur in nature. As a result neither do they provide funding for clinical research on natural progesterone, or promote it to healthcare professionals.

Progesterone is a specific molecule made by the adrenal glands or by the ovary during ovulation. Natural progesterone cream is derived from organic compounds found in nature and is molecularly identical to progesterone manufactured by the human body. Synthetic progestins are molecularly altered and have negative side effects when placed in the human body. For example: Progesterone is essential through out pregnancy, whereas synthetic progestins carry a warning that their use in early pregnancy may increase the risk of miscarriage.

Natural Progesterone Cream contains the natural hormone, which has been accurately synthesized from wild yams. Supplementing with natural progesterone has NO side effects - even during pregnancy.

Compare Effects - Natural Progesterone to Synthetic

	Conditions Natural Progesterone (real)	Progestins (synthetic)
Increases sodium and water in body cells		X
Causes loss of mineral electrolytes from cells		X
Causes intracellular edema		X
Causes depression		X
Increases birth defect risks		X
Causes facial hirsutism, loss of scalp hair		X
Causes thrombophlebitis, embolism risk		X
Decreases glucose tolerance		X
Causes allergic reactions		X

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		Age 40+
Increases risk for cholestatic jaundice		X
Causes acne, skin rashes		X
Protects against endometrial cancer	X	X
Protects against ovarian cancer	X	
Protects against breast cancer	X	
Normalizes libido	X	
Causes less hirsutism, regrowth Of scalp hair	X	
Improves lipid profile	X	
Improves in vitro fertilization	X	
Improves new bone formation	X	
Increases risk of coronary vasospasm		Modestly
Decreases risk of coronary vasospasm	X	
Facilitates thyroid hormone action	X	
Usually effective in treating PMS	X	
Prevents implantation of fertilized ovum	X	
Is essential for successful pregnancy	X	
Is essential for myelinization of nerves	X	
Restores normal sleep patterns	X	
Is a precursor of other steroid hormones	X	
Is essential also for males	X	

Published Studies

Synthetic progestins and natural progesterone have only one common function: ability to sustain secretory endometrium. Progestins don't have the full spectrum of progesterone's activity. Clinic Use of Sex Steroids, 1980

Progestins have an adverse effect on insulin resistance. They can also raise triglycerides, and are related to breast cancer risk. American Journal of Obstetrics & Gynecology, 1994 Monographs/National Cancer Institute, 1994

Synthetic progestins have a wide variety of side effects. Clinic Use of Sex Steroids, 1980

Natural progesterone shows improved lipid profile, amenorrhea without endometrial problems, and has no side effects when compared with medroxyprogesterone acetate (Provera). Optimal Health Guidelines, 1993

Any change in the molecular configuration of steroids alters their effects. Optimal Health Guidelines, 1992

Synthetic progestins induce proliferation of breast tumor cells. Molecular and Cellular Endocrinology, 1994

The risk of cancer with long-term perimenopausal estrogen treatment may be increased with the addition of progestins. New England Journal of Medicine, 1989

During the past decade, several isolated reports have linked an increased incidence of breast cancer with the use of synthetic progestins. Cancer, 1993

Overwhelming evidence shows that breast cancer risk is closely related to exposure to synthetic estrogens and

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Synthetic Estrogen & Progesterone

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progestogens. Monograph, National Cancer Institute, 1994

Synthetic estrogen and progestin therapy have an adverse effect on bone because of their impact on magnesium excretion. Magnesium and Trace Elements, 1991-1992

Synthetic progestens suppress the immune system. Cleveland Clinical Journal of Medicine, 1994

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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 by the Commission, 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 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 § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Shelly Black is an individual trading and doing business as Progesterone Advocates Network with her principal office or place of business is at Post Office Box 1004, Trabuco Canyon, California 92678. Individually, or in concert with others,

Decision and Order

she formulates, directs, controls, or participates in the policies, acts, or practices of Progesterone Advocates Network.

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:

1. Unless otherwise specified, “Respondent” shall mean Shelly Black, individually and trading and doing business as Progesterone Advocates Network.
2. “Competent and reliable scientific evidence” shall mean 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.
3. “Progesterone product” shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Nature’s Precise Cream.
4. “Food,” shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.

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5. “Drug” shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. “Device” shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
7. “Covered product or service” shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. “Commerce” shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any

Decision and Order

State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.

9. “Endorsement” shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondent, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user’s risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user’s risk of developing breast cancer;

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- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondent, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondent from making any representation for any drug that is permitted in 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;

Decision and Order

- B. Nothing in this order shall prohibit Respondent 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
- C. Nothing in this order shall prohibit Respondent from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

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 reasonable notice 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 her 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 shall deliver a copy of this order to all current and future principals, officers, directors, and managers, and to all current and future employees,

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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 the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change with regard to Progesterone Advocates Network or any business entity that Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; 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 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. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondent, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of her current business or employment; or of her affiliation with any new business or

Decision and Order

employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which she has complied with this order.

IX.

This order will terminate on November 13, 2027, 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 Respondent 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

Analysis to Aid Public Comment

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 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 Shelly Black, an individual trading and doing business as Progesterone Advocates Network (“respondent”).

The proposed consent order has been placed on the public record for thirty (30) days for reception 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 the advertising and promotion of Nature’s Precise Cream, a transdermal cream that, according to its label, contains, among other ingredients, natural progesterone. According to the FTC complaint, respondent represented that Nature’s Precise Cream: (1) is effective in preventing, treating, or curing osteoporosis; (2) is effective in preventing or reducing the risk of

Analysis to Aid Public Comment

estrogen-induced endometrial (uterine) cancer; and (3) does not increase the user's risk of developing breast cancer and/or is effective in preventing or reducing the user's risk of developing breast cancer. The complaint alleges that respondent failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondent to keep copies of relevant advertisements and materials substantiating claims made in

Analysis to Aid Public Comment

the advertisements; to provide copies of the order to certain of her personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. 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 agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**MERILOU BARNEKOW,
TRADING AND DOING BUSINESS AS
WOMEN'S MENOPAUSE HEALTH CENTER**

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 5 AND SEC. 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-4208; File No. 072 3143

Complaint, November 19, 2007 – Decision, November 19, 2007

This consent order addresses the deceptive advertising and promotion of Preserve Progesterone Cream and Return to Eden Progesterone Cream transdermal creams in violation of the FTC Act. According to their labels, the creams contained, among other ingredients, natural progesterone. The complaint alleged that the respondent had no substantiation for its claims that the creams were effective (a) in preventing, treating, or curing osteoporosis; (b) in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (c) in reducing or alleviating the user's risk of developing breast cancer. The consent order requires respondent to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing any disease. The order further prevents the respondent from engaging in similar acts and practices in the future and prohibits the respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Participants

For the *Commission*: Gregory A. Ashe, Laura DeMartino, Janice P. Frankle, James A. Kohm, and Michael Ostheimer.

For the *Respondents*: Not represented by counsel.

Complaint

COMPLAINT

The Federal Trade Commission, having reason to believe that Merilou Barnekow, an individual trading and doing business as Women's Menopause Health Center ("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 Merilou Barnekow is an individual trading and doing business as Women's Menopause Health Center with her principal office or place of business at 1026 Blue Water Highway, Surfside Beach, Texas 77541, 709-2 Plaza Drive #105, Chesterton, Indiana 46304, and 3900 Orange Grove Boulevard #54, North Fort Myers, Florida 33903. Individually, or in concert with others, she formulates, directs, controls, or participates in the policies, acts, or practices of Women's Menopause Health Center, including the acts and practices alleged in this complaint.

2. 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.

3. Many women experience symptoms of menopause including hot flashes (also called flushes), night sweats, sleep disturbances, and painful intercourse. To relieve the symptoms of menopause, some doctors prescribe hormone therapy. This typically involves the use of either estrogen alone (for women who have had a hysterectomy) or (for women who have not had a hysterectomy) estrogen with an orally administered progestagen. Progestagen is a general term that includes progesterone (which is the progestagen produced by the human body or which can be synthesized as a drug) and progestins (which are synthetic forms of progestagens). A progestagen is added to estrogen to prevent hyperplasia (cell overgrowth) in the endometrium (lining of the uterus). This overgrowth can lead to endometrial (uterine) cancer. While

Complaint

progestagens decrease a woman's risk of estrogen-induced endometrial cancer, progestins have been found to increase a woman's risk of developing breast cancer.

4. Respondent has advertised, offered for sale, sold, and distributed products to the public throughout the United States, including Preserve Progesterone Cream and Return to Eden Progesterone Cream. Respondent primarily advertises and offers the products for sale through the Internet site www.womens-menopause-health.com.

5. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Preserve Progesterone Cream and Return to Eden Progesterone Cream are "drugs" as defined in Section 15(c) of the FTC Act, 15 U.S.C. § 55(c).

6. Preserve Progesterone Cream is a drug labeled as containing USP Natural Progesterone and other ingredients. A 3.5 ounce bottle costs \$34.95 plus shipping and handling. Return to Eden Progesterone Cream is a drug labeled as containing USP Progesterone. A 2 ounce jar costs \$19.95 plus shipping and handling. Preserve Progesterone Cream and Return to Eden Progesterone Cream are applied transdermally.

7. Until on or about August 1, 2007, to induce consumers to purchase Preserve Progesterone Cream, Respondent disseminated or caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit A. These advertisements contain the following statements and depictions, among others, on Respondent's website:

- A. Women today, armed with educated health information, know that there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned that it is clinically proven that one of the benefits of natural progesterone like that

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found in Preserve natural progesterone cream is that it can actually rebuild bone tissue with no known side effects.

With large studies* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead. The Preserve superb quality progesterone cream formula was developed by a team of physicians based on Dr. John Lee's research.

* * *

A natural course of action makes a lot more sense with progesterone cream's proven safety. Researchers have conducted clinical tests proving progesterone cream to be effective and safe with no side effects.

* * *

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast cancers. Dr. Lee calls this "estrogen dominance." Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by

Complaint

adequate progesterone like that found in Preserve progesterone cream.

Estrogen levels drop only 40% to 60% during menopause, but progesterone levels may drop to near zero in some women. Because progesterone is the precursor to so many other steroid hormones, its use can enhance hormone balance after menopause. Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone provides many benefits and combats estrogen dominance providing protection against cancers of the breast, ovaries, uterus, (endometrium), and in men, the prostate.

(Exhibit A at 5-7.)

- B. The benefits of natural progesterone cream are said to be many:

* * *

Rebuilds lost bone mass at a rate of 5-15% per year.
Improves new bone formation.

* * *

Reduces risk of breast cancer.
Reduces risk of uterine cancer.

(Exhibit A at 9-10.)

- C. Research and study information also shows that natural progesterone - in addition to diet and lifestyle changes - provides far greater benefit to bone health.

* * *

Progesterone works to actively build new bone tissue. By supplying the body with adequate supplies of bone-

Complaint

building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

* * *

Research shows that osteoporosis prevention measures of a healthy calcium-rich diet, exercise and progesterone work better than using hormone replacement therapy.
(Exhibit A at 13, 15.)

- D. An increasing number of studies show that progesterone as a natural alternative to traditional osteoporosis treatment is highly effective in not only preventing bone loss but in actually increasing bone density. This natural alternative to traditional osteoporosis treatment not only helps build bone mass, but also helps decrease menopause symptoms without side effects associated with hormone replacement therapy or drugs [sic] used for the treatment of osteoporosis.

* * *

For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone is the perfect natural alternative. The lack of progesterone causes a decrease in new bone formation. Using progesterone cream as a natural osteoporosis alternative can increase bone mass and actually reverse osteoporosis!

Complaint

In addition to improving new bone formation and warding off osteoporosis, progesterone balances estrogen dominance, improves lipid profile, improves blood sugar control, improves the ability to burn body fat. Progesterone cream eliminates hot flashes, helps with sleep disorders, normalizes and restores sexual desire, promotes youthful skin appearance and reduces the risk of breast cancer and uterine cancer.

* * *

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone less while progesterone aids the body in building new bone.

* * *

This is the good news. Even if bones have lost density, there is opportunity to gain it back.
(Exhibit A at 16-17.)

- E. Fortunately, women have safe and effective natural hormone replacement therapy alternatives to ease them through menopause without the risks associated with non-natural hormone replacement therapy.

In addition to the multi-dimensional plant-based estrogen complex in Preserve, the Preserve formula also contains the following ingredients found effective in reducing menopause symptoms:

* * *

Progesterone: A naturally occurring hormone which works with estrogen compounds, important for its abilities to

Complaint

correctly balance estrogen activity, and helps to maintain bone density.

(Exhibit A at 21.)

- F. Excess fatty tissue is a source of circulating estrogen in your body, and breast cancer risk is directly linked to how much estrogen you're exposed to during your lifetime. (Another significant reason to avoid synthetic estrogen replacement therapy (ERT) and balance hormones with Preserve Progesterone Cream or Preserve as a part of your breast cancer prevention regimen [sic].

(Exhibit A at 24.)

- G. Natural progesterone cream helps:

* * *

-Rebuild lost bone mass.
-Improves new bone formation.

* * *

-Reduce risk of breast cancer.
-Reduce risk of uterine cancer.

* * *

If you have not already kicked the hormone replacement therapy [sic], now is as good a time as any. Order a bottle of Preserve and a pump container of Preserve Natural Progesterone Cream and experience healthy menopause for yourself.

(Exhibit A at 27-28.)

- H. The next step in the osteoporosis prevention plan is to begin using a high quality progesterone cream like

Complaint

Preserve to give the body the hormonal building block components for new bone growth. Progesterone serves a dual purpose. While providing positive effects on osteoporosis by promoting the building of new bone mass, progesterone also decreases menopause symptoms typical in the age group of women at risk for osteoporosis.
(Exhibit A at 29.)

8. From on or about August 1, 2007, to induce consumers to purchase Return to Eden Progesterone Cream, Respondent has disseminated or has caused to be disseminated advertisements, including but not necessarily limited to those contained in the attached Exhibit B. These advertisements contain the following statements and depictions, among others, on Respondent's website:

- A. Women today armed with educated health information, know there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned what women in Great Britain and Europe have known for decades - the benefits of natural progesterone like that found in Return to Eden natural progesterone cream. These women believe, from decades of use, that it can actually rebuild bone tissue with no known side effects.

With large studies* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead.

* * *

Complaint

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast cancers. Dr. Lee calls this “estrogen dominance.” Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Return to Eden all-natural progesterone cream.

* * *

Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone may provide many benefits and combats estrogen dominance.

(Exhibit B at 5, 7.)

- B. The benefits of natural diosgenin (nicknamed progesterone) cream are said to be many:

* * *

Balances estrogen dominance.

(Exhibit B at 9.)

- C. Given the positive benefits of progesterone cream and the low incidence of progesterone side effects, many women choose this natural alternative to achieve normal progesterone levels.

* * *

Complaint

To achieve the optimal benefits of progesterone cream without progesterone side effects to achieve normal progesterone levels, use the natural progesterone cream 500 mg/oz Return to Eden formula.

(Exhibit B at 12.)

- D. The Federal Drug Administration recently mandated a new boxed warning on the danger of estrogen therapy and estrogen/progestin products such as Premarin and Prempro. This is the highest FDA warning level for drug labeling. The FDA estrogen information warning states an increased risk for heart disease, heart attacks, strokes, and breast cancer and also emphasizes that estrogen products are not approved for heart disease prevention.

* * *

The government report cites data from human epidemiology studies that show a connection between estrogen therapy and an increase in endometrial cancer and breast cancer.

* * *

Stopping hormone replacement therapy would be a difficult choice without effective alternatives to hormone replacement therapy. Fortunately, there are effective alternatives for women who no longer wish to take hormone replacement therapy.

A quality progesterone cream like Return to Eden natural progesterone cream, may gently alleviate menopause symptoms as well as hormone replacement therapy.

Natural progesterone cream helps:

* * *

Balances estrogen dominance.

Complaint

(Exhibit B at 14-15.)

- E. Women in Great Britain and Europe have found that progesterone is a natural alternative to traditional osteoporosis treatment. This natural alternative to traditional osteoporosis treatment is believed by them to build bone mass, and help decrease menopause symptoms without side effects associated with synthetic hormone replacement therapy or drugs [sic] used for the treatment of osteoporosis.

* * *

For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone may be the perfect natural alternative. The lack of progesterone is thought to cause a decrease in new bone formation.

Progesterone balances estrogen dominance. . .

* * *

For a natural alternative to osteoporosis treatment, post-menopausal women may use up to one teaspoon of high quality progesterone cream daily for three weeks each month. The week off progesterone maintains the sensitivity of the progesterone receptors. We recommend Return to Eden natural USP progesterone cream.

* * *

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone loss while progesterone aids the body in building bone.

Complaint

* * *

This is the good news. Even if bones have lost density, there is opportunity to gain it back. But, in order for new bone to be made, bones need an adequate supply of nutrients like calcium, regular weight-bearing exercise and hormonal balance conducive to bone growth.

(Exhibit B at 17-18.)

- F. Given the serious health risks associated with estrogen and the lack of long-term benefit, hormone replacement therapy is one of the least appropriate osteoporosis treatment methods women should take.

Women in Great Britain and Europe have been using natural progesterone like that found in Return to Eden all-natural progesterone cream for decades to combat osteoporosis.

* * *

Progesterone is thought to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

(Exhibit B at 21.)

Complaint

G. Post Menopausal symptoms include . . . osteoporosis. . .

* * *

The above symptoms of menopause are successfully relieved for the majority of women when using Return to Eden as directed.

(Exhibit B at 24.)

H. The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

* * *

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites enabling estrogen to work more efficiently without being dominant.

* * *

The benefits of natural progesterone cream are said to be many:

* * *

Balances estrogen dominance.

* * *

Rebuilds lost bone mass at a rate of 5-15% per year.

Complaint

Improves new bone formation.

* * *

Reduces risk of breast cancer.

Reduces risk of uterine cancer.

(Exhibit B at 28-29.)

9. Through the means described in Paragraphs 6 through 8, Respondent has represented, expressly or by implication, that:

A. Preserve Progesterone Cream and Return to Eden Progesterone Cream are effective in preventing, treating, or curing osteoporosis;

B. Preserve Progesterone Cream and Return to Eden Progesterone Cream are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and

C. Preserve Progesterone Cream and Return to Eden Progesterone Cream do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer.

10. Through the means described in Paragraphs 6 through 8, Respondent has represented, expressly or by implication, that she possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 9, at the time the representations were made.

11. In truth and in fact, Respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 9 at the time the representations were made. Therefore, the representation set forth in Paragraph 10 was, and is, false or misleading.

12. The acts and practices alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false

Complaint


advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, on this nineteenth day of November, 2007, has issued this complaint against respondent.

By the Commission.

Complaint

Exhibit A


Women's Menopause Health Center

[Menopause Products](#) | [Hormone Replacement Therapy](#) | [Menopause Symptoms](#) | [Perimenopause Symptoms](#) | [Prempro](#) | [Controlling Hot Flashes](#) | [Premarin](#) | [Natural Hormone Replacement](#) | **New!** [Progesterone Cream](#) | [Menopause FAQ](#) | [Depression](#) | [Home](#)


Welcome To Women's Menopause Health Center.
Specializing in sales of [natural hormone replacement therapy](#) supplements (HRT), and [progesterone cream](#) [herb](#) free of cancer-causing synthetic hormones as found in [Premarin](#) and [Prempro](#), for [perimenopause](#), [menopause symptoms](#), and [hot flashes](#).

XML RSS Menopause News.

Perimenopause. Perimenopause Pregnancy , Perimenopause Treatment , Depression Perimenopause , Perimenopause Weight Gain , Perimenopause Anti-Aging , Perimenopause Symptoms , Perimenopause and Thyroid .	Menopause. Menopause anxiety , Menopause fatigue , Menopause symptoms .	Hormone Replacement. Hormone Replacement Therapy & Osteoporosis , Stopping Hormone Replacement Therapy , Estrogen Hormone Replacement Therapy , Hormone Replacement Therapy , Prempro Ingredient .
Hot Flashes. Home remedies for hot flashes , Herbal remedy for hot flashes , Treatment for hot flashes night sweats , Controlling hot flashes .	Progesterone Cream. Progesterone cream ingredients , Benefits progesterone cream , How to use progesterone cream , Preserve Progesterone Cream .	Depression. Depression Help , Medication for Depression , Depression Symptom , Cause of Depression , Type of Depression .
Menopause Health Articles. Menopause Essential Nutrients .	Depression Health Articles.	Holistic and Alternative Health Articles.

INTRODUCING - THE ALL NEW IMPROVED!

Preserve Progesterone Cream.



- 20mg USP progesterone 100% pharmaceutical grade per one pump stroke - 750 mg/oz.
- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
- 3.5 oz bottle.

1 bottle Preserve Progesterone Cream ~~MSRP \$42.05~~
\$34.95 ea. [Buy Now](#)
2 bottles Preserve Progesterone Cream
\$33.95 ea. [Buy Now](#)
3 bottles Preserve Progesterone Cream
\$32.95 ea. [Buy Now](#)

[Progesterone ingredients](#) | [Progesterone information](#) | [Progesterone use](#).

Complaint

[Click here to view our Medical Advisory Board.](#)

Hormone replacement therapy increases the risk of cancer, of heart disease, of strokes and blood clots. New studies also place women taking synthetic hormones at double the health risk of Alzheimer's Disease and dementia. And contrary to prevailing thought, hormone replacement therapy does not protect against osteoporosis.

Why then, given the serious risk to women's health, do women take hormone replacement therapy? For many, the simple answer is that women need relief from hot flashes and other menopause symptoms.

Finding relief from menopause symptoms is not a black-and-white choice between taking hormone replacement therapy or doing nothing at all. Women do not need to place themselves in harm's way to eliminate hot flashes, mood swings, weight gain, headaches and other effects of menopause.

The Women's Menopause Health Center offers real solutions for menopause and perimenopause symptoms that improve the quality of life instead of placing women at risk for serious and potentially life threatening hormone replacement side effects.

The Women's Menopause Health Center offers highly effective natural hormone replacement therapy that are the result of extensive research to find the purest, highest quality, clinically formulated and tested formulas available today.

With the in-depth menopause information offered at the Women's Menopause Health Center, women can make informed health care decisions that improve women's health instead of compromising women's health.

Before you start taking Premarin, Prempro or any other synthetic hormones, carefully consider the harmful effects on women's health.

The large-scale Women's Health Initiative study released in 2002 show that hormone replacement therapy (HRT) is linked to substantial increases in the risk of developing breast cancer, heart disease, strokes and blood clots. Additionally, when estrogen is prescribed alone, it can increase the risk of ovarian cancer.

The most recent arm of the Women's Health Initiative study, released in May 2003, adds to already damning 2002 studies of the effects of hormone replacement therapy. New research shows that women on synthetic hormones like Premarin and Prempro are at double the risk for Alzheimer's Disease and dementia.

The in-depth government Women's Health Initiative study reshaped how women and their physicians now approach managing menopause symptoms. Many doctors are now recommending hormone replacement therapy only for their patients with severe menopause symptoms. Even then, most physicians tell their patients that the benefits often do not outweigh the women's health risks involved.

Hormone replacement therapy use in the United States fell by about one-third - from 15 million women to 10 million - after the 2002 Women's Health Initiative announcements.

Complaint

Yet, there are still 10 million American women taking hormone replacement therapy. How does this number affect women's health?

The Women's Health Initiative found that for every 10,000 women using hormone replacement therapy, there were 7 additional heart attacks, 8 additional strokes, 8 additional cases of breast cancer and 23 additional cases of dementia.

Those numbers seem quite low until translated into real-life numbers. Using hormone replacement therapy will add an additional 7,000 heart attacks, 8,000 strokes, 8,000 cases of breast cancer and 23,000 new cases of dementia and Alzheimer's Disease for the 10 million women currently using synthetic hormones.

That is an additional 46,000 women who will suffer damaging health effects - or worse. Even one added case cannot justify the damaging effects that dementia will place on a woman's family. Even one additional case of breast cancer cannot justify the grief of children and grandchildren losing a woman they love to an unnecessary death.

News of the health risks unearthed in the Women's Health Initiative menopause study galvanized many women's decision to find natural hormone replacement therapy alternatives to deal with the effects of menopause.

The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

If you have tried other natural hormone replacement products and still suffer menopause symptoms, give our superior products a try. Experience how a commitment to quality and integrity, pure ingredients, and top notch medical oversight can make a difference for you. Don't settle for less!

Not all menopause products are created equal. **The progesterone cream and all our menopause products offered are of the purest and highest quality women's health products on the market today.**

Our products are created to the **highest manufacturing standards**. A menopause supplement is only as good as its ingredients AND its manufacturing standards. With the vast number of supplements on the market today, consumers must be wary of purchasing "Parking Lot" supplements - those manufactured without exacting standards.

There are over 10,000 nutritional manufacturing facilities in the United States. Less than one-half of one percent of the nutritional manufacturing facilities in the country match the exacting standards followed in our facility.

We believe that good formulas can only lead to good health by starting with quality and efficacious product ingredients. Thus, we offer assurance that all of the ingredients used in our formulations are simply the best available in the world.

Vaxa's Preserve provides nutritional tools with a unique combination of micro-nutritionals, rare Chinese dietary herbs, free form amino acids and vitamins and minerals specifically targeted to support and address hormonal pathway imbalances and reducing menopause symptoms.

Preserve

[Preserve Information](#)

[Dosage & Ingredients](#)

Complaint

DO YOU WANT TO GET BACK YOUR MENOPAUSE SYMPTOMS? PROGESTERONE CREAM, NATURAL SUPPLEMENT FOR MENOPAUSE HEALTH. AUGUST 2007



- Helps normalize hormonal levels,
- Helps diminish night sweats and hot flashes.
- Helps soothe and stabilize mood, reducing moodiness, depression and irritability.
- Helps reduce the uncomfortable and painful menopause signs and menopause symptoms such as pain, cramping and headache.

1 Bottle	\$26.95	Buy Now
2 Bottles	\$51.90	Buy Now
3 Bottles	\$76.35	Buy Now

This complete menopause natural hormone replacement therapy contains phytoestrogens, plant-based estrogens that are used widely in Europe and Great Britain as a safe alternative to synthetic hormone therapy.

The Women's Menopause Health Center also offers progesterone cream, the most complete all-natural cream on the market. Our progesterone cream is chock full of USP progesterone to stop hot flashes.

Receiving the best menopause therapy possible during the transition between the child-rearing years and new possibilities dramatically increases the quality of women's lives. With unpleasant menopause symptoms under control, women can look at and live through menopause with a positive mental attitude and exciting new possibilities.

[Archived Women's Menopause Health Newsletters.](#)

[Women's Menopause Health Resources.](#)

For powerful alternatives to Ritalin, visit the [Attention Deficit Disorder Help Center.](#)

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NOTICE: PROGESTERONE Cream is the best quality bio-identical natural USP progesterone cream as recommended by Dr. John Lee, M.D.

Menopause Hormone Therapy Sterling, VA MD specializing in natural bioidentical hormones. www.BodyLogicMD.com	Progesterone Cream- \$5.86 Made to Dr. Lee's specifications. USP. Satisfaction guaranteed. www.onelifeusa.com	All Natural Hormones Bio-Identical Hormone Replacement Safer Alternative to Synthetic HRT www.profilehealth.com	Free Sample of Remifemin® or Remifemin Good Night! Hot Flash relief PLUS 88% improved sleep. www.remifemin.com
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Best Natural USP Progesterone Cream for Menopause and Perimenopause

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Quality Natural Preserve USP Progesterone Cream for Menopause Perimenopause Symptoms and Hot Flashes.

INTRODUCING - THE ALL NEW IMPROVED!

Preserve Progesterone Cream.



- 20mg USP progesterone 100% pharmaceutical grade per one pump stroke - 750 mg/oz.
- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
- 3.5 oz bottle.

1 bottle Preserve Progesterone Cream ~~MSRP \$42.95~~
\$34.95 ea. [Buy Now](#)
2 bottles Preserve Progesterone Cream
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Women today, armed with educated health information, know that there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned that it is clinically proven that one of the benefits of natural progesterone like that found in Preserve natural progesterone cream is that it can actually rebuild bone tissue with no known side effects.

With large studies* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead. The Preserve superb quality progesterone cream formula was developed by a team of physicians based on Dr. John Lee's research.

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John R. Lee, M.D. is an international authority and pioneer in the use of natural progesterone cream and natural hormone balance. He authored the best-selling book, "What Your Doctor May Not Tell You About Menopause: The Breakthrough Book on Natural Progesterone."
(Recommended reading.)

A natural course of action makes a lot more sense with progesterone cream's proven safety. Researchers have conducted clinical tests proving progesterone cream to be effective and safe with no side effects.

Be warned, though, that not all progesterone cream and lotions are the same. It is important to insist upon a high quality natural progesterone supplement, not a supplement made from uncertified cheap ingredients exported from foreign countries with lax regulations.

Our products are created to the **highest manufacturing standards**. A menopause supplement is only as good as its ingredients AND its manufacturing standards. With the vast number of supplements on the market today, consumers must be wary of purchasing "Parking Lot" supplements - those manufactured without exacting standards.

Preserve natural progesterone cream is:

- **State of the art pump delivery system** insures that oxygenation doesn't degrade the progesterone content cream and preserves freshness.
- **Independent laboratory certified for the quality of USP progesterone content** of about 20mg per pump stroke which translates to the 750mg/oz recommended by Dr. Lee. Many "popular creams" sold today contain little or no USP progesterone, or at best, have inconsistent levels of progesterone. One study showed that 50 percent of these progesterone creams didn't contain any measurable progesterone. Preserve is one brand of progesterone cream that is reliable!
- **Made from USP progesterone, not wild yam extract.** No published studies conclude that yam increases progesterone levels in animals or humans. While the diosgenin molecule from wild yams can be converted to a progesterone molecule in the laboratory, it can NOT be in the human body. Unconverted diosgenin is a cheap way to produce a progesterone cream, and according to Dr. Lee does not work well. It is important to insist upon USP progesterone, not uncertified cheap ingredients made in some foreign countries.
- **Free of Stearyl Konium Chloride**, an emulsifier. According to the University of Texas database, ingestion of 3 cc of this toxic compound is enough to cause fatal convulsions in an adult human.

There are over 10,000 nutritional manufacturing facilities in the United States. Less than one-half of one percent of the nutritional manufacturing facilities in the country match the exacting standards followed in our facility.

What are the benefits of using progesterone cream?

Unlike Provera, which, first, is a synthetic progesterone or progestin, progesterone creams are applied to the skin (transdermal, which means "through the skin"). Hormones, if taken by mouth, are immediately passed from the small intestine to the liver and returned in water soluble form back to the start of the small intestine. During the process, 80% to 90% of the hormone is lost through the liver. Only a small fraction of ingested hormones end up circulating in the blood able to attach to appropriate receptors.

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Dr. Lee recommends the transdermal progesterone cream rather than oral progesterone, because approximately 80% to 90% of the oral dose is lost through the liver. A 200 to 400 mg is needed on a daily basis to achieve a physiologic dose of 50 to 24 mg. Not only is the liver unnecessarily taxed adding to its toxic overload, such high doses create undesirable metabolites.

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast cancers. Dr. Lee calls this "estrogen dominance." Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Preserve progesterone cream..

Estrogen levels drop only 40% to 60% during menopause, but progesterone levels may drop to near zero in some women. Because progesterone is the precursor to so many other steroid hormones, its use can enhance hormone balance after menopause. Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone provides many benefits and combats estrogen dominance providing protection against cancers of the breast, ovaries, uterus, (endometrium), and in men, the prostate.

**Harvard researcher, Dr. Graham Colditz - a world authority on the subject, conducted studies which showed that women who use estrogen for more than five years have a 46% higher risk of breast cancer than women who use none. Dr. Colditz' study results came from a sampling of 121,700 women tracked for 24 years from the famous Nurses Health Study as reported in The New England Journal of Medicine, June 1995.*

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Increase Your Libido Naturally.
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Best Natural USP Menopause Progesterone Cream Benefits.

Experience the benefits of natural progesterone cream. Say goodbye to women's menopausal symptoms and the effects of aging!

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites enabling estrogen to work more efficiently without being dominant. Progesterone is a precursor to other hormones in the body including estrogen, testosterone, and especially the corticosteroids.

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Preserve Progesterone Cream.



- 20mg USP progesterone 100% pharmaceutical grade per one pump stroke - 750 mg/oz.
- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
- 3.5 oz bottle.

1 bottle Preserve Progesterone Cream ~~MSRP \$42.95~~
\$34.95 ea. **Buy Now**
2 bottles Preserve Progesterone Cream
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3 bottles Preserve Progesterone Cream
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The benefits of natural progesterone cream are said to be many:

- Brings hormonal balance back into your body.
- Balances estrogen dominance.
- Improves lipid profile.
- Improves blood sugar control.
- Improves burn up of body fat.
- Rebuilds lost bone mass at a rate of 5-15% per year.
- Improves new bone formation.

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LEARN THE BENEFITS OF Organic Natural Progesterone Cream With Physiological And Pure Ingredients As An Alternative To Hormone Replacement Therapy. Page 2 Of 3

- Natural anti-depressant.
- Natural diuretic.
- Eliminates hot flashes.
- Creates the myelin sheath over nerves.
- Gives people more energy.
- Helps with sleep disorders.
- Helps with Fibrocystic Breast Disease.
- Normalizes and restores sexual desire.
- Promotes youthful skin appearance.
- Resists facial hair growth.
- Reduces risk of breast cancer.
- Reduces risk of uterine cancer.
- Improves blood sugar control.
- Promotes youthful skin appearance. (The late diet guru, Dr. Robert Atkins, M.D. was enthusiastic about natural progesterone cream for skin care. He endorsed its use because he found it the best wrinkle eradicator he ever had experienced.)

Perimenopause symptoms also can benefit from natural progesterone cream. The following may reflect early hormonal imbalances:

- Hot flashes.
- Fibrocystic breast disease.
- Hot flashes.
- Insomnia.
- Night sweats.
- Mood swings.
- Depression.
- Vaginal dryness.
- Reduced sexual desire.

MSM and Bone Loss: MSM provides the building blocks for the restoration of cartilage, helping when there has been bone loss. It is a potent natural anti-inflammatory, which allows you to better use your own healing system. For more information concerning MSM, click [here](#).

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Hormone Replacement Therapy & Osteoporosis.

Osteoporosis is a gradual decrease in bone mass and density that hits postmenopausal women especially hard. Though information varies, most osteoporosis information places postmenopausal Caucasian women at a 50 to 80 percent risk of sustaining a hip, spine, or forearm fracture due to osteoporosis.

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Osteoporosis is almost entirely preventable and even reversible with prevention and treatment measures. New research information shows that hormone replacement therapy does not adequately protect women from osteoporosis.

Though women often associate osteoporosis with menopause, bone loss actually begins years before menopause. Most women reach peak bone density at about 30 and will lose about .7 percent on their bone density after that. Bone loss accelerates for three to five years around the time of menopause and then continues to decline at the rate of about 1 to 1.5% per year.

Because bone loss accelerates at menopause, at the time estrogen levels decline, conventional medicine adopted the belief that estrogen deficiency cause osteoporosis. Following that assumption, physicians regularly used hormone replacement therapy to prevent osteoporosis.

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However, new study information places the hormone replacement therapy benefit to osteoporosis as myth and makes it clear that hormone replacement therapy is not the correct course of osteoporosis treatment.

- The Journal of the American Medical Association (JAMA) reported a 14-year study that showed no significant difference in the frequency of hip fractures between women who used hormone replacement therapy and those who did not use hormone replacement therapy.
- The New England Journal of Medicine published an 8-year study following almost 10,000 menopausal women. This study also showed no significant difference in the frequency of hip fractures between women who used hormone replacement therapy and those who did not use hormone replacement therapy.

Given the serious health risks associated with estrogen and the lack of long-term benefit, hormone replacement therapy is one of the least appropriate osteoporosis treatment methods women should take.

Research and study information also shows that natural progesterone - in addition to diet and lifestyle changes - provides far greater benefit to bone health.

With osteoporosis, bone tissue dies faster than new bone tissue is made. Over time, bones become less dense and more porous. If the bones become too weak to support the skeleton, bones can break easily. If frail enough, a minor fall, bump or even a hard sneeze can cause a bone fracture.

Progesterone works to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

Many other factors play a significant role in osteoporosis prevention. Caucasian women - especially those with a family history of osteoporosis or poor diets in their younger years - are at the greatest risk of osteoporosis after menopause. Women with poor diets, low calcium intake, low body weight, low physical activity and alcoholism are also at risk for osteoporosis.

You cannot change your sex, race or age but you can change other factors that contribute to osteoporosis.

Osteoporosis Risk Factors: (Other than being a postmenopausal woman):

- Family history of osteoporosis.
- Caucasian.
- Low body weight.
- Early menopause Low calcium intake.

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Osteoporosis hormone replacement therapy, Osteoporosis information, Osteoporosis bone density test kit... Page 3 of 4

- Low physical activity.
- Cigarette smoking.
- Drinking more than two alcohol drinks daily.
- Long-term steroid therapy.
- Long-term anti-convulsant therapy.
- Drug therapy that causes dizziness.
- Hyperthyroidism.
- Coffee intake of more than two cups daily.
- Alcohol intake of more than two drinks daily.
- Regular antacid use.

Early signs of osteoporosis include gradual loss of height, loose teeth and persistent low back pain. Sudden insomnia and restlessness and nightly leg and foot cramps are also early warning signs of osteoporosis.

Many women are not aware that they are losing bone mass until after a bone fracture. It behooves women of menopause age to know the status of their bone health and use osteoporosis prevention measures to prevent bone loss before it begins.

One way of testing bone loss is to check your height every six months. If you start losing height, you are losing bone on your spine. This method of checking bone loss does not give a comprehensive profile of bone health but it does give a general indication of bone loss.

The best way to determine bone density and fracture risk before a fracture occurs is to have a bone mineral density (BMD) test. A bone density test measures bone density in the spine, hip and/or wrist, the most common sites of fractures due to osteoporosis. There are bone density tests now available that measure bone density in the middle finger and the heel or shinbone.

The bone density test identifies risk for fracture. The lower the bone density, the greater the risk for fracture. The bone density test compares a person's bone density to the expected bone density of a person of the same age, sex and size, along with a comparison of bone density at the optimal peak bone density of a healthy young adult of the same sex.

Hospitals and imaging centers offer bone density tests. There are many different bone density test methods. All are painless and noninvasive. The dual energy X-ray absorptiometry is one of the best scanning techniques that offers accuracy and minimal radiation exposure.

Women should have a bone density test performed as they enter menopause. The early bone density test serves as baseline information to compare against future bone density tests.

Many experts recommend having a second bone density test 12 to 24 months after starting an osteoporosis prevention regime to make sure the protective program is working. After that, additional tests aren't needed unless lifestyle or other health conditions change.

Women taking hormone replacement therapy for osteoporosis prevention should

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Osteoporosis hormone replacement therapy, Osteoporosis information, Osteoporosis bone density test results Page 4 of 7

use the bone density test to verify that hormone replacement therapy is indeed providing positive benefit to bone health. If bone loss continues while using hormone replacement therapy - and studies show that it likely will - women should change their osteoporosis prevention regime to one that will provide better results.

Research shows that osteoporosis prevention measures of a healthy calcium-rich diet, exercise and progesterone work better than using hormone replacement therapy.

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Osteoporosis Treatment

An increasing number of studies show that progesterone as a natural alternative to traditional osteoporosis treatment is highly effective in not only preventing bone loss but in actually increasing bone density. This natural alternative to traditional osteoporosis treatment not only helps build bone mass, but also helps decrease menopause symptoms without side effects associated with hormone replacement therapy drugs used for the treatment of osteoporosis.

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- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
- 3.5 oz bottle.

1 bottle	Preserve Progesterone Cream	MSRP \$42.95	\$34.95 ea.
Buy Now			
2 bottles	Preserve Progesterone Cream		\$33.95 ea.
Buy Now			
3 bottles	Preserve Progesterone Cream		
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Researchers for decades suspected that the decrease in estrogen contribute osteoporosis, mostly because women typically begin to notice the effects of osteoporosis after going through menopause. Based on that assumption, doctors prescribed estrogen as osteoporosis treatment during menopause. However, recent studies clearly show that estrogen alone as an osteoporosis treatment does little for long-term prevention of bone loss.

Given the serious health risks associated with estrogen and the lack of long-term benefit, estrogen is one of the least appropriate osteoporosis treatment methods women should take. New medication alternatives for the treatment of osteoporosis pose less harmful side effects than hormone replacement therapy, but these drugs used for osteoporosis treatment also have unpleasant and potentially harmful side effects and are still sometimes ineffective for long-term bone health.

The medication drugs most commonly prescribed for osteoporosis treatment are Calcitonin (Miacalcin) and Alendronate (Fosamax). Forteo, a new drug medication for the treatment of osteoporosis also promises good results.

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For women seeking osteoporosis treatment while simultaneously addressing menopause related symptoms and health concerns, progesterone is the perfect natural alternative. The lack of progesterone causes a decrease in new bone formation. Using progesterone cream as a natural osteoporosis alternative can increase bone mass and actually reverse osteoporosis!

In addition to improving new bone formation and warding off osteoporosis, progesterone balances estrogen dominance, improves lipid profile, improves blood sugar control, improves the ability to burn body fat. Progesterone cream eliminates hot flashes, helps with sleep disorders, normalizes and restores sexual desire, promotes youthful skin appearance and reduces the risk of breast cancer and uterine cancer.

For a healthy and natural alternative to osteoporosis treatment, postmenopausal women should use up to one teaspoon of high quality progesterone cream daily for three weeks each month. The week off progesterone maintains the sensitivity of the progesterone receptors. We recommend Preserve natural USP progesterone cream. Preserve USP progesterone cream has one of the highest levels of progesterone in creams on the market today and uses only high quality ingredients, with no artificial fillers.

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone loss while progesterone aids the body in building new bone. Bones are living tissue that is constantly dying off and rejuvenating. The larger bones in the body are replaced every 10 to 12 years while smaller, less dense bones are replaced every two to three years.

This is the good news. Even if bones have lost density, there is opportunity to gain it back. But, in order for new bone to be made, bones need an adequate supply of nutrients, regular weight-bearing exercise and hormonal balance conducive to bone growth.

Help for Osteoporosis	Osteoporosis Treatment	Osteoporosis Treatment	Osteoporosis & Fractures
The 7 supplements you must have to reverse and overcome osteoporosis. health-reports.com	Compare Osteoporosis Treatments Comprehensive Info on Osteoporosis OsteoporosisTreatments.Info	Learn How To Slow, Treat And Even Reverse Symptoms Of Osteoporosis! HealthSmarts.com	Minimally Invasive treatment for vertebral compression fractures www.Kyphon.com

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Natural Hormone Replacement.

Women want to increase their quality of life through menopause. Woman want to live free of hot flashes, free of depression, free of sleep problems and other symptoms related to menopause, while remaining free of the health risks associated with synthetic hormones.

Preserve



- Helps normalize hormonal levels,
- Helps diminish night sweats and hot flashes.
- Helps soothe and stabilize mood, reducing moodiness, depression and irritability.
- Helps reduce the uncomfortable and painful menopause signs and menopause symptoms such as pain, cramping and headache.


1 Bottle	\$26.95	Buy Now
2 Bottles	\$51.90	Buy Now
3 Bottles	\$76.35	Buy Now

Women, educated on the harmful effects of synthetic hormone replacement therapy, are now beginning to realize the great benefits of natural hormone replacement therapy that women in other parts of the world have known for ages.

The proof of natural hormone replacement therapy's healthful effectiveness is found in pocket regions of the world where women routinely lean on nature's remedy for menopause with natural hormone replacement therapy.

A high concentration of women in Asia and some Mediterranean and Latin American countries use natural hormone replacement therapy instead of synthetics and these women typically breeze through menopause.

The women using natural hormone replacement therapy report fewer hot flashes and other menopause symptoms, improved mental states and better sleep patterns. Women in these



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NATURAL HORMONE REPLACEMENT THERAPY, ESROGEN, NATURAL HORMONE

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cultures using natural hormone replacement therapy have less heart disease and less breast cancer.

- A 2001 New England Research Institutes survey found that Asian-American women who consumed a diet high in natural hormone replacement substances reported fewer hot flashes and night sweats than their American counterparts.
- A 2001 University of California literary review and international studies also show that women with diets high in natural hormone replacement substances have lower rates of osteoporosis, cancers, and heart disease.

Simply put, women using natural hormone replacement therapy report fewer problems and discomforts associated with menopause while reaping the benefits of a stronger heart, stronger bones and healthier body than women taking non-natural hormone replacement therapy.

Natural Hormone Replacement Therapy: The Phytoestrogens Connection.

Phytoestrogens (plant-derived estrogen) are a key group of natural substances in natural hormone replacement therapy. Natural plant estrogen, also known as phenolic estrogen, is what Asian and Latin American women consume daily in their normal diets.

Although it is best to add these plant-derived estrogen substances through whole foods, the typical American diet is often void of foods high in natural hormone replacement therapy substances.

That is why supplementation is so important for women in menopause and beyond.

Aging (wherein neuro-signaling may become impaired) and the dietary and tissue/ovarian deficiencies that may arise because of menopause or other change of life patterns, cause higher demands for these specially targeted elements in women's bodies.

Preserve is a unique combination of micro-nutritionals, rare Chinese dietary herbs, free form amino acids and vitamins and minerals specifically targeted to support and address hormonal pathway imbalances and reducing menopause symptoms.

Preserve provides the body with those executive instructions and nutritive materials needed to calm itself and provide relief for the symptoms of menopause by providing the body elements needed to naturally balance itself, rejuvenate and repair itself.

Preserve allows women to experience the time of natural reproductive change with little uncomfortable disruption of normal life functioning. Preserve will not interfere with any complementing prescriptive strategy a physician or health professional would prescribe.

The Preserve formula is chock full of phytoestrogens and other beneficial ingredients that supply the body with safe, naturally-occurring phytoestrogen complexes. The Preserve formula contains calming herbs to help naturally diminish the discomfort of menopausal symptoms and essential nutrients so often lacking during and after menopause. The ingredients in this MultiDimensional formula support the body's abilities to naturally normalize hormonal levels and diminish menopause symptoms.

An effective aspect of the scientific Preserve formula is the multi-dimensional plant-based

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estrogen complex of black cohosh, dong quai, and sage. This combination is widely used in Europe and Great Britain as a safe alternative to synthetic hormone therapy and hormone replacement therapy and provides more complete coverage for menopause symptoms than soy products.

These Preserve formula elements are capable of binding to estrogen-receptors, potentially reducing activity when estrogen levels are high, and exerting estrogen-like activity by the same mechanism when estrogen levels are low.

According to Reginald B. Cherry, M.D. in his book, *God's Pathway to Healing - Menopause*, "plant or phenolic estrogens can attach to receptors for certain organs of the body, such as the breast and uterus. They actually modulate or block the effect of a woman's own estrogen on these tissues. The bottom line is that plant estrogens can protect a woman from breast, ovarian and uterine cancer in her later years!

This is likely a major reason that breast cancer, for example, is so low in Asia and parts of Latin America - people in these nations consume phyto (phenolic) estrogens in their foods most of their lives."

During a woman's childbearing years, a woman's ovaries produce what are known as steroidal estrogens. This type of estrogen causes the ovaries to produce eggs and enables a woman to have a baby. Although the steroidal estrogens are necessary for reproduction and do protect women from heart disease, bone thinning and other problems, they are not totally benign. The longer women are exposed to naturally produced estrogen, the greater the risk she will have in later years for developing ovarian and breast cancer.

Breast cancer is higher in women who begin their periods early and go through menopause late. Women who have many children are at lower risk because the body ceases estrogen production during pregnancy. So when a doctor prescribes a steroidal estrogen like Premarin for a menopausal woman, she may feel better, but her cancer risk increases. Women using HRT/hormone replacement therapy are simply adding those steroidal estrogens to their bodies much longer than nature intended.

Fortunately, women have safe and effective natural hormone replacement therapy alternatives to ease them through menopause without the risks associated with non-natural hormone replacement therapy.

In addition to the multi-dimensional plant-based estrogen complex in Preserve, the Preserve formula also contains the following ingredients found effective in reducing menopause symptoms:

Vitex Agnus Castus: Aids in soothing menopausal difficulties; directly affects two pituitary hormones which regulate progesterone and estrogen use throughout the body.

Progesterone: A naturally occurring hormone which works with estrogen compounds, important for its abilities to correctly balance estrogen activity, and helps to maintain bone density. **Chinese Female Balancing Herbs (Radix Bupleuri, Fo-Ti & Radix Multiflori-Polygoni):** Aid in the normalization of hormone levels by enhancing the flow of energy and circulation while helping to soothe the adverse reactions of menopause.

St. John's Wort, GABA & DLPA: Help the body relax, stabilize mood and nutritionally inhibit the production of those enzymes which defeat naturally occurring "pain-relievers (endorphins and

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enkephalins), aiding in the reduction of pain and inflammation, while helping to reduce the severity of hot flashes.

For a complete listing of Preserve ingredients and recommended dosage, click [\[here.\]](#)

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Women's Menopause Health Center October 15, 2006 Newsletter.

Breast Cancer Prevention Tips and Treatments.

Did you know that almost 213,000 women (and a small percentage of men) will be diagnosed with invasive breast cancer this year alone? So what is new on the horizon in breast cancer treatment and breast cancer prevention? Here's a sampling of what's new.

INTRODUCING - THE ALL NEW IMPROVED!

Preserve Progesterone Cream.



- 20mg USP progesterone 100% pharmaceutical grade per one pump stroke - 750 mg/oz.
- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
- 3.5 oz bottle.

1 bottle Preserve Progesterone Cream ~~MSRP \$42.95~~
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When Maureen Moore, 48, of Collierville Tennessee was diagnosed with advanced (stage four) breast cancer in April 2005, she had a mastectomy to remove her left breast, followed by chemotherapy, a stem cell transplant, and radiation. Then she went one step further and had genetic testing to determine if hers was among the estimated 5 to 10 percent of breast cancer cases that result from inherited mutations or alterations in the breast cancer susceptibility genes, BRCA1 and BRCA2. It was. The test results influenced Moore's breast cancer prevention decision to have a preventive hysterectomy and mastectomy of the right breast to help head off not only further breast cancer but ovarian cancer as well.

Genetic testing information can help doctors plan for better breast cancer prevention health care or treatment if the disease does develop. Physicians may refer patients with a family history of the disease to a genetic counselor who can do more testing. To find a genetic counselor in your area, visit nsgc.org.

A Women's Health Initiative study failed to definitively show that a lowfat diet (29%

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of total calories from fat) significantly helps breast cancer prevention, but don't reach for the potato chips just yet. A low-fat diet can help women maintain a healthy weight. And overweight women run a higher risk of getting breast cancer especially if the excess weight is gained later in life. Excess fatty tissue is a source of circulating estrogen in your body, and breast cancer risk is directly linked to how much estrogen you're exposed to during your lifetime. (Another significant reason to avoid synthetic estrogen replacement therapy (ERT) and balance hormones with Preserve Progesterone Cream or Preserve as a part of your breast cancer prevention regimen. Preserve and Preserve Progesterone Cream help control hot flashes and other menopause / perimenopause symptoms.)

Women who are premenopausal or under age 50 and those with dense breast tissue can benefit from the new digital mammogram technology, according to a study funded by the National Cancer Institute. Digital mammograms let radiologists magnify, darken, or lighten images to better spot abnormalities. It may not be available nationwide for a few years. Meanwhile, the experts say, the main message is still to get an annual mammogram as part of your breast cancer prevention strategy.

When a mammogram leads to a diagnosis of cancer, breastconserving surgery (lumpectomy) followed by radiation is one course of treatment women may consider. This year marked the end of a longterm study confirming that it's as effective as removing the entire breast (mastectomy). If a woman with breast cancer chooses a lumpectomy, radiation is administered five days a week for six to seven weeks.

Here are some breast cancer prevention techniques you may employ without the aid of high technology. Embrace some powerful lifestyle habits and feel good knowing you're doing all you can to reduce your breast cancer risk.

Regular exercise can help you maintain a healthy weight. Aim for at least 30 minutes of exercise on most days of the week. If you haven't been particularly active for a while, start slowly. Include weightbearing exercises, such as walking, jogging, or working out on an elliptical machine. If you're undergoing hormone replacement therapy (HRT), discuss your options with your doctor. You may be able to manage your menopausal symptoms with exercise, dietary changes, or non hormonal therapies like progesterone cream to balance the excess estrogen for hot flash relief and relief of other menopause / perimenopause symptoms. If you decide the benefits of short-term HRT outweigh the risks, consider the lowest hormone dosage for the shortest time.

Another weapon in your breast cancer prevention arsenal is to limit foods that contain pesticides, growth hormones, or nitrates. Research at the Mayo Clinic shows that the molecular structure of some pesticides closely resembles that of estrogen, which may increase breast cancer risk.

Plentiful intake of plant lignans could help in breast cancer prevention in premenopausal women researchers in Germany report. Lignans, which are present in dietary sources such as flaxseed, sesame seeds, fruits, and vegetables, are metabolized by microorganisms in the colon to phytoestrogens such as

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Breast cancer prevention tips and treatments for premenopausal women

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enterolactone. Scientists found that premenopausal women with greater dietary intake of lignans and higher plasma enterolactone levels demonstrated a substantially decreased risk of breast cancer.

Alcohol consumption and breast cancer have a strong link, according to the Mayo Clinic. But the American Cancer Society says an occasional alcoholic beverage is unlikely to increase risk significantly, especially if you already exercise regularly, eat a healthy diet, and maintain a healthy weight.

It's unclear if stress adds to breast cancer risk (some studies claim a link), but women with emotional support experience less stress and are more resilient to life's curveballs.

October Menopause Food Recipe: [Autumn Harvest Crock Pot Stew](#).

October Bath and Body Recipe: [Fall Bounty Molasses and Apple Cider Hair Conditioner](#).

October Exercise Tip: [Even Accidental Exercise Helps Menopause Symptoms](#).

We hope you enjoyed this edition of the Women's Menopause Health newsletter. If you have friends or family that could benefit from this information, feel free to pass this newsletter along. We like to share!

If you received this email in error, or to be removed from this mailing list, reply to this newsletter and write "Remove" in the subject line.

For more information about the Women's Menopause Health Center, visit us at <http://www.womens-menopause-health.com>

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Women's Menopause Health Center August 1, 2003 Newsletter

Estrogen Information and Danger of Estrogen Therapy

Women looking for estrogen information about the danger of estrogen therapy do not need to look very far. The Women's Health Initiative study two years ago provided a wealth of information about the danger of estrogen therapy. Since that time, information about the danger of estrogen therapy seems to surface on a regular basis.

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- Highest quality natural hormone creams on market today!
- Unique liposome formula for instant transdermal absorption!
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The Federal Drug Administration recently mandated a new boxed warning of the danger of estrogen therapy and estrogen/progestin products such as Premarin and Prempro. This is the highest FDA warning level for drug labeling. The FDA estrogen information warning states an increased risk for heart disease, heart attacks, strokes, and breast cancer and also emphasizes that estrogen products are not approved for heart disease prevention.

At about the same time the FDA mandated boxed warnings of the danger of estrogen therapy, a study revealed information about yet another danger of estrogen therapy. This portion of the Women's Health Initiative study found that hormone replacement therapy double women's risk of developing dementia and Alzheimers Disease.

If that estrogen information was not enough to encourage women to rethink their menopause health

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choices, hormone replacement therapy earned a prominent place on the United State's National Toxicology Program's carcinogen list.

The federal government recently added steroidal estrogen products to its list of known human carcinogens. Steroidal estrogens are a group of related hormones commonly used in estrogen replacement therapy and in oral contraceptives.

The government report cites data from human epidemiology studies that show a connection between estrogen therapy and an increase in endometrial cancer and breast cancer. The report also suggests that estrogen-containing oral contraceptives may be associated with an increased risk of breast cancer but may protect against ovarian and endometrial cancers.

The National Toxicology Program, an arm of the Department of Health and Human Services, publishes reports of carcinogens every two years after intensive scientific reviews.

The report distinguishes between "known" human carcinogens (where there is sufficient evidence from human studies) and "reasonably anticipated" human carcinogens (where there is either limited evidence from human studies or sufficient evidence from animal studies).

A number of individual steroidal estrogens were already listed as "reasonably anticipated" carcinogens in past reports. This most recent report upgraded steroidal estrogens to "known" carcinogens and was the first report to list all steroidal estrogens together as a group.

Hundreds of government and non-government scientists contribute to these reports to ensure that the public is made aware of cancer hazards. The public at this point should be very aware of the danger of estrogen therapy. Thousands of women responded to the Women's Health Initiative study by stopping hormone replacement therapy. Yet, thousands upon thousands of women still remain on hormone replacement therapy.

Stopping hormone replacement therapy would be a difficult choice without effective alternatives to hormone replacement therapy. Fortunately, there are effective alternatives for women who no longer wish to take hormone replacement therapy.

Preserve is a unique combination of micro-nutritionals, rare Chinese dietary herbs, free form amino acids and vitamins and minerals specifically targeted to support and address hormonal pathway imbalances and reducing menopause symptoms.

The Preserve formula supplies the body with safe, naturally-occurring phytoestrogen complexes, calming herbs to help naturally diminish the discomfort of menopausal symptoms and essential nutrients so often lacking during and after menopause. The ingredients in this MultiDimensional formula support the body's abilities to naturally normalize hormonal levels and diminish menopause symptoms.

Preserve, used in conjunction with a quality progesterone cream like Return to Eden natural progesterone cream, can gently alleviate menopause symptoms as well as hormone replacement therapy - without the dangers of hormone replacement therapy.

Natural progesterone cream helps;

- Brings hormonal balance back into your body.
- Balances estrogen dominance.
- Improve lipid profile.
- Improve blood sugar control.

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Estrogen Replacement and Benefits of Estrogen Therapy Page 3 of 3

- Burn up of body fat.
- Rebuild lost bone mass.
- Improves new bone formation.
- Eliminate hot flashes.
- Create the myelin sheath over nerves.
- Create more energy.
- Sleep disorders.
- Fibrocystic Breast Disease.
- Normalize and restore sexual desire.
- Promote youthful skin appearance.
- Resist facial hair growth.
- Reduce risk of breast cancer.
- Reduce risk of uterine cancer.
- Improve blood sugar control.
- Promote youthful skin appearance.

If you have not already kicked the hormone replacement therapy, now is as good a time as any. Order a bottle of Preserve and a pump container of Preserve Natural Progesterone Cream and experience healthy menopause for yourself.

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Osteoporosis Prevention.

Research is clear that osteoporosis prevention measures of healthy diet, regular exercise, supplementing the body with natural progesterone and eliminating risk factors that cause osteoporosis all have dramatic and positive effects on osteoporosis.

Most women are unaware that they have osteoporosis until the first tell-tale symptom, a bone fracture occurs. The osteoporosis prevention plan ideally should begin before the first symptom appears. Although it is never too late to start, sooner is always better than later.

Postmenopausal osteoporosis is significantly influenced by several prevention measures, all of which offer many positive physical and emotional effects beyond osteoporosis benefits.

Women - especially Caucasian women with a family history of osteoporosis - should eliminate risk factors before the first symptom of osteoporosis appears. Starting early with an aggressive osteoporosis prevention program greatly reduces the risk of osteoporosis.

Smoking, inactivity, heavy alcohol, caffeine and soft drink consumption and inadequate calcium intake all cause a decrease in bone mass and cause osteoporosis symptom conditions in the body. The first osteoporosis prevention step is to eliminate these osteoporosis cause risks.

Limit alcohol consumption to beer and wine only, with no more than two drinks daily. Caffeinated coffee and soft drinks should also be limited to two or less cups per day. Women should avoid high-phosphate soft drinks altogether. Water is the best alternative. Foods high in fat and protein inhibit calcium absorptions and cause negative effects on osteoporosis. Antacids also cause negative effects on osteoporosis and should be avoided altogether.

The next step in the osteoporosis prevention plan is to begin using a high quality progesterone cream like Preserve to give the body the hormonal building block components for new bone growth. Progesterone serves a dual purpose. While providing positive effects on osteoporosis by promoting the building of new bone mass, progesterone also decreases menopause symptoms typical in the age group of women at risk for osteoporosis.

Exercise and diet effects the building of bone mass and play an integral role in osteoporosis prevention. Weight-bearing exercise cause bones to use more calcium. A healthy, calcium-rich osteoporosis diet provides bones with materials they need and progesterone cause bones to produce more new tissue. Research shows that regular weight-bearing exercise, coupled with 1500 mg of calcium and 400-800 IU of vitamin D daily, can stop bone loss for some postmenopausal women.

Diet:
 Although adequate calcium intake is crucial for osteoporosis prevention, about 70% of people do not receive the recommended daily allowance of calcium. The osteoporosis prevention diet contains food: low in fat and high in vegetables, fruits, whole grains and calcium-rich foods. Low-fat dairy products,

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Osteoporosis prevention exercise cause stress symptoms

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soy products, dark green vegetables, grains, beans and some fish are all excellent osteoporosis prevention foods.

The National Institutes for Health (NIH) recommends that post menopausal women and people at risk for osteoporosis receive 1500 mg of calcium daily. Pre-menopausal women need about 1000 mg daily for osteoporosis prevention.

Below is a list of calcium-rich foods and the approximate mg of calcium per cup. Choose low-fat options for weight control;

Milk	350-400 mg
Calcium fortified orange juice	350 mg
Collard greens (cooked)	300 mg
Yogurt	275-400 mg
Tofu	250 to 700 mg
Calcium fortified soy milk	250- 300 mg
Cottage cheese	150 mg
Beans (cooked)	100 mg
Broccoli (cooked)	100 mg
Kale (cooked)	100 mg

Other calcium-rich foods:

Sardines, canned w/ bones (3oz.)	350 mg
Salmon, canned w/ bones (3oz.)	200 mg
Cheese Cheddar, 1 oz.	200 mg
Sesame seeds, 2Tbsp.	175 mg
Blackstrap molasses, 1Tbsp.	175 mg
Dried figs, 5 pieces	130 mg
Tahini, 2Tbsp.	130 mg
Orange, 1 medium	50 mg

Women should attempt to gain most of their calcium through food sources since calcium in food is best absorbed by the body. Supplements should be used for osteoporosis prevention if women cannot meet their daily requirements through food sources.

Eating large amounts of calcium-rich foods may not prevent osteoporosis if there is not enough vitamin D to aid calcium absorption. The skin synthesizes vitamin D when exposed to direct sunlight for at least 15 minutes daily. Since the body breaks down Vitamin D in supplement form, rendering it less adequate for calcium absorption, exposure to the sun remains the best way to receive Vitamin D.

However, nutritionists suggest using a Vitamin D supplement during the winter months. People over 60 should take a vitamin D supplement year round since aging reduces the capacity of the skin to use sunlight to produce vitamin D.

Pre-menopausal women need about 200 IU of Vitamin D when not exposed to sunlight. Menopausal women need about 400 IU and postmenopausal women need about 800 IU Vitamin D. Most multivitamins contain 400 IU of Vitamin D.

Exercise for Osteoporosis Prevention:

Extensive research clearly shows that inactivity cause bones to weaken. Most experts agree that exercise 30 minutes, five to six days a week is enough to cause substantial difference in bone health.

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Exercise also improves coordination and strengthens muscles, which reduces the risk of falls. Exercise also cause positive effects on the cardiovascular system, emotional well being and helps women control menopause weight gain.

"Weight-bearing" exercise encourages 'bone loading'. Weight-bearing exercise is exercise that places weight on the skeletal structure. Brisk walking, jogging, strength training, hiking, and aerobic exercises are the best weight-bearing exercises for strengthening bones. Swimming and bicycling, though good aerobic exercises, do not place enough weight on bones to work as osteoporosis prevention exercise.

The chosen osteoporosis prevention exercise should focus on the sites where fractures most often occur - the upper arm at the shoulder, the lower arm at the wrist, the hip and spine. Walking, jogging, aerobic exercise and cross-country skiing focus on the spine and hip. Weight lifting and strength training focusing on the arms builds density in bones in the arms. Women should set a goal of exercising a minimum of 30 minutes five days each week, with time divided between weight-bearing exercise, strength training and stretching.

If new to exercising, start slowly and gradually work up to the recommended exercise time. Always consult a physician if starting a new exercise regime.

Sedentary women can start by walking 10 minutes per day three times each week and increase the time by a few minutes each week. With exercise for osteoporosis prevention, listen to your body. When the current level of exercise becomes easy, increase the time and/or intensity of the exercise workout.

Be patient and don't give up. The hardest aspect of starting this portion of an osteoporosis prevention regime is actually getting started. The sooner you start, the sooner your bones and body will be in shape to meet the physical challenges that age cause.

Help for Osteoporosis

The 7 supplements you must have to reverse and overcome osteoporosis.
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Welcome To Women's Menopause Health Center.


Specializing in sales of natural hormone replacement therapy supplements (HRT), and progesterone cream herb free of cancer-causing synthetic hormones as found in Premarin and Prempro, for perimenopause, menopause symptoms, and hot flashes.

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Return to Eden Chemical Preservative **FREE** Natural Progesterone Cream.

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- HIGHEST QUALITY NATURAL INGREDIENTS PROGESTERONE CREAM ON MARKET TODAY.
- 500 mg/oz USP progesterone, 100% pharmaceutical grade.

1- 2oz Jar Return to Eden Progesterone Cream ~~MSRP \$26.00~~ \$19.95 ea.
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Hormone replacement therapy increases the risk of cancer, of heart disease, of strokes and blood clots. New studies also place women taking synthetic hormones at double the health risk of Alzheimer's Disease and dementia. And contrary to prevailing thought, hormone replacement therapy does not protect against osteoporosis.

Why then, given the serious risk to women's health, do women take hormone replacement therapy? For many, the simple answer is that women need relief from hot flashes and other menopause symptoms.

Finding relief from menopause symptoms is not a black-and-white choice between taking hormone replacement therapy or doing nothing at all. Women do not need to place themselves in harm's way to eliminate hot flashes, mood swings, weight gain, headaches and other effects of menopause.

The Women's Menopause Health Center offers solutions for menopause and perimenopause symptoms that may improve the quality of life instead of placing women at risk for serious and potentially life threatening synthetic hormone replacement side effects.

The Women's Menopause Health Center offers natural hormone replacement therapy that are the result of extensive research to find the purest, highest quality, clinically formulated formulas available today.

With the in-depth menopause information offered at the Women's Menopause Health Center, women can make informed health care decisions that improve women's health instead of compromising women's health.

Before you start taking Premarin, Prempro or any other synthetic hormones, carefully consider the harmful effects on women's health.

The large-scale Women's Health Initiative study released in 2002 show that hormone replacement therapy (HRT) is linked to substantial increases in the risk of developing breast cancer, heart disease, strokes and blood clots. Additionally, when estrogen is prescribed alone, it can increase the risk of ovarian cancer.

The most recent arm of the Women's Health Initiative study, released in May 2003, adds to already damning 2002 studies of the effects of hormone replacement therapy. New research shows that women on synthetic hormones like Premarin and Prempro are at double the risk for Alzheimer's Disease and dementia.

The in-depth government Women's Health Initiative study reshaped how women and their physicians now approach managing menopause symptoms. Many doctors are now

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recommending hormone replacement therapy only for their patients with severe menopause symptoms. Even then, most physicians tell their patients that the benefits often do not outweigh the women's health risks involved.

Hormone replacement therapy use in the United States fell by about one-third - from 15 million women to 10 million - after the 2002 Women's Health Initiative announcements.

Yet, there are still 10 million American women taking hormone replacement therapy. How does this number affect women's health?

The Women's Health Initiative found that for every 10,000 women using hormone replacement therapy, there were 7 additional heart attacks, 8 additional strokes, 8 additional cases of breast cancer and 23 additional cases of dementia.

Those numbers seem quite low until translated into real-life numbers. Using hormone replacement therapy will add an additional 7,000 heart attacks, 8,000 strokes, 8,000 cases of breast cancer and 23,000 new cases of dementia and Alzheimer's Disease for the 10 million women currently using synthetic hormones.

That is an additional 46,000 women who will suffer damaging health effects - or worse. Even one added case cannot justify the damaging effects that dementia will place on a woman's family. Even one additional case of breast cancer cannot justify the grief of children and grandchildren losing a woman they love to an unnecessary death.

News of the health risks unearthed in the Women's Health Initiative menopause study galvanized many women's decision to find natural hormone replacement therapy alternatives to deal with the effects of menopause.

The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

If you have tried other natural hormone replacement products and still suffer menopause symptoms, give our superior products a try. Experience how a commitment to quality and integrity, pure ingredients, and top notch medical oversight can make a difference for you. Don't settle for less!

Not all menopause products are created equal. **The progesterone cream and all our menopause products offered are of the purest and highest quality women's health products on the market today.**

Our products are created to the **highest manufacturing standards**. A menopause supplement is only as good as its ingredients AND its manufacturing standards. With the vast number of supplements on the market today, consumers must be wary of purchasing "Parking Lot" supplements - those manufactured without exacting standards.

There are over 10,000 nutritional manufacturing facilities in the United States. Less than one-half of one percent of the nutritional manufacturing facilities in the country match the exacting standards followed in our facility.

We believe that good formulas can only lead to good health by starting with quality and efficacious product ingredients. Thus, we offer assurance that all of the ingredients used in our formulations are simply the best available in the world.

Complaint

The Women's Menopause Health Center also offers [Return to Eden](#) progesterone cream, the most complete all-natural cream on the market. Our progesterone cream is chock full of USP progesterone that may stop hot flashes.

Receiving the best menopause therapy possible during the transition between the child-rearing years and new possibilities dramatically increases the quality of women's lives. With unpleasant menopause symptoms under control, women can look at and live through menopause with a positive mental attitude and exciting new possibilities.

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For powerful alternatives to Ritalin, visit the [Attention Deficit Disorder Help Center.](#)

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SP Progesterone Cream is recommended by Dr. Lee Page 1 of 4

SP Progesterone Cream-
oz. sold out. 4oz in stock, \$8.32 Made in
SA to Dr. Lee's specs.
www.onelifeusa.com

Progensa 20 Progesterone
What Holistic doctors recommend Find out why
www.womenlivingnaturally.com

Menopause Hormone Therapy
Sterling, VA MD specializing in natural
bioidentical hormones.
www.BodyLogicMD.com

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Best Natural USP Progesterone Cream for Menopause and Perimenopause.

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Quality Natural Return to Eden USP Progesterone Cream for Menopause Perimenopause Symptoms and Hot Flashes.

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- HIGHEST QUALITY NATURAL INGREDIENTS DIOSGENIN (NICKNAMED PROGESTERONE CREAM ON MARKET TODAY.
- 500 mg/oz USP Diosgenin (nicknamed progesterone), 100% pharmaceutical grade.

1-2oz jar **Return to Eden Diosgenin (Progesterone) Cream** ~~MSRP \$26.99~~
\$19.95 **Buy Now**
2-2oz jars **Return to Eden Diosgenin (Progesterone) Cream**
\$35.95 **Buy Now**

Women today, armed with educated health information, know that there is a better, safer way to protect against osteoporosis and heart disease than by using synthetic hormones. They have learned what women in Great Britain and Europe have know for decades - the benefits of natural progesterone like that found in Return to Eden natural progesterone cream. These women believe, from decades of uses, that it can actually rebuild bone tissue with no known side effects.

With large studies* revealing that women using synthetic estrogen for more than five years have a 46% higher risk of breast cancer than women who don't use it, progressive women are deciding on a more natural course of action. They are deciding to reduce their cancer risks while experiencing the benefits of natural USP progesterone cream. After all, what discriminating woman would want to increase her risk of cancer by about 50%? Women are seeing the benefits of our physician formulated and independent lab tested progesterone cream instead. The Preserve superb quality progesterone cream formula was developed by a team of physicians based on Dr. John Lee's research.

Complaint

John R. Lee, M.D. is an international authority and pioneer in the use of natural progesterone cream and natural hormone balance. He authored the best-selling book, "What Your Doctor May Not Tell You About Menopause: The Breakthrough Book on Natural Progesterone." (Recommended reading.)

A natural course of action, like Return to Eden USP progesterone cream, makes a lot more sense. Be warned, though, that not all progesterone cream and lotions are the same. It is important to insist upon a high quality natural progesterone supplement, not a supplement made from uncertified cheap ingredients exported from foreign countries with lax regulations.

Our products are created to the **highest manufacturing standards**. A menopause supplement is only as good as its ingredients AND its manufacturing standards. With the vast number of supplements on the market today, consumers must be wary of purchasing "Parking Lot" supplements - those manufactured without exacting standards.

Return to Eden natural chemical free progesterone cream is:

- **Completely artificial preservative free.** No harmful chemical preservatives.
- **Made in small batches** to insure that your superb natural progesterone cream reaches you in the freshest condition possible.
- **Quality USP progesterone content** of 500 mg/oz per Dr. John Lee's recommendation. Many "popular creams" sold today contain little or no USP progesterone, or at best, have inconsistent levels of progesterone. One study showed that 50 percent of them didn't contain any measurable progesterone. Return to Eden is one brand that is reliable!
- **Made from USP progesterone, not wild yam extract.** No published studies conclude that yam increases progesterone levels in animals or humans. While the diosgenin molecule from wild yams can be converted to a progesterone molecule in the laboratory, it can NOT be in the human body. Unconverted diosgenin is a cheap way to produce a progesterone cream, and according to Dr. Lee does not work well. It is important to insist upon USP progesterone, not uncertified cheap ingredients made in some foreign countries.
- **Free of Methyl Paraben, Propyl Paraben, Butyl Paraben** or any of the related Parabens or estrogenic herbs. Those ingredients are used as preservatives and contribute to estrogen dominance. Paraben-class preservatives also can irritate the skin.
- **Free of ethoxylated wetting agents**, such as PEG 8 Stearate, PEG 100 Stearate, Polyethylene Glycol, Polysorbate 60, or Polysorbate 80, which may be contaminated with 1,4-dioxane, a known carcinogen.
- **Free of mineral oil.** Mineral oil blocks the absorption of natural progesterone.
- **Free of Stearyl Konium Chloride**, an emulsifier. According to the University of Texas database, ingestion of 3 cc of this toxic compound is enough to cause fatal convulsions in an adult human.

There are over 10,000 nutritional manufacturing facilities in the United States. Less than one-half of one percent of the nutritional manufacturing facilities in the country match the exacting standards followed in our facility.

What are the benefits of using progesterone cream?

Unlike Provera, which, first, is a synthetic progesterone or progestin, progesterone creams are

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applied to the skin (transdermal, which means "through the skin"). Hormones, if taken by mouth, are immediately passed from the small intestine to the liver and returned in water soluble form back to the start of the small intestine. During the process, 80% to 90% of the hormone is lost through the liver. Only a small fraction of ingested hormones end up circulating in the blood able to attach to appropriate receptors.

Dr. Lee recommends the transdermal progesterone cream rather than oral progesterone, because approximately 80% to 90% of the oral dose is lost through the liver. A 200 to 400 mg is needed on a daily basis to achieve a physiologic dose of 50 to 24 mg. Not only is the liver unnecessarily taxed adding to its toxic overload, such high doses create undesirable metabolites.

Why do women need progesterone cream?

The most important of many reasons that progesterone is needed in hormone replacement therapy for menopausal women is to balance or oppose the effects of estrogen. Unopposed estrogen creates a strong risk for reproductive and breast cancers. Dr. Lee calls this "estrogen dominance." Estrogen, as mentioned, is a potent and potentially dangerous hormone when not balanced by adequate progesterone like that found in Return to Eden all-natural progesterone cream..

Estrogen levels drop only 40% to 60% during menopause, but progesterone levels may drop to near zero in some women. Because progesterone is the precursor to so many other steroid hormones, its use can enhance hormone balance after menopause. Since progesterone stimulates bone-building, it also helps protect against osteoporosis.

Thus, the application of progesterone may provide many benefits and combats estrogen dominance.

**Harvard researcher, Dr. Graham Colditz - a world authority on the subject, conducted studies which showed that women who use estrogen for more than five years have a 46% higher risk of breast cancer than women who use none. Dr. Colditz' study results came from a sampling of 121,700 women tracked for 24 years from the famous Nurses Health Study as reported in The New England Journal of Medicine, June 1995.*

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Menopause 20 Progesterone
that Holistic doctors recommend
and out why
www.womenlivingnaturally.com

Progesterone Cream- \$8.32
4 oz. natural progesterone. Made
in USA to Dr. Lee's specifications.
www.onelifeusa.com

Natural Menopause Help
Get the facts. Become Hormone
Well. Dr. C.W. Randolph
www.HormoneWell.com

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Best Natural USP Menopause Diosgenin (nicknamed Progesterone) Cream Benefits.

Experience the benefits of natural diosgenin (progesterone) cream. Say goodbye to women's menopausal symptoms and the effects of aging!

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites enabling estrogen to work more efficiently without being dominant. Progesterone is a precursor to other hormones in the body including estrogen, testosterone, and especially the corticosteroids.

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- 500 mg/oz USP Diosgenin (nicknamed progesterone), 100% pharmaceutical grade.

1- 2oz jar **Return to Eden Diosgenin (Progesterone) Cream** ~~MSP \$26.00~~
\$19.95 **Buy Now**
2- 2oz jars **Return to Eden Diosgenin (Progesterone) Cream**
\$35.95 **Buy Now**

The benefits of natural diosgenin (nicknamed progesterone) cream are said to be many:

- Brings hormonal balance back into your body.
- Balances estrogen dominance.
- Improves lipid profile

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- Improves blood sugar control.
- Improves burn up of body fat.
- Natural anti-depressant.
- Natural diuretic.
- Eliminates hot flashes.
- Creates the myelin sheath over nerves.
- Gives people more energy.
- Helps with sleep disorders.
- Normalizes and restores sexual desire.
- Promotes youthful skin appearance.
- Resists facial hair growth.
- Improves blood sugar control.
- Promotes youthful skin appearance. (The late diet guru, Dr. Robert Atkins, M.D. was enthusiastic about natural progesterone cream for skin care. He endorsed its use because he found it the best wrinkle eradicator he ever had experienced.)

Perimenopause symptoms also can benefit from natural progesterone cream. The following may reflect early hormonal imbalances:

- Hot flashes.
- Hot flashes.
- Insomnia.
- Night sweats.
- Mood swings.
- Depression.
- Vaginal dryness.
- Reduced sexual desire.

MSM and Bone Loss: MSM provides the building blocks for the restoration of cartilage, helping when there has been bone loss. It is a potent natural anti-inflammatory, which allows you to better use your own healing system. For more information concerning MSM, click [here](#).

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Progesterone Cream- \$8.32
1/2 oz. natural progesterone. Made
USA to Dr. Lee's specifications.
www.onelifeusa.com

Progesta 20 Progesterone
What Holistic doctors recommend
Find out why
www.womenlivingnaturally.com

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How to Use Return to Eden USP Menopause Diosgenin (nicknamed Progesterone) Cream.

Return to Eden Progesterone Cream for:

[andrometricals](#) | [fibrocystic breasts](#) | [ovarian cysts](#) | [perimenopause](#) | [PMS](#) | [post menopause](#) | [uterine fibroid tumors](#) | [how to use progesterone cream](#)

In addition to the many benefits of diosgenin (nicknamed progesterone) cream for PMS, perimenopause and menopause symptoms, progesterone cream can also help with other female conditions without side effects associated with invasive or drug-therapy treatments.

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- 500 mg/oz USP Diosgenin (nicknamed progesterone), 100% pharmaceutical grade.

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\$19.95 [Buy Now](#)
2- 2oz jars [Return to Eden Diosgenin \(Progesterone\) Cream](#)
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Given the positive benefits of progesterone cream and the low incidence of progesterone side effects, many women choose this natural alternative to achieve normal progesterone levels. For women looking for quality progesterone cream to achieve normal progesterone levels, Return to Eden natural progesterone cream 500 mg/oz potency is of the best on the market today.

To achieve the optimal benefits of progesterone cream without progesterone side effects to achieve normal progesterone levels, use the natural progesterone cream 500 mg/oz Return to Eden formula.

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How to Use Progesterone Cream:

Application instructions for Return to Eden natural progesterone cream 500 mg/oz for:

[Premenstrual syndrome](#) | [Perimenopause symptoms](#) | [Post menopause](#) | [Osteoporosis](#) |
[Ovarian cysts](#) | [Endometriosis](#) | [Uterine fibroids](#) | [Fibrocystic Breasts](#) | [Progesterone Cream](#)
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[Women's Menopause Health Center August 1, 2003 Newsletter](#)

Estrogen Information and Danger of Estrogen Therapy

Women looking for estrogen information about the danger of estrogen therapy do not need to look very far. The Women's Health Initiative study two years ago provided a wealth of information about the danger of estrogen therapy. Since that time, information about the danger of estrogen therapy seems to surface on a regular basis.

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2- 2oz jars
\$35.95

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The Federal Drug Administration recently mandated a new boxed warning of the danger of estrogen therapy and estrogen/progestin products such as Premarin and Prempro. This is the highest FDA warning level for drug labeling. The FDA estrogen information warning states an increased risk for heart disease, heart attacks, strokes, and breast cancer and also emphasizes that estrogen products are not approved for heart disease prevention.

At about the same time the FDA mandated boxed warnings of the danger of estrogen therapy, a study revealed information about yet another danger of estrogen therapy. This portion of the Women's Health Initiative study found that hormone replacement therapy double women's risk of developing dementia and Alzheimers Disease.

If that estrogen information was not enough to encourage women to rethink their menopause

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health choices, hormone replacement therapy earned a prominent place on the United State's National Toxicology Program's carcinogen list.

The federal government recently added steroidal estrogen products to its list of known human carcinogens. Steroidal estrogens are a group of related hormones commonly used in estrogen replacement therapy and in oral contraceptives.

The government report cites data from human epidemiology studies that show a connection between estrogen therapy and an increase in endometrial cancer and breast cancer. The report also suggests that estrogen-containing oral contraceptives may be associated with an increased risk of breast cancer but may protect against ovarian and endometrial cancers.

The National Toxicology Program, an arm of the Department of Health and Human Services, publishes reports of carcinogens every two years after intensive scientific reviews.

The report distinguishes between "known" human carcinogens (where there is sufficient evidence from human studies) and "reasonably anticipated" human carcinogens (where there is either limited evidence from human studies or sufficient evidence from animal studies).

A number of individual steroidal estrogens were already listed as "reasonably anticipated" carcinogens in past reports. This most recent report upgraded steroidal estrogens to "known" carcinogens and was the first report to list all steroidal estrogens together as a group.

Hundreds of government and non-government scientists contribute to these reports to ensure that the public is made aware of cancer hazards. The public at this point should be very aware of the danger of estrogen therapy. Thousands of women responded to the Women's Health Initiative study by stopping hormone replacement therapy. Yet, thousands upon thousands of women still remain on hormone replacement therapy.

Stopping hormone replacement therapy would be a difficult choice without effective alternatives to hormone replacement therapy. Fortunately, there are effective alternatives for women who no longer wish to take hormone replacement therapy.

A quality progesterone cream like Return to Eden natural progesterone cream, may gently alleviate menopause symptoms as well as hormone replacement therapy.t therapy.

Natural progesterone cream helps:

- _ Brings hormonal balance back into your body.
- _ Balances estrogen dominance.
- _ Improve lipid profile.
- _ Improve blood sugar control.
- _ Burn up of body fat.
- _ Eliminate hot flashes.
- _ Create the myelin sheath over nerves.
- _ Create more energy.
- _ Sleep disorders.
- _ Fibrocystic Breast Disease.
- _ Normalize and restore sexual desire.
- _ Promote youthful skin appearance.
- _ Resist facial hair growth.
- _ Improve blood sugar control.

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_ Promote youthful skin appearance.

If you have not already kicked synthetic hormone replacement therapy, now is as good a time as any. Order a jar of Return to Eden All-Natural USP Progesterone Cream and experience a gentler transition through menopause for yourself.

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Osteoporosis Treatment | Osteoporosis Prevention | Hormone Replacement Therapy & Osteoporosis | Hormone
Replacement Therapy.

Osteoporosis Treatment

Women in Great Britain and Europe have found that progesterone is a natural alternative to traditional osteoporosis treatment. This natural alternative to traditional osteoporosis treatment is believed by them to build bone mass, and help decrease menopause symptoms without side effects associated with synthetic hormone replacement therapy or drugs used for the treatment of osteoporosis.

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1- 2oz jar **Return to Eden Diosgenin (Progesterone) Cream** ~~MSRP \$26.99~~
\$19.95 Buy Now
 2- 2oz jars **Return to Eden Diosgenin (Progesterone) Cream**
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Researchers for decades suspected that the decrease in estrogen contributed to osteoporosis, most because women typically begin to notice the effects of osteoporosis after going through menopause. Based on that assumption, doctors prescribed estrogen as osteoporosis treatment during menopause. However, recent studies clearly show that estrogen alone as an osteoporosis treatment does little for long-term prevention of bone loss.

Given the serious health risks associated with estrogen and the lack of long-term benefit, estrogen is one of the least appropriate osteoporosis treatment methods women should take. New medication alternatives for the treatment of osteoporosis pose less harmful side effects than hormone replacement therapy, but these drugs used for osteoporosis treatment also have unpleasant and potentially harmful side effects and are still sometimes ineffective for long-term bone health.

The medication drugs most commonly prescribed for osteoporosis treatment are Calcitonin (Miacalcin) and Alendronate (Fosamax). Forteo is a new drug medication for the treatment of osteoporosis.

For women seeking osteoporosis treatment while simultaneously addressing menopause related

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symptoms and health concerns, progesterone may be the perfect natural alternative. The lack of progesterone is thought to cause a decrease in new bone formation.

Progesterone balances estrogen dominance, and may improve lipid profile, improves blood sugar control, improves the ability to burn body fat. Progesterone cream may also eliminate hot flashes, help with sleep disorders, normalize and restore sexual desire, and promote youthful skin appearance.

For a natural alternative to osteoporosis treatment, postmenopausal women may use up to one teaspoon of high quality progesterone cream daily for three weeks each month. The week off progesterone maintains the sensitivity of the progesterone receptors. We recommend Return to Eden natural USP progesterone cream. Return to Eden USP progesterone cream uses only high quality ingredients, with no artificial fillers.

Women do not need to take estrogen for osteoporosis treatment given the natural alternative of progesterone. Estrogen works to diminish bone loss while progesterone aids the body in building new bone. Bones are living tissue that is constantly dying off and rejuvenating. The larger bones in the body are replaced every 10 to 12 years while smaller, less dense bones are replaced every two to three years.

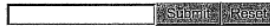
This is the good news. Even if bones have lost density, there is opportunity to gain it back. But, in order for new bone to be made, bones need an adequate supply of nutrients like calcium, regular weight-bearing exercise and hormonal balance conducive to bone growth.

<p>Menopause Hormone Therapy Sterling, VA MD specializing in natural bioidentical hormones. www.BodyLogicMD.com</p>	<p>Osteoporosis Treatment Learn How To Treat Postmenopausal Osteoporosis With Medication www.boniva.com</p>
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[Hormone Replacement Therapy](#)

Hormone Replacement Therapy & Osteoporosis.

Osteoporosis is a gradual decrease in bone mass and density that hits postmenopausal women especially hard. Though information varies, most osteoporosis information places postmenopausal Caucasian women at a 50 to 80 percent risk of sustaining a hip, spine, or forearm fracture due to osteoporosis.

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Osteoporosis is almost entirely preventable and even reversible with prevention and treatment measures. New research information shows that hormone replacement therapy does not adequately protect women from osteoporosis.

Though women often associate osteoporosis with menopause, bone loss actually begins years before menopause. Most women reach peak bone density at about 30 and will lose about .7 percent on their bone density after that. Bone loss accelerates for three to five years around the time of menopause and then continues to decline at the rate of about 1 to 1.5% per year.

Because bone loss accelerates at menopause, at the time estrogen levels decline, conventional medicine adopted the belief that estrogen deficiency cause osteoporosis. Following that assumption, physicians regularly used hormone replacement therapy to prevent

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osteoporosis.

However, new study information places the hormone replacement therapy benefit to osteoporosis as myth and makes it clear that hormone replacement therapy is not the correct course of osteoporosis treatment.

- The Journal of the American Medical Association (JAMA) reported a 14-year study that showed no significant difference in the frequency of hip fractures between women who used hormone replacement therapy and those who did not use hormone replacement therapy.
- The New England Journal of Medicine published an 8-year study following almost 10,000 menopausal women. This study also showed no significant difference in the frequency of hip fractures between women who used hormone replacement therapy and those who did not use hormone replacement therapy.

Given the serious health risks associated with estrogen and the lack of long-term benefit, hormone replacement therapy is one of the least appropriate osteoporosis treatment methods women should take.

Women in Great Britain and Europe have been using natural progesterone like that found in Return to Eden USP all-natural progesterone cream for decades to combat osteoporosis.

With osteoporosis, bone tissue dies faster than new bone tissue is made. Over time, bones become less dense and more porous. If the bones become too weak to support the skeleton, bones can break easily. If frail enough, a minor fall, bump or even a hard sneeze can cause a bone fracture.

Progesterone is thought to actively build new bone tissue. By supplying the body with adequate supplies of bone-building progesterone, new tissue can be made to replace old bone tissue. For women taking hormone replacement therapy for the prevention of osteoporosis, this is great news. Women no longer need to choose hormone replacement therapy and its side effects - endometrial cancer, phlebitis, weight gain, high blood pressure, jaundice, vaginal candidiasis, depression, skin rashes, hair loss, nausea, vomiting, abdominal cramps, cysts and more - to halt bone loss.

Many other factors play a significant role in osteoporosis prevention. Caucasian women - especially those with a family history of osteoporosis or poor diets in their younger years - are at the greatest risk of osteoporosis after menopause. Women with poor diets, low calcium intake, low body weight, low physical activity and alcoholism are also at risk for osteoporosis.

You cannot change your sex, race or age but you can change other factors that contribute to osteoporosis.

Osteoporosis Risk Factors: (Other than being a postmenopausal woman):

- Family history of osteoporosis.

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- Caucasian.
- Low body weight.
- Early menopause Low calcium intake.
- Low physical activity.
- Cigarette smoking.
- Drinking more than two alcohol drinks daily .
- Long-term steroid therapy.
- Long-term anti-convulsant therapy.
- Drug therapy that causes dizziness.
- Hyperthyroidism.
- Coffee intake of more than two cups daily.
- Alcohol intake of more than two drinks daily.
- Regular antacid use.

Early signs of osteoporosis include gradual loss of height, loose teeth and persistent low back pain. Sudden insomnia and restlessness and nightly leg and foot cramps are also early warning signs of osteoporosis.

Many women are not aware that they are losing bone mass until after a bone fracture. It behooves women of menopause age to know the status of their bone health and use osteoporosis prevention measures to prevent bone loss before it begins.

One way of testing bone loss is to check your height every six months. If you start losing height, you are losing bone on your spine. This method of checking bone loss does not give a comprehensive profile of bone health but it does give a general indication of bone loss.

The best way to determine bone density and fracture risk before a fracture occurs is to have a bone mineral density (BMD) test. A bone density test measures bone density in the spine, hip and/or wrist, the most common sites of fractures due to osteoporosis. There are bone density tests now available that measure bone density in the middle finger and the heel or shinbone.

The bone density test identifies risk for fracture. The lower the bone density, the greater the risk for fracture. The bone density test compares a person's bone density to the expected bone density of a person of the same age, sex and size, along with a comparison of bone density at the optimal peak bone density of a healthy young adult of the same sex.

Hospitals and imaging centers offer bone density tests. There are many different bone density test methods. All are painless and noninvasive. The dual energy X-ray absorptiometry is one of the best scanning techniques that offers accuracy and minimal radiation exposure.

Women should have a bone density test performed as they enter menopause. The early bone density test serves as baseline information to compare against future bone density tests.

Many experts recommend having a second bone density test 12 to 24 months after starting an osteoporosis prevention regime to make sure the protective program is working. After that, additional tests aren't needed unless lifestyle or

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other health conditions change.

Women taking hormone replacement therapy for osteoporosis prevention should use the bone density test to verify that hormone replacement therapy is indeed providing positive benefit to bone health. If bone loss continues while using hormone replacement therapy - and studies show that it likely will - women should change their osteoporosis prevention regime to one that will provide better results.

Research shows that osteoporosis prevention measures of a healthy calcium-rich diet, and exercise work better than using hormone replacement therapy.

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SP Progesterone Cream-
oz. sold out. 4oz in stock, \$8.32 Made in
3A to Dr. Lee's specs.
www.onelifeusa.com

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[endometriosis](#) | [fibrocystic breasts](#) | [ovarian cysts](#) | [perimenopause](#) | [PMS](#) | [post menopause](#) | [uterine fibroid tumors](#) | [how to use progesterone cream](#)

Return to Eden USP Progesterone Cream during Post Menopause.

Post Menopausal symptoms include hot flashes, water retention, headaches, dry, thin and wrinkly skin, mood swings, depression, increase in facial hair, lack of concentration, short term memory loss, decreased libido, vaginal dryness and atrophy, body aches and pains, fatigue, thinning of scalp hair, irritability, sleep disturbances, osteoporosis, fat and weight gain, especially in abdomen, hips, thighs.

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Dr. Lee believes that menopause is a natural part of a woman's life that should be embraced with joy and enthusiasm. Preserve allows you to achieve hormonal balance without using synthetic estrogens. The above symptoms of menopause are successfully relieved for the majority of women when using Return to Eden as directed. We wish you the best on your journey.

WHERE TO APPLY: Return to Eden natural progesterone cream is best absorbed on thin skin. Natural progesterone cream absorbs into the skin to the fatty layer then it is transferred into the

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bloodstream. Apply Return to Eden natural progesterone cream to the neck, hands, breasts, chest, arms, inner legs, abdomen and feet until absorbed. Remember to rotate sites when applying natural progesterone cream. If you apply progesterone cream to your chest in the morning, for instance, apply progesterone cream to your feet in the evening. Before applying natural progesterone cream to your face, perform a patch test by applying a small amount of progesterone cream to a small area on the side of your face to check for sensitivity reactions. Your face is the most sensitive skin area on your body.

WHEN TO APPLY AND HOW MUCH TO APPLY:

Months 1 through 3: Apply up to one teaspoon Return to Eden natural progesterone cream TWICE A DAY for three weeks. During the fourth week either come completely off the progesterone cream or half the regular progesterone cream dose TWICE A DAY. Beginning in month 4, you may decrease dosage to 1/8 to 1/4 teaspoon TWICE A DAY for three weeks, again stopping progesterone cream or decreasing the dose in the fourth week.

See separate progesterone cream application instructions if you have:

[Premenstrual syndrome](#) | [Perimenopause symptoms](#) | [Post menopause](#) | [Osteoporosis](#) |
[Ovarian cysts](#) | [Endometriosis](#) | [Uterine fibroids](#) | [Fibrocystic Breasts](#) | [Progesterone Cream Use.](#)

IMPORTANT INFORMATION:

- Natural progesterone cream is not suggested for birth control. Progesterone cream can suppress ovulation if used prior to ovulation time. Progesterone cream can enhance conception if used starting on the first day of ovulation.
- If you are using the birth control pill, it is recommended that you use natural progesterone cream seven days prior to your period. You may get some relief of your PMS but women not on the pill obtain the best results.
- Although there have been no reports of significant side effects or health problems associated with natural progesterone cream, we encourage you to find a trusted health care provider to work with you as you use natural progesterone cream.
- There have been reports of incidental spotting, which may be associated with progesterone cream use. This is usually temporary. A physician should always check any persistent spotting or breakthrough bleeding. Because some PMS and Menopausal symptoms may indicate other conditions, please be sure to consult a health care provider if you ever experience headaches or progressive symptoms.
- Natural progesterone cream can potentially INCREASE THYROID ACTIVITY. If you are taking thyroid supplements, you should consult your health care provider and consider lowering the amount of thyroid supplementation you use.
- DOSAGE MAY VARY PER INDIVIDUAL. A woman typically produces 20 to 40 mg of progesterone per day in her ovaries during the luteal phase of her cycle. During pregnancy, the production of progesterone is taken over by the placenta. A woman in her third trimester of pregnancy produces up to 400 mg of progesterone per day.

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- For vaginal dryness, you may apply part of your dosage of progesterone cream intra-vaginally.
- For migraines, headaches or night sweats, you may use a dab of progesterone cream every 15 minutes for an hour.

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Lung Cancer and Menopausal Hormone Therapy (MHT) Connection.

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Women's Menopause Health Center February 15, 2006 Newsletter.

Hormone Replacement Therapy and Lung Cancer Connection.

Recent studies regarding hormone replacement therapy (HRT), or the new preferred term, menopausal hormone therapy (MHT), are confusing. Most results now have doctors discouraging synthetic hormone use or are recommending minimal use, while others suggest that it is beneficial for certain age groups.

However, according to a January 26, 2006 Reuters Health article, another recent a study suggests Women who develop lung cancer appear to have lower survival rates if they have a history of using hormone replacement therapy (HRT).

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Dr. Apar Kishor Ganti, from the University of Nebraska Medical Center in Omaha and colleagues took a look-back at nearly 500 women diagnosed with lung cancer between January 1994 and December

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1999. The majority -- 86 percent -- had a history of smoking and 17 percent had taken HRT for at least 6 consecutive weeks anytime before being diagnosed with lung cancer.

Those researchers reported in the Journal of Clinical Oncology, January 1, 2006, that overall survival was much better in women without a history of using synthetic hormones, compared with those who had taken hormone replacement therapy or menopausal hormone therapy in the past. Additionally, survival rates decreased even further when a history of smoking existed with a history of synthetic hormone use.

Further, they found that women who used synthetic menopausal hormone therapy were younger when diagnosed with lung cancer. The median age was 63, compared with 68 for women who had used synthetic menopausal hormone therapy.

The conclusion was that unless post-menopausal symptoms are severe, and can't be treated by other medications, synthetic hormone replacement therapy should be avoided.

Why then, given the serious risk to women's health, do women take hormone replacement therapy? For many, the simple answer is that women need relief from hot flashes and other menopause symptoms.

Finding relief from menopause symptoms is not a black-and-white choice between taking hormone replacement therapy or doing nothing at all. Women do not need to place themselves in harm's way to eliminate hot flashes, mood swings, weight gain, headaches and other effects of menopause.

The answer to managing menopause symptoms requires a multi-pronged approach that includes healthy lifestyle choices, natural hormone replacement therapy and the use of progesterone cream to encourage hormonal balance and harmony.

Preserve[Preserve Information](#) [Dosage & Ingredients](#)

Product discontinued. Sorry for the inconvenience.

- Helps normalize hormonal levels,
- Helps diminish night sweats and hot flashes.
- Helps soothe and stabilize mood, reducing moodiness, depression and irritability.
- Helps reduce the uncomfortable and painful menopause signs and menopause symptoms such as pain, cramping and headache.

1 Bottle

\$26.95

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2 Bottles	\$51.90	Buy Now
3 Bottles	\$76.35	Buy Now

Many women find that by supplementing their hormone production with natural progesterone that they will reduce many or most of their menopausal symptoms. The presence of progesterone in the body sensitizes estrogen receptor sites enabling estrogen to work more efficiently without being dominant. Progesterone is a precursor to other hormones in the body including estrogen, testosterone, and especially the corticosteroids.

The benefits of natural progesterone cream are said to be many:

Brings hormonal balance back into your body.
 Balances estrogen dominance.
 Improves lipid profile.
 Improves blood sugar control.
 Improves burn up of body fat.
 Rebuilds lost bone mass at a rate of 5-15% per year.
 Improves new bone formation.
 Natural anti-depressant.
 Natural diuretic.
 Eliminates hot flashes.
 Creates the myelin sheath over nerves.
 Gives people more energy.
 Helps with sleep disorders.
 Helps with Fibrocystic Breast Disease.
 Normalizes and restores sexual desire.
 Promotes youthful skin appearance.
 Resists facial hair growth.
 Reduces risk of breast cancer.
 Reduces risk of uterine cancer.
 Improves blood sugar control.
 Promotes youthful skin appearance. (The late diet guru, Dr. Robert Atkins, M.D. was enthusiastic about natural progesterone cream for skin care. He endorsed its use because he found it the best wrinkle eradicator he ever had experienced.)

So with the addition of a regular exercise regimen, healthful diet with lots of fresh fruits and vegetables, and practical, common sense remedies for hot flashes and anxiety, menopause can be a nearly symptom free transition.

February Menopause Recipe: [Delicious Hamburger Substitute Crock Pot Lasagna.](#)

February Bath and Body Recipe: [Soothe Away the Aches and Pains Bath Salt Recipe.](#)

February Exercise Tip: [Is Tai Chi the Ultimate Exercise?](#)

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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 by the Commission, 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 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 § 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings, and enters the following order:

1. Respondent Merilou Barnekow is an individual trading and doing business as Women's Menopause Health Center with her principal office or place of business at 1026 Blue Water Highway, Surfside Beach, Texas 77541. Individually, or in concert with

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others, she formulates, directs, controls, or participates in the policies, acts, or practices of Women's Menopause Health Center.

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:

1. Unless otherwise specified, "Respondent" shall mean Merilou Barnekow, individually and trading and doing business as Women's Menopause Health Center.
2. "Competent and reliable scientific evidence" shall mean 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.
3. "Progesterone product" shall mean any product containing or purporting to contain any progestagen (whether natural or synthetic), including but not limited to progesterone (whether produced by the human body or produced outside the human body but having the same chemical structure as the progesterone produced by the human body) or any progestin, including but not limited to Preserve Progesterone Cream and Return to Eden Progesterone Cream.
4. "Food," shall mean (a) articles used for food or drink for man or other animals, (b) chewing gum, and (c) articles used for components of any such article.

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5. "Drug" shall mean (a) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; (b) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (c) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (d) articles intended for use as a component of any article specified in clause (a), (b), or (c); but does not include devices or their components, parts, or accessories.
6. "Device" shall mean an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (a) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (b) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (c) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.
7. "Covered product or service" shall mean any dietary supplement, food, drug, device, or any health-related service or program.
8. "Commerce" shall mean commerce among the several States or with foreign nations, or in any Territory of the United States or in the District of Columbia, or between any such Territory and another, or between any such Territory and any

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State or foreign nation, or between the District of Columbia and any State or Territory or foreign nation.

9. "Endorsement" shall mean any advertising message (including verbal statements, demonstrations, or depictions of the name, signature, likeness or other identifying personal characteristics of an individual or the name or seal of an organization) which message consumers are likely to believe reflects the opinions, beliefs, findings, or experience of a party other than the sponsoring advertiser. The party whose opinions, beliefs, findings, or experience the message appears to reflect will be called the endorser and may be an individual, group or institution.

I.

IT IS THEREFORE ORDERED that Respondent, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service, in or affecting commerce, shall not represent, in any manner, expressly or by implication, including through the use of a product name or endorsement:

- A. That such product or service is effective in preventing, treating, or curing osteoporosis;
- B. That such product or service is effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer;
- C. That such product or service does not increase the user's risk of developing breast cancer;
- D. That such product or service is effective in preventing or reducing the user's risk of developing breast cancer;

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- E. That such product or service is safe for human use or has no side effects;
- F. That such product or service is effective in the mitigation, treatment, prevention, or cure of any disease, illness or health conditions; or
- G. About the health benefits, performance, efficacy, safety, or side effects of such product or service;

unless the representation is true, not misleading, and, at the time it is made, Respondent possesses and relies upon competent and reliable scientific evidence that substantiates the representation.

II.

IT IS FURTHER ORDERED that Respondent, directly or through any person, partnership, corporation, subsidiary, division, trade name, or other device, in connection with the labeling, advertising, promotion, offering for sale, sale, or distribution of any Progesterone product or any other covered product or service in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that:

- A. Nothing in this order shall prohibit Respondent from making any representation for any drug that is permitted in 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;

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- B. Nothing in this order shall prohibit Respondent 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
- C. Nothing in this order shall prohibit Respondent from making any representation for any device that is permitted in labeling for such device under any new medical device application approved by the Food and Drug Administration.

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 reasonable notice 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 her 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 shall deliver a copy of this order to all current and future principals, officers,

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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 the order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VI.

IT IS FURTHER ORDERED that Respondent shall notify the Commission at least thirty (30) days prior to any change with regard to Women's Menopause Health Center or any business entity that Respondent directly or indirectly controls, or has an ownership interest in, that may affect compliance obligations arising under this order, including but not limited to incorporation or other organization; 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 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. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VII.

IT IS FURTHER ORDERED that Respondent, for a period of seven (7) years after the date of issuance of this order, shall notify the Commission of the discontinuance of her current business or employment; or of her affiliation with any new business or

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employment. The notice shall include respondent's new business address and telephone number, a description of the nature of the business or employment, and their duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Washington, D.C. 20580.

VIII.

IT IS FURTHER ORDERED that Respondent shall, within sixty (60) days after service of this order, and, upon reasonable notice, at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which she has complied with this order.

IX.

This order will terminate on November 19, 2027, 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 Respondent in such complaint; and
- C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Analysis to Aid Public Comment

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 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 Merilou Barnekow, an individual trading and doing business as Women's Menopause Health Center ("respondent").

The proposed consent order has been placed on the public record for thirty (30) days for reception 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 the advertising and promotion of Preserve Progesterone Cream and Return to Eden Progesterone Cream, transdermal creams that, according to their labels, contain, among other ingredients, natural progesterone. According to the FTC

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complaint, respondent represented that Preserve Progesterone Cream and Return to Eden Progesterone Cream: (1) are effective in preventing, treating, or curing osteoporosis; (2) are effective in preventing or reducing the risk of estrogen-induced endometrial (uterine) cancer; and (3) do not increase the user's risk of developing breast cancer and/or are effective in preventing or reducing the user's risk of developing breast cancer. The complaint alleges that respondent failed to have substantiation for these claims. The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts and practices in the future.

Part I of the proposed order requires respondents to have competent and reliable scientific evidence substantiating claims that any progesterone product or any other dietary supplement, food, drug, device or health-related service or program is effective in preventing, treating, or curing osteoporosis, in preventing or reducing the risk of estrogen-induced endometrial cancer or breast cancer, or in the mitigation, treatment, prevention, or cure of any disease, illness, or health condition; that it does not increase the user's risk of developing breast cancer, is safe for human use, or has no side effects; or about its health benefits, performance, efficacy, safety, or side effects.

Part II of the proposed order prevents respondent from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part III of the proposed order provides that the order does not prohibit respondent from making representations for any drug that are permitted in labeling for the drug under any tentative final or final Food and Drug Administration ("FDA") standard or under any new drug application approved by the FDA; representations for any medical device that are permitted in labeling under any new medical device application approved by the FDA; and representations for any product that are specifically permitted in labeling for that product by

Analysis to Aid Public Comment

regulations issued by the FDA under the Nutrition Labeling and Education Act of 1990.

Parts IV through VIII require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to certain of her personnel; to notify the Commission of changes in corporate structure and changes in employment that might affect compliance obligations under the order; and to file compliance reports with the Commission. 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 agreement and proposed order or to modify in any way their terms.

Complaint

IN THE MATTER OF

**KYPHON INC.,
DISC-O-TECH MEDICAL TECHNOLOGIES LTD.
AND
DISCOTECH ORTHOPEDIC TECHNOLOGIES
INC.**

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

Docket C-4201; File No. 071 0101

Complaint, October 5, 2007 – Decision, December 3, 2007

This consent order addresses the \$220 million acquisition by Kyphon Inc. (“Kyphon”) of certain assets from Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (collectively “Disc-O-Tech”). Respondents compete in the market for minimally invasive vertebral compression fracture (“MIVCF”) treatments, which doctors use to relieve pain when one or more vertebrae collapse. MIVCF treatments were developed to provide doctors and their patients with a safer and more effective treatment than pain management and open surgery. The complaint alleges that Disc-O-Tech developed an innovative MIVCF treatment system known as Confidence. The complaint further alleges that the acquisition of the assets related to Disc-O-Tech’s Confidence product lines would remove an actual, direct, and substantial competitor from the U.S. market for MIVCF treatment products. Under the consent order, both Kyphon and Disc-O-Tech must divest all Confidence assets (including intellectual property) to a third party and enable that third party to manufacture and sell the Confidence cement and delivery system. The order further requires Kyphon to provide a license for any other assets it acquired from Disc-O-Tech, which will ensure that the acquirer will be able to remain a viable competitor in the MIVCF treatment product market.

Participants

For the Commission: *Stephanie C. Bovee, Richard H. Cunningham, Sean G. Dillon, Daniel P. Ducore, Nwamaka Ejebe, Jonathan S. Klarfeld, Richard A. Levy, Randall A. Long, Michael R.*

Complaint

Moiseyev, Jana Pariser, Jeffrey H. Perry, Amy S. Posner, Ashley E. Reichenbach, and Matthew Riley.

For the Respondents: William Baer and Deborah L. Feinstein, Arnold & Porter LLP; Karen Silverman, Latham & Watkins, LLP; Rhett R. Krulla and John R. Ingrassia, Proskauer Rose LLP.

COMPLAINT

Pursuant to the Clayton Act and the Federal Trade Commission Act, and its authority thereunder, the Federal Trade Commission, having reason to believe that Kyphon Inc., a corporation subject to the jurisdiction of the Commission, has agreed to acquire certain assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc., corporations 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 (“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. DEFINITIONS

1. “Commission” means the Federal Trade Commission.
2. “Kyphon” means Kyphon Inc., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Kyphon Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
3. “Disc-O-Tech” means Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), its directors, officers, employees, agents, representatives, predecessors, successors, and

Complaint

assigns; its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation), including Discotech Orthopedic Technologies Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.

4. “Vertebral Compression Fracture” or “VCF” means a fracture of the vertebral body such as that which may result from osteoporosis, cancer, or trauma.

5. “Kyphoplasty” means a minimally invasive vertebral compression fracture treatment during which bone cement is injected through a needle into the vertebral body after a void in the vertebral body has been created by the insertion and inflation of one or two balloon-tipped catheters.

6. “Vertebroplasty” means a minimally invasive vertebral compression fracture treatment during which cement is injected through a needle into the vertebral body.

7. “FDA” means the United States Food and Drug Administration.

II. RESPONDENTS

8. Respondent Kyphon 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 1221 Crossman Avenue, Sunnyvale, California 94089. Kyphon, among other things, is engaged in the design, manufacture, marketing, and sale of single-use and implantable medical device products used in minimally invasive therapies for the treatment and restoration of spinal anatomy, including the KyphX Kyphoplasty products.

Complaint

9. Respondent Disc-O-Tech is a corporation organized, existing, and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha'hoshlim Street, Herzeliya, Israel 46724. Disc-O-Tech's United States subsidiary, doing business as Discotech Orthopedic Technologies Inc., is located at 7 Centre Dr., Suite 1, Monroe Township, New Jersey 08831. Disc-O-Tech, among other things, is engaged in the research, development, marketing, and sale of medical device products used in minimally invasive therapies for the treatment and restoration of spinal anatomy, including the Confidence Vertebroplasty system.

10. 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 "commerce" is defined in Section 4 of the Federal Trade Commission Act, as amended, 15 U.S.C. § 44.

III. PROPOSED ACQUISITION

11. On December 20, 2006, Kyphon agreed to acquire the spinal assets of Disc-O-Tech (the "Acquisition"), including Disc-O-Tech's intellectual property, sales agreements, and other assets relating to its Confidence minimally invasive VCF treatment product business. The Acquisition was structured as two transactions - an Asset Purchase Agreement (Vertebroplasty Assets) and an Asset Purchase Agreement (Non-Vertebroplasty Assets) - that have a combined value of approximately \$220 million.

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IV. RELEVANT MARKET

12. For the purposes of this Complaint, the relevant line of commerce in which to analyze the effects of the Acquisition is the research, development, manufacture, and sale of minimally invasive VCF treatment products. Minimally invasive VCF treatment products include, among other things, Kyphoplasty products, Disc-O-Tech's Confidence system, and traditional Vertebroplasty products.

13. 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. To compete in the United States minimally invasive VCF treatment product market, a firm must have FDA approval or clearance for its device, establish a local sales and service organization, and its product must not infringe any other firm's intellectual property.

V. STRUCTURE OF THE MARKET

14. Kyphon's Kyphoplasty products account for more than 90 percent of the market (by revenue) for research, development, manufacture, and sale of minimally invasive VCF treatment products. Disc-O-Tech's recently-launched Confidence system is a novel Vertebroplasty product that uses a highly viscous cement and proprietary delivery system. It is the only product currently on the market that is likely to provide significant and unique competition to Kyphon in the near term and is poised to take a significant share of Kyphon's sales. Disc-O-Tech's Confidence system would provide particularly vigorous competition to Kyphon if acquired by a major spine competitor, as would have occurred but for the Acquisition. Traditional Vertebroplasty products differ significantly from Kyphoplasty products and the Confidence system, and are low-cost products that are virtually commodities and provide only limited competition to Kyphon. There are other competitors in the minimally invasive VCF treatment product market, including

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Medtronic and Spineology, but none of those competitors provide the near-term competitive threat to Kyphon that Disc-O-Tech does. Although several additional firms are attempting to enter the minimally invasive VCF treatment product market, the time line for commercialization of those firms' products is significantly behind that of the Confidence system, and none appears to have the Confidence system's ultimate prospects for success.

VI. ENTRY CONDITIONS

15. Developing minimally invasive VCF treatment products, working around and/or acquiring the necessary licenses to critical intellectual property, obtaining FDA approval, and building a marketing infrastructure, takes significantly longer than two years. Therefore, entry into the relevant line of commerce described in Paragraph 12 would not be timely, likely, or sufficient in magnitude, character, and scope to deter or counteract the anticompetitive effects of the Acquisition.

VII. EFFECTS OF THE ACQUISITION

16. The effects of the Acquisition, if consummated, would be substantially to 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, among others:

- a. eliminating actual, direct, and substantial competition between Kyphon and Disc-O-Tech in the market for the research, development, marketing, and sale of minimally invasive VCF treatment products;
- b. increasing Kyphon's ability to raise prices unilaterally in the relevant market; and
- c. reducing research and development in the relevant market.

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VIII. VIOLATIONS CHARGED

17. The Asset Purchase Agreement (Vertebroplasty Assets) constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

18. The Acquisition described in Paragraph 11, 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 fifth day of October, 2007, issues its Complaint against said Respondents.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

ORDER TO HOLD SEPARATE AND MAINTAIN ASSETS

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition of certain vertebral compression fracture repair system assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (hereafter collectively referred to as “Respondent DOT”) by Kyphon Inc. (hereafter referred to as “Respondent Kyphon”), and Respondents Kyphon and DOT 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

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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 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 Kyphon 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 1221 Crossman Avenue, Sunnyvale, CA 94089.
2. Respondent Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha’hoshlim St., 46724 Herzeliya, Israel.

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3. Respondent Discotech Orthopedic Technologies 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 7 Centre Dr., Suite 1, Monroe Township, NJ 08831.

4. 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 Hold Separate Order, the definitions in Paragraph I of the Decision and Order attached to the Agreement Containing Consent Orders in this matter shall apply to all capitalized terms in this Hold Separate Order, in addition to the following definitions:

- A. "Held Separate Business" means the Confidence Assets and the on-going manufacturing, distribution, marketing and sale of the Confidence Products.

II.

IT IS FURTHER ORDERED that:

- A. Until the Date Of Divestiture, Respondents shall:
1. take such actions as are necessary to maintain the viability and marketability of the Confidence Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of the Confidence Assets, except for ordinary wear and tear;

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2. not sell, transfer, encumber or otherwise impair the economic viability, marketability, or competitiveness of the Confidence Assets; and
3. not consummate the acquisition contemplated by the Kyphon-DOT APA (Vertebroplasty Assets).

B. Until the Date Of Divestiture:

1. Respondent DOT's personnel operating the Held Separate Business must retain and maintain all Material Confidential Information of the Held Separate Business on a confidential basis, separate and apart from Respondent Kyphon and, except as is requested by Kyphon for purposes of the divestiture of the Confidence Assets 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 Kyphon or with Respondent Kyphon's personnel. Such DOT personnel shall also execute confidentiality agreements prohibiting the disclosure of any Material Confidential Information of the Held Separate Business; and
2. Respondent Kyphon and Respondent Kyphon's personnel shall not receive or use Material Confidential Information of the Held Separate Business except for purposes of divesting the Confidence Assets as required by the Decision and Order, in this matter.

C. Until the Date Of Divestiture and unless otherwise provided for in this Hold Separate Order, Respondent Kyphon shall not permit any of its employees, officers, or directors to be involved in the operations of the Held Separate Business.

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- D. Until the Date Of Divestiture, Respondent Kyphon shall not offer Respondent DOT employees Related To the Held Separate Business positions with Respondent Kyphon.
- E. Until the Date Of Divestiture, Respondents shall do nothing to prevent or discourage Suppliers that, prior to the Date Of Divestiture, supplied goods and services for the Confidence Assets from continuing to supply goods and services for the Confidence Assets.
- F. No later than five (5) days after the date this Hold Separate Order becomes final, Respondent DOT shall circulate to employees of the Held Separate Business and to Respondent DOT's employees who are responsible for the development, manufacture and sale of Confidence Products, a copy of this Hold Separate Order and the Consent Agreement.
- G. The purposes of this Hold Separate Order are to: (1) preserve the Held Separate Business as a viable, competitive, and ongoing business independent of Respondent Kyphon until the divestiture required by the Decision and Order is achieved; (2) assure that no Material Confidential Information is exchanged between Respondent Kyphon and the Held Separate Business, 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 Acquisition.

III.

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

- A. Any proposed dissolution of Respondent Kyphon,

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- B. Any proposed acquisition, merger, or consolidation of Respondent Kyphon, *provided, however*, if Medtronic acquires Respondent Kyphon, that acquisition shall be excluded from this notice requirement, or
- C. Any other change in Respondent Kyphon 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 Respondent Kyphon.

IV.

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 Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during 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 Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondent, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

V.

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

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- B. the day after the Date Of Divestiture required by the Consent Agreement.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

DECISION AND ORDER

The Federal Trade Commission (“Commission”), having initiated an investigation of the proposed acquisition of certain vertebral compression fracture repair system assets of Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (hereafter collectively referred to as “Respondent DOT”) by Kyphon Inc. (hereafter referred to as “Respondent Kyphon”), and Respondents Kyphon and DOT 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

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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 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 Kyphon 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 1221 Crossman Avenue, Sunnyvale, CA 94089.

2. Respondent Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) is a corporation organized, existing and doing business under and by virtue of the laws of the State of Israel, with its office and principal place of business located at 11 Ha'hoshlim St., 46724 Herzeliya, Israel.

3. Respondent Discotech Orthopedic Technologies 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 7 Centre Dr., Suite 1, Monroe Township, NJ 08831.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of 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. “Kyphon” or “Respondent Kyphon” means Kyphon Inc., its directors, officers, employees, agents, representatives, successors (including Medtronic, if Kyphon is acquired by Medtronic), and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Kyphon, Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- B. “DOT” or “Respondent DOT” means Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc., their directors, officers, employees, agents, representatives, successors, and assigns; and their joint ventures, subsidiaries, divisions, groups and affiliates controlled by Disc-O-Tech Medical Technologies Ltd. and Discotech Orthopedic Technologies Inc., and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Commission” means the Federal Trade Commission.
- D. “Acquirer” means each Person that receives the prior approval of the Commission to acquire the Confidence Assets pursuant to Paragraphs II or III of this Order. DOT is not excluded from being considered an Acquirer.
- E. “Affiliate” means any entity or acquired business that directly or indirectly is controlled by either Respondent or Acquirer, but only so long as such control exists, control being the direct or indirect ownership of at least fifty percent (50%) of the stock entitled to vote upon election of directors

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or persons performing similar functions, or direct or indirect ownership of the maximum percentage permitted under local laws or regulations in those countries where fifty percent (50%) ownership by a foreign entity is not permitted.

- F. “Assumed Contracts” means those contracts as defined and listed in the Kyphon-DOT APA (Vertebroplasty Assets).
- G. “Confidence Assets” means all assets and intellectual property of Respondent DOT Relating To the research, development, manufacture, marketing, distribution, and sale of products accessing, diagnosing, or treating spinal disease states or disorders that are proposed to be acquired or have been acquired by Respondent Kyphon pursuant to the Kyphon-DOT APA (Vertebroplasty Assets), which assets and intellectual property include, but are not limited to:
 - 1. the Confidence Products, together with the related cement system and cement injectors including, but not limited to:
 - a. documents Relating To quality control,
 - b. documents Relating To Suppliers,
 - c. copies of contracts with Suppliers, unless such contracts cannot, according to their terms, be disclosed to third parties even with the permission of Kyphon or DOT to make such disclosure;
 - 2. all Assumed Contracts;
 - 3. all Intangible Property exclusively Relating To the Confidence Products and the Next Generation Product;
 - 4. all technology rights licenses, franchises, know-how, inventions, designs, specifications, plans and drawings primarily used in the research, development,

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manufacture, marketing, distribution, and sale of products accessing, diagnosing, or treating spinal disease states or disorders;

5. all Books and Records, as that term is defined in the Kyphon-DOT APA (Vertebroplasty Assets);
6. brochures and marketing information;
7. all permits and licenses that are necessary to enable the Acquirer to manufacture, sell, and distribute the Confidence Products, including the related cement system and cement injectors;

Provided, however, that “Confidence Assets” does not include Excluded Assets.

- H. “Confidence Products” means the products or product line currently manufactured and sold by Respondent DOT and that the Acquirer develops, manufactures, distributes, or sells as a result of the acquisition of the Confidence Assets including, but not limited to, the cement and cement delivery system. Confidence Products refers solely to vertebroplasty products.
- I. “Date Of Divestiture” means the date upon which the Confidence Assets are divested to an Acquirer pursuant to this Order.
- J. “Excluded Assets” means:
 1. assets and Intangible Property that are proposed to be acquired or have been acquired from Respondent DOT by Respondent Kyphon pursuant to the Kyphon-DOT APA (Non-Vertebroplasty Assets) including, but not limited to, the B-Twin products and related Intangible

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Property, the SKy Bone Expander products and related Intangible Property, and other rights and assets proposed to be acquired or acquired pursuant to the Kyphon-DOT APA (Non-Vertebroplasty Assets);

2. all cash, cash equivalents, and short term investments of cash;
 3. accounts and notes receivable;
 4. rights to the names “Kyphon,” and “Disc-O-Tech” and any variation of those names;
 5. prepaid items or rebates;
 6. minute books, tax returns, and other corporate books and records;
 7. any inter-company balances due to or from DOT;
 8. all benefits plans;
 9. 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 specifically Relates To the Confidence Assets;
 10. assets specifically excluded in the Kyphon-DOT APA (Vertebroplasty Assets).
- K. “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.

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- L. “Governmental Approvals For Divestiture” means any Governmental Approvals that an Acquirer must have to own, develop, manufacture, distribute, and sell the Confidence Assets.
- M. “Intangible Property” means intangible property 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.
- N. “Kyphon-DOT APA (Non-Vertebroplasty Assets)” means the December 20, 2006, Asset Purchase Agreement (Non-Vertebroplasty Assets) by and among Disc-O-Tech Medical Technologies Ltd. (In Liquidation), Discotech Orthopedic Technologies Inc., and Kyphon Inc., including all amendments, exhibits, attachments, agreements, and schedules thereto.
- O. “Kyphon-DOT APA (Vertebroplasty Assets)” means the December 20, 2006, Asset Purchase Agreement (Vertebroplasty Assets) by and among Disc-O-Tech Medical Technologies Ltd. (In Liquidation), Discotech Orthopedic Technologies Inc., and Kyphon Inc., including all amendments, exhibits, attachments, agreements, and schedules thereto.
- P. “Material Confidential 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.

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- Q. “Medtronic” means Medtronic, Inc., its directors, officers, employees, agents, representatives, successors, and assigns; and its joint ventures, subsidiaries, divisions, groups, and affiliates controlled by Medtronic, Inc. (including Kyphon, after the date on which it acquires Kyphon) and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- R. “Next Generation Product” means a vertebral compression fracture repair system, not yet fully developed or marketed by DOT, defined in Exhibit D (the “Non-Competition, Confidentiality and Development Agreement”) to the Kyphon-DOT APA (Vertebroplasty Assets).
- S. “Patents” means all patents, patent applications, and statutory invention registrations (which shall be deemed to include provisional applications, invention disclosures, certificates of invention and applications for certificates of invention), in each case existing as of the date this Order is accepted by the Commission for public comment, and includes all reissues, divisions, continuations, continuations-in-part, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the world.
- T. “Person” means any natural person, partnership, corporation, association, trust, joint venture, government, government agency, or other business or legal entity.
- U. “Relating To” or “Related To” means pertaining in any way to, and is not limited to that which pertains exclusively to or primarily to.
- V. “Remedial Agreement” means any agreement between both or either of the Respondents and an Acquirer (or between a

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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 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.

- W. “Successor” means the Acquirer’s successor or Affiliate, or any Person or Persons to whom the Acquirer transfers, licenses, or authorizes to manufacture, develop or sell Confidence Products or Next Generation Products pursuant to Intangible Property transferred or licensed pursuant to Paragraphs II or III of this Order.
- X. “Supplier” means any Person that has sold to DOT any goods or services for use with the Confidence Assets.
- Y. “Third Party” means any private entity other than the following: (1) Respondents, (2) Medtronic, or (3) the Acquirer.
- Z. “Transferred Non-Vertebroplasty Intangible Property” means any Intangible Property that is proposed to be transferred or has transferred to Respondent Kyphon from Respondent DOT as part of the Kyphon-DOT APA (Non-Vertebroplasty Assets).
- AA. “Transferred Vertebroplasty Intangible Property” means any Intangible Property that has been transferred or licensed to the Acquirer from Respondents pursuant to the Remedial Agreement and this Decision and Order.

II.

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IT IS FURTHER ORDERED that:

- A. Respondent Kyphon shall, within sixty (60) days after the date on which the Agreement Containing Consent Orders, in this matter, is accepted by the Commission for placement on the public record for comment, divest, absolutely, and in good faith, at no minimum price, the Confidence Assets to an acquirer that receives the prior approval of the Commission and only in a manner that receives the prior approval of the Commission.
- B. Respondent DOT shall:
 - 1. take no actions to interfere with the divestiture of the Confidence Assets;
 - 2. enter into and execute all documents, agreements, and other instruments that may be required to consummate the divestiture of the Confidence Assets to an Acquirer; and
 - 3. transfer all assets and intellectual property required to be transferred to the Acquirer pursuant to the Remedial Agreement.
- C. Until the Date Of Divestiture, Respondents shall:
 - 1. take such actions as are necessary to maintain the viability and marketability of the Confidence Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of the Confidence Assets, except for ordinary wear and tear;
 - 2. not sell, transfer, encumber or otherwise impair the economic viability, marketability, or competitiveness of the Confidence Assets; and

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3. not consummate the acquisition contemplated by the Kyphon-DOT APA (Vertebroplasty Assets).

D. Respondent Kyphon shall:

1. not join, file, induce, prosecute or maintain any suit, in law or equity, against the Acquirer or Successor to the extent that such suit alleges that such Acquirer or Successor has infringed or is infringing any Transferred Non-Vertebroplasty Intangible Property with the Confidence Product or Next Generation Product developed, designed, manufactured, licensed, or otherwise sold by or on behalf of Acquirer or Successor pursuant to the Transferred Vertebroplasty Intangible Property, if such suit would have the potential to interfere with the Acquirer's freedom to practice in the research, development, manufacture, use, import, export, distribution or sale of such Confidence Products or Next Generation Products; and
 2. in the event it assigns, transfers, or licenses Transferred Non-Vertebroplasty Intangible Property to a Third Party, include in such assignment, transfer, or license a covenant not to sue the Acquirer or Successor at least as protective as those extended pursuant to the preceding Paragraph II.D.1, as a condition of such assignment, transfer or license.
- E. Any Remedial Agreement related to the Confidence Assets shall be deemed incorporated into this Order, and any failure by Respondents to comply with any term of such Remedial Agreement related to the Confidence Assets shall constitute a failure to comply with this Order.
- F. The Remedial Agreement shall not vary or contradict, or be construed to vary or contradict, the terms of this Order.

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Nothing in this Order shall reduce, or be construed to reduce, any rights or benefits of the Acquirer, or any obligations of Respondents, under the Remedial Agreement.

- G. Respondent Kyphon shall include in any Remedial Agreement related to the Confidence Assets the following provisions:
1. Respondent Kyphon shall covenant to the Acquirer that Respondent Kyphon shall not join, file, induce, prosecute or maintain any suit, in law or equity, against the Acquirer or Successor to the extent that such suit alleges that such Acquirer or Successor has infringed or is infringing any Transferred Non-Vertebroplasty Intangible Property with the Confidence Product or Next Generation Product developed, designed, manufactured, licensed, or otherwise sold by or on behalf of Acquirer or Successor pursuant to the Transferred Vertebroplasty Intangible Property, if such suit would have the potential to interfere with the Acquirer's freedom to practice in the research, development, manufacture, use, import, export, distribution or sale of such Confidence Products or Next Generation Product; and
 2. Respondent Kyphon shall covenant to the Acquirer that any Third Party assignee, transferee or licensee of Transferred Non-Vertebroplasty Intangible Property shall agree to provide a covenant not to sue the Acquirer or Successor at least as protective as those extended pursuant to the preceding Paragraph II.G.1, as a condition of such assignment, transfer or license.
- H. Respondents shall grant to the Acquirer royalty-free, perpetual, worldwide, non-exclusive licenses to the Transferred Non-Vertebroplasty Intangible Property for the field of use of vertebroplasty that, as of the time of the signing of the Agreement Containing Consent Orders in this

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matter, is used in the research, development, manufacture, use, export, distribution, or sale of Confidence Products or Next Generation Products (including the right to transfer or sublicense such license rights in such Intangible Property, exclusively or nonexclusively, to others by any means).

- I. Until the Date Of Divestiture, Respondents shall:
 1. cooperate with the Acquirer and assist the Acquirer, at no cost to the Acquirer, before the Date Of Divestiture in obtaining all Government Approvals For Divestiture;
 2. do nothing to prevent or discourage Suppliers that, prior to the Date Of Divestiture, supplied goods and services for the Confidence Assets from continuing to supply goods and services for the Confidence Assets.
- J. Respondent DOT shall, (i) at the option of the Acquirer, (ii) no later than the Date Of Divestiture, and (iii) as part of the Remedial Agreement, enter into:
 1. one or more transition agreements for the short-term provision of services to be provided by Respondent DOT to the Acquirer. *Provided, however,* Respondent DOT shall not be required to agree to transition services (i) other than those similar in form and substance to the transition services that are a part of the Kyphon-DOT APA (Vertebroplasty Assets), and (ii) for a term longer than nine (9) months, but in any case such transition agreements shall not terminate later than December 1, 2008; and
 2. one or more non-competition, confidentiality, and development agreements between Respondent DOT and the Acquirer similar in form and substance and length of time as similar agreements in Exhibit D to the Kyphon-DOT APA (Vertebroplasty Assets).

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- K. The purpose of Paragraph II of this Order is to ensure the continuation of the Confidence Assets as part of an ongoing viable enterprise engaged in the same business in which such assets were engaged at the time of the announcement of the acquisition by Kyphon of the Confidence Assets, to ensure that the Confidence Assets are operated independently of, and in competition with, Kyphon, and to remedy the lessening of competition alleged in the Commission's Complaint.

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

A. If Respondents:

1. have not divested, absolutely and in good faith and with the Commission's prior approval, the Confidence Assets pursuant to Paragraph II of this Order, the Commission may appoint a trustee to divest the Confidence 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. 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 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 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

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statute enforced by the Commission, for any failure by Respondents to comply with this Order; or

2. close the Kyphon-DOT APA (Vertebroplasty Assets) before the Date Of Divestiture as prohibited in Paragraph II.C of this Order, the Commission immediately may appoint a trustee to divest the Confidence Assets that have not been divested pursuant to Paragraph II of this Order, notwithstanding that the time allowed to divest pursuant to Paragraph II.A has not expired, in a manner that satisfies the requirements of Paragraph II 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 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 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 Respondents to comply with this Order.
- B. The Commission shall select the trustee, subject to the consent of Respondents, which consent shall not be unreasonably withheld. The 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 trustee within ten (10) days after receipt of notice by the staff of the Commission to Respondents of the identity of any proposed

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trustee, Respondents shall be deemed to have consented to the selection of the proposed trustee.

- C. Within ten (10) days after appointment of a trustee, Respondents 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, Respondents 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 the Confidence Assets that have not been divested pursuant to Paragraph II of this Order.
 - 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 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. Respondents shall develop such financial or other information as the trustee may request

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and shall cooperate with the trustee. Respondents shall take no action to interfere with or impede the trustee's accomplishment of the divestiture. Any delays in divestiture caused by Respondents shall extend the time for divestiture under this Paragraph III 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 Respondents'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 trustee receives 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 Respondents from among those approved by the Commission; *provided, further, however*, that Respondents 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 Kyphon, 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 Respondents, 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

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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 Respondents, 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. Respondents 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, 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 Respondents and to the Commission every sixty (60) days concerning the trustee's efforts to accomplish the divestiture.
9. Respondents 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.

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- 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 III.
- 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.

IV.

IT IS FURTHER ORDERED that for a period of two (2) years from the date this Order becomes final, Respondent Kyphon shall not, without providing advance written notification to the Commission in the manner described in this paragraph, directly or indirectly acquire or receive a license for any of the Confidence Assets transferred pursuant to the Remedial Agreement.

Said advance written notification shall contain (i) either a detailed term sheet for the proposed acquisition or license or the proposed agreement or license 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 Kyphon and not from any other party to the transaction. Kyphon 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,

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representatives of the Commission make a written request for additional information or documentary material (within the meaning of 16 C.F.R. § 803.20), Kyphon 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 Bureau of Competition.

Provided, further, 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.

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

- A. Beginning thirty (30) days after the date this Order becomes final, and every thirty (30) days thereafter until Respondents have fully complied with Paragraphs II.A, II.B., II.C., II.G. II.H., II.I., and II.J. of this Order, 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 the terms of this Order and the Hold Separate Order.
- B. On the first and second anniversary of the date this Order becomes final, Respondent Kyphon shall submit to the Commission a verified written report setting forth in detail the manner and form in which it is complying and has complied with this Order, the Hold Separate Order, and the Remedial Agreement. Respondent Kyphon shall submit at the same time a copy of these reports to the Monitor, if any Monitor has been appointed.

VI.

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

- A. Any proposed dissolution of Respondent Kyphon,
- B. Any proposed acquisition, merger, or consolidation of Respondent Kyphon, *provided, however*, if Medtronic acquires Respondent Kyphon, that acquisition shall be excluded from this notice requirement, or
- C. Any other change in Respondent Kyphon 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 Respondent Kyphon.

VII.

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 Respondents, Respondents shall permit any duly authorized representative of the Commission:

- A. Access, during 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 Respondents related to compliance with this Order; and
- B. Upon five (5) days' notice to Respondents and without restraint or interference from Respondents, to interview officers, directors, or employees of Respondents, who may have counsel present, regarding such matters.

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VIII.

IT IS FURTHER ORDERED that this Order shall terminate on December 3, 2012.

By the Commission, Commissioner Harbour and Commissioner Kovacic recused.

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**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 Kyphon Inc. (“Kyphon”) and Disc-O-Tech Medical Technologies Ltd. (Under Voluntary Liquidation) and Discotech Orthopedic Technologies Inc. (collectively “Disc-O-Tech”). The purpose of the proposed Consent Agreement is to remedy the anticompetitive effects that would otherwise result from Kyphon’s acquisition of Disc-O-Tech’s Confidence assets. Under the terms of the proposed Consent Agreement, Kyphon and Disc-O-Tech are required to divest all assets (including intellectual property) related to Disc-O-Tech’s Confidence business to a third party, enabling that third party to manufacture and sell the Confidence cement and delivery system for the treatment of vertebral compression fractures.

The proposed Consent Agreement has been placed on the public record for thirty days to solicit comments from 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 the proposed Consent Agreement or make it final.

On December 20, 2006, Kyphon agreed to acquire certain spine-related assets from Disc-O-Tech, including the intellectual property, sales agreements, and other assets relating to Disc-O-Tech’s B-Twin, SKy Bone Expander, and Confidence product lines for approximately \$220 million (the “Acquisition”). The Commission’s complaint alleges that the proposed acquisition of the assets related to the Confidence system, if consummated, would violate Section 7 of the Clayton Act, as amended, 15 U.S.C. § 18, and Section 5 of the

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Federal Trade Commission Act, as amended, 15 U.S.C. § 45, by removing an actual, direct, and substantial competitor from the U.S. market for minimally invasive vertebral compression fracture (“MIVCF”) treatment products. The proposed Consent Agreement would remedy the alleged violation by requiring a divestiture that will replace the competition that otherwise would be lost in this market as a result of the Acquisition.

II. The Parties

Kyphon develops and markets medical devices used to restore and preserve spinal function and diagnose the source of low back pain, including products used to treat vertebral compression fractures in a minimally invasive manner. In 2006, Kyphon reported worldwide sales of approximately \$408 million, and U.S. sales of \$324 million.

Disc-O-Tech, an Israeli corporation and its U.S. subsidiary that develops, manufactures, and sells products for minimally invasive orthopedic surgeries, introduced the Confidence system to the U.S. market in July 2006. Disc-O-Tech’s global revenues were approximately \$14 million in 2006.

III. Minimally Invasive Vertebral Compression Fracture Treatments

Vertebral compression fractures (“VCFs”) occur when one or more vertebral bodies collapse. Osteoporosis, a degenerative bone disease that largely affects elderly women, causes the vast majority of VCFs, but they can also be caused by cancerous tumors or traumatic injury. For some patients, VCFs cause extreme, persistent, and debilitating pain.

Doctors and their patients have few ways to effectively treat VCFs. In the past, physicians most commonly treated VCF patients with a variety of pain management techniques such as back braces, bed rest, and pain medication. For many patients, these techniques

Analysis to Aid Public Comment

do not control the pain associated with VCFs and could lead to later health problems. Open surgery involving the placement of metal hardware is rarely performed to repair a VCF because the patients are typically elderly and not good candidates for successful procedures. MIVCF treatments were developed to provide doctors and their patients with a VCF treatment that is more effective than pain management and safer and more effective than open surgery.

Vertebroplasty, the first MIVCF treatment to be introduced, involves the injection of a fairly liquid polymethylmethacrylate bone cement into the fractured vertebral body under fluoroscopy image guidance. The bone cement sets quickly, stabilizing the fracture and eliminating painful movement of loose bone in the vertebra. Vertebroplasty effectively relieves pain, but many doctors have safety concerns regarding the risk of the liquid bone cement leaking out of the vertebral body.

Kyphoplasty, introduced by Kyphon in 1999, is similar to vertebroplasty, except that the physician performs the additional step of inflating one or two balloons inside the vertebral body before injecting the bone cement. The principal advantage of kyphoplasty is that the inflation of the balloons creates a cavity into which the bone cement can flow, reducing the likelihood that cement will leak outside of the vertebral body. Kyphoplasty may have the additional benefit of helping to restore the vertebral body towards its pre-fracture shape and height. Because of its safety advantage and other perceived advantages, kyphoplasty is the most widely used MIVCF treatment product in the United States.

Because of the superiority of MIVCF treatment products over alternatives, the relevant product market in which to analyze the competitive effects of the Acquisition is no larger than MIVCF treatment products. The relevant geographic market is the United States. MIVCF treatment products are medical devices that are regulated by the United States Food and Drug Administration ("FDA"). MIVCF treatment products sold outside the United States,

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but not approved for sale in the United States, are not viable alternatives for U.S. consumers and hence are not in the relevant market.

Kyphon's premium-priced kyphoplasty product dominates the MIVCF treatment product market with more than a ninety percent share based on revenues. Disc-O-Tech's Confidence system is the first MIVCF treatment product that uses a highly viscous cement. Both Kyphon's product, which uses balloons, and Disc-O-Tech's product, which uses a highly viscous cement, have substantially lower risks of leakage from the vertebral body following injection than do the "traditional" vertebroplasty products offered by numerous other firms. All of the latter inject a low viscosity cement. As a result, Disc-O-Tech's Confidence system is poised to become a closer substitute for Kyphon's product than are the traditional vertebroplasty products. For this reason, traditional vertebroplasty products will not constrain the prices for Kyphon's product to the same extent that Disc-O-Tech's Confidence system would, absent its acquisition by Kyphon.

There are other competitors in the MIVCF treatment product market, including Medtronic and Spineology, but none provides the near-term competitive threat to Kyphon posed by Disc-O-Tech's offering. Medtronic has had limited success selling its Arcuate XP product to date, and its product appears to hold limited growth prospects. Spineology's MIVCF offering has been and appears likely to remain a niche product that competes primarily for younger VCF patients. Although several additional firms are attempting to enter the MIVCF treatment product market, the time line for commercialization of these products is significantly behind that of the Confidence system, and none appears to have the Confidence system's immediate prospects for success.

IV. Competitive Effects and Entry Conditions

The Acquisition would cause significant competitive harm in the market for MIVCF treatment products. Confidence is Kyphon's principal competitive threat, and, but for the Acquisition, would

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make significant inroads into Kyphon's near-monopoly position. Because both products offer a safe method for treating VCFs, many physicians consider the Confidence system to be the best alternative to kyphoplasty, particularly for elderly osteoporotic patients who receive the vast majority of kyphoplasty treatments. By eliminating such a close competitor, the Acquisition would likely allow Kyphon to unilaterally raise prices in the MIVCF treatment market. The anticompetitive effects of the Acquisition are exacerbated by the fact that it appears to have been undertaken with the specific goal of precluding other major spine companies from acquiring Confidence and marketing it against kyphoplasty, which would have happened had Kyphon not acquired Confidence itself. By enabling Kyphon, rather than a major spine company, to control the further development and positioning of Confidence, Kyphon would be able to avoid the competition that it otherwise would have faced in the MIVCF treatment product market. As such, the Acquisition, if consummated, would have a significant, adverse effect on competition.

New entry is not likely to avert the anticompetitive effects of the proposed transaction. It likely would take more than two years for a would-be entrant to develop a product, conduct clinical trials, and submit the product for FDA approval. After submitting an application for FDA clearance or approval, a firm must wait for the FDA to review the material and respond to any questions the FDA may have. In addition to the development and regulatory time requirements for firms seeking to enter the MIVCF treatment product market, there are substantial intellectual property barriers an entrant must overcome. Patent litigation among competitors in this market is ongoing, and key patents act as a major obstacle to any prospective entrant. As such, any new MIVCF treatment device of any competitive significance would have to be designed around existing patents. Finally, even after a non-infringing design is developed and the product is manufactured, a firm would still need to establish a U.S. sales and marketing force. Considering all these factors, entry into the manufacture and sale of MIVCF treatment

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products is likely to take longer than two years. Thus, timely and sufficient entry in response to a small but significant price increase is extremely unlikely.

V. The Proposed Consent Agreement

The parties have agreed, pursuant to the proposed Consent Agreement, to divest Disc-O-Tech's Confidence assets to a Commission-approved acquirer no later than 60 days after the Commission accepts the Consent Agreement for public comment, effectively remedying the Acquisition's anticompetitive effects in the MIVCF treatment product market. The Consent Agreement requires that the parties divest all assets relating to the Confidence system, including tangible property, intellectual property, and any permits and licenses that are necessary to manufacture, distribute, and sell the Confidence system. In addition, the parties must divest the rights to certain Disc-O-Tech development efforts related to the Confidence system. To the extent that an acquirer of the Confidence assets requires additional assets not included in the asset package, the Consent Agreement requires Kyphon to provide a license to any other assets it acquired from Disc-O-Tech, which will ensure that the acquirer will be able to immediately enter the MIVCF treatment product market and remain a viable competitor.

The proposed Consent Agreement contains several provisions to help ensure that the divestiture is successful. First, the Commission will evaluate possible purchasers of the divested assets to ensure that the competitive environment that would have existed but for the transaction is restored. If the parties do not divest the Confidence assets within the 60-day time period to a Commission-approved buyer, or if Kyphon closes on the acquisition of the Confidence assets, the Consent Agreement provides for the Commission to appoint a trustee to divest the assets. Second, Disc-O-Tech is required to provide transitional services to the Commission-approved buyer. These transitional services, which are similar in form to what Disc-O-Tech would have provided to Kyphon, may be necessary for a smooth transition of the Confidence assets to the

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acquirer and to ensure continued and uninterrupted service to customers during the transition. The Consent Agreement also requires that Kyphon covenant not to sue the acquirer of the Confidence assets for infringing any intellectual property Kyphon acquired from Disc-O-Tech that is not being divested. This covenant covers not only the Confidence assets, but also extends to any developments an acquirer might make to the Confidence assets. This provision is designed as a safety net to ensure that Kyphon does not interfere with the acquirer's freedom to compete in the U.S. MIVCF treatment product market with a patent infringement lawsuit based on former Disc-O-Tech intellectual property. Finally, to ensure that the Commission will have an opportunity to review any attempt by Kyphon to acquire or license any of the Confidence assets at any time within the next two years, the proposed Consent Agreement contains a prior notice provision committing Kyphon to an H-S-R framework, even if such a transaction otherwise would be non-reportable.

The Order to Hold Separate and Maintain Assets that is included in the Consent Agreement requires that Disc-O-Tech maintain the viability of the Confidence business as a competitive operation until the business is transferred to a Commission-approved buyer. Specifically, Disc-O-Tech must maintain the confidentiality of sensitive business information, and take all actions required to prevent the destruction or wasting of the Confidence assets. Kyphon may not interfere with the Confidence business during the pendency of the divestiture by having any involvement in the Confidence business, making offers of employment to Disc-O-Tech employees involved in the Confidence business before the Confidence assets are divested, or interfering with Disc-O-Tech's suppliers of materials for the Confidence product.

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 Decision and Order or to modify its terms in any way.

KYPHON INC.

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Complaint

IN THE MATTER OF

OWENS CORNINGCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket C-4210; File No. 061 0281**Complaint, December 4, 2007 – Decision, December 4, 2007*

This consent order addresses the acquisition by Owens Corning (“Respondent”) of certain assets of Compagnie de Saint Gobain (“Saint Gobain”). The complaint alleges that Respondent and Saint Gobain account for more than 90 percent of the Continuous Filament Mat (“CFM”) sold in North America. CFM is an input in the production of non-electrical laminate, marine parts and accessories, and other products where its strength and other desirable characteristics make it the most cost effective material to use. The complaint alleges that the acquisition would reduce competition by eliminating direct competition between these two companies. Under the consent order, Respondent must divest its CFM business to AGY Holding Corp., which develops, manufactures, and markets a wide range of glass fiber yarns and reinforcement materials, within 10 days of the acquisition. Respondent is also required to divest its Huntingdon Facility that produces CFM and its Marbles Furnace, which supplies the Huntingdon Facility with essential glass fiber marbles used in production.

Participants

For the *Commission*: Daniel P. Ducore, Wallace W. Easterling, Mark Frankena, David Glasner, Sebastian Lorigo, David Morris, Catherine M. Moscatelli, Louis Silvia, Jacqueline Tapp, and Leonor Valazquez.

For the *Respondent*: Deborah L. Feinstein and Mark R. Merley, Arnold and Porter LLP.

Complaint

COMPLAINT

Pursuant to the provisions of the Federal Trade Commission Act and of the Clayton Act, and by virtue of the authority vested by said Acts, the Federal Trade Commission (the “Commission”), having reason to believe that respondent Owens Corning (“Owens Corning”), a corporation, and Compagnie de Saint Gobain (“Saint Gobain”), a corporation, both subject to the jurisdiction of the Commission, have agreed to an acquisition by Owens Corning of certain fiberglass reinforcements and composite fabrics assets of Saint Gobain 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. RESPONDENT

1. Respondent Owens Corning is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Owens Corning Parkway, Toledo, Ohio, 43659. Owens Corning is a global company engaged in a wide variety of businesses, including the development, manufacture, marketing, and sale of glass fiber reinforcements.

II. JURISDICTION

2. Owens Corning 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.

Complaint

III. THE PROPOSED TRANSACTION

3. Saint Gobain is a French company with its head office in Courbevoie, France. Saint Gobain controls a number of companies in the United States, including, but not limited to, Saint Gobain Vetrotex America, Inc. (“Vetrotex America”) located at 4515 Allendale Rd, Wichita Falls, Texas, 76310. Saint Gobain is a global company engaged in a wide variety of businesses, including the development, manufacture, marketing, and sale of glass fiber reinforcements.

4. Owens Corning and Saint Gobain originally planned to combine their respective glass fiber reinforcement businesses in a new entity to be called Owens Corning Vetrotex Reinforcements (“OCVR”). The new entity was to be owned 60% by Owens Corning and 40% by Saint Gobain.

5. In August 2007, the parties restructured the transaction and entered into an acquisition agreement whereby Owens Corning will acquire Saint Gobain’s glass fiber reinforcements and composite fabric business assets worldwide with several important exclusions. Owens Corning will not acquire Saint Gobain assets of the glass fiber reinforcements business located in the United States. Additionally, certain assets located in Europe will be divested pursuant to an agreement entered into between the parties and the European Commission. Consequently, Saint Gobain’s glass fiber reinforcements business and assets located in the United States will be excluded from the proposed acquisition as well as certain assets located in Europe. However, the proposed acquisition still includes Saint Gobain assets that are located in Europe and used in the design, manufacture, and sale of Continuous Filament Mat (“CFM”), a unique glass fiber reinforcement product.

Complaint

IV. CONTINUOUS FILAMENT MAT AND RELATED TECHNOLOGY

6. CFM is a unique glass fiber reinforcement product manufactured by melting quarry inputs (combinations of silica, clay, and other materials) in a refractory lined furnace. The resulting molten glass product is drawn through a holed surface called a bushing. The resulting filaments (in the case of standard furnaces), or the resulting spheres, also known as marbles (in the case of marble furnaces), are then diverted to a separate production function which reheats the materials and uses various chemical and physical processes to alter its properties, ultimately tailoring it for a range of end use applications. In contrast to other types of glass fiber reinforcement products, CFM is a non-woven material in which filament or marbles are ultimately converted into a mat using soluble and insoluble binders. Consequently, once the initial filaments or marbles are produced, the downstream production processes and equipment (on which CFM is produced) are unique to CFM and are not used to produce other types of glass fiber reinforcement products.

V. THE RELEVANT PRODUCT MARKET

7. CFM has distinct performance characteristics and physical properties, including, but not limited to, strength, toughness, and ease of processing in automated manufacturing processes. CFM is used where its properties are important, such as compression molding processes. CFM allows the manufacturer that uses it to cost effectively produce non-electrical laminates, turbine blades, marine products such as boat parts and accessories, as well as a variety of products for which its performance characteristics are desirable and cost effective. Because of the superior performance and cost effectiveness of CFM in the applications in which it is used, consumers of CFM would not switch to other materials in response to a small but significant and non-transitory increase in the price of CFM. More than \$60 million dollars worth of CFM was purchased in the United States last year.

Complaint

8. Owens Corning and Saint Gobain are leaders in the CFM industry, both in product sales and technology. Owens Corning produces and sells CFM in North America, and was the leading seller of CFM in the United States in 2006. Its focus is on performance products, and it developed a proprietary furnace technology which is used to produce glass fiber filaments or marbles used in the manufacture of glass reinforcement products, including CFM. Saint Gobain is also a leading producer of CFM and a leading developer of glass fiber reinforcement products and related technology. Saint Gobain does not produce CFM in the United States. It develops and produces CFM products in Italy, which it imports to the United States. Owens Corning and Saint Gobain account for more than 90 percent of the CFM sold in North America. The only other substantial supplier is PPG Industries, a firm that accounted for less than 10 percent of the CFM sold in the United States last year.

VI. RELEVANT GEOGRAPHIC MARKET

9. The relevant geographic market within which to analyze the likely effects of the proposed transaction is the design, manufacture, and sale of CFM and related technology in North America, including imports.

VII. CONCENTRATION IN THE RELEVANT MARKET

10. The relevant market would be highly concentrated as a result of the acquisition. Post-acquisition, Respondent would account for more than 90 percent of CFM sales in North America.

VIII. CONDITIONS OF ENTRY

11. 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.

Complaint

IX. EFFECTS OF THE ACQUISITION

12. The effects of the acquisition, if consummated, may be substantially to lessen competition and 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. Specifically, the acquisition would:

- a. Eliminate actual, direct, and substantial competition between Owens Corning and Saint Gobain in the relevant market;
- b. Reduce innovation competition among developers of the relevant product, including the delay of, or redirection of, research and development projects in the relevant product and CFM applications;
- c. Substantially increase the level of concentration in the relevant market and enhance the probability of coordination; and
- d. Increase Respondent's ability to exercise market power unilaterally in the relevant market.

X. VIOLATIONS CHARGED

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

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

WHEREFORE, THE PREMISES CONSIDERED, the Federal Trade Commission on this fourth day of December, 2007, issues its Complaint against said Respondent.

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By the Commission.

DECISION AND ORDER

The Federal Trade Commission (“Commission”) having initiated an investigation of the proposed acquisition by Owens Corning (“Respondent”) of certain fiberglass reinforcements and composite fabrics assets of Compagnie de Saint Gobain (“Saint Gobain”) and Respondent having been furnished thereafter with 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 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 Order (“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 thereupon having issued its Complaint, and having accepted the executed Consent Agreement and placed

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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 Owens Corning is a publicly traded 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 One Owens Corning Parkway, Toledo, Ohio 43659.

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. “Respondent Owens Corning” or “Owens Corning” means Owens Corning, a corporation, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Owens Corning, and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each.
- B. “Saint Gobain” means Compagnie de Saint Gobain, a corporation, its directors, officers, employees, agents, attorneys, representatives, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates

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controlled by Saint Gobain, and the respective directors, officers, employees, agents, attorneys, representatives, predecessors, successors, and assigns of each.

- C. “Commission” means the Federal Trade Commission.
- D. “Acquisition” means the proposed acquisition by Respondent Owens Corning of certain fiberglass reinforcements and composite fabrics assets from Saint Gobain pursuant to and as described in the Purchase Agreement dated as of July 26, 2007 by and between “Owens Corning, Société De Participations Financieres Et Industrielles S.A.S., and the Other Parties Named Herein.”
- E. “Acquisition Date” means the date on which the Acquisition is consummated.
- F. “AGY” means AGY Holding Corp., a privately held 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 2556 Wagener Road, Aiken, South Carolina 29801.
- G. “AGY Acquisition Agreement” means the Asset Purchase Agreement dated as of August 31, 2007 between Owens Corning Composite Materials, LLC and AGY Huntington LLC, with amendments, attachments, exhibits, and schedules thereto, attached as Confidential Appendix B to this Order.
- H. “Confidential Business Information” means all information that is not in the public domain related to research, development, manufacture, marketing, commercialization, distribution, importation, cost, pricing, supply, sales, sales support, or use of the particular assets.
- I. “CFM” means continuous filament mat.

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- J. “Designated OC Employee” means those persons, or persons identified in Confidential Appendix A to this Order.
- K. “Divestiture Trustee” means any trustee appointed by the Commission pursuant to Paragraph IV of this Order.
- L. “Effective Date of OC Glass Fiber Divestiture” means the date on which Respondent (or a Divestiture Trustee) divests to the OC Acquirer the OC North American CFM Business completely and as required by Paragraphs II or IV of this Order.
- M. “Governmental Entity” means any Federal, state, local or non-U.S. government or any court, legislature, governmental agency or governmental commission or any judicial or regulatory authority of any government.
- N. “Intellectual Property” means any intellectual property including, but not limited to, software, computer programs, patents, know-how, goodwill, technology, trade secrets, technical information, marketing information, protocols, research and development, quality control information, trademarks, trade names, service marks, logos, and the modifications or improvements to such intellectual property.
- O. “Marbles” means glass fiber marbles used in the production of, among other things, CFM at the OC Huntingdon Facility.
- P. “Marbles Furnace” means the furnace for the production of Marbles including, all attachments and assets used on, attached to, appurtenant or adjacent to, or directly related to the furnace and used in the operation of the furnace in the production or distribution of Marbles produced at the OC Anderson Facility, and includes, but is not limited to:

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1. copies of all books, records, and documents, including but not limited to electronically stored documents and records produced in an electronically readable form, together with all necessary instructions and software, or access to software licenses, relating to the Marbles Furnace and to the production, marketing, distribution, or sale of products produced by the Marbles furnace; *provided, however*, that if any such books, records, or documents also include matters not related to the Marbles Furnace or Marbles produced at the OC Anderson Facility, then only those portions of the books, records, and documents that relate to the furnace that produces Marbles at the OC Anderson Facility or the Marbles produced at the facility may be included;
2. raw materials in use at the time of the divestiture in the marbles furnace at the OC Anderson Facility, alloy metals currently used with the furnace at the OC Anderson Facility (or stored at and designated for use with the marbles furnace at the OC Anderson Facility, or held elsewhere on account for use with the marbles furnace at the OC Anderson Facility), work-in-process, finished goods, and packaging materials, *provided, however*, Respondent may, at the OC Acquirer's option and with the Commission's approval, not sell all or some of the alloy metals to the OC Acquirer;
3. exclusive right to all Intellectual Property used solely in the operation of the Marbles Furnace or in the production, marketing, distribution, or sale of the Marbles produced at the OC Anderson Facility, and a non-exclusive right to all other Intellectual Property used in the operation of the Marbles Furnace and in the production, marketing, distribution, or sale of the products produced at the Marbles Furnace for the field of use of CFM;

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4. all plans (including proposed and tentative plans, whether or not adopted), specifications, drawings, and other assets (including the non-exclusive right to use patents, know-how, and other Intellectual Property relating to such plans) related to the operation of the Marbles Furnace;
5. all licenses, permits, contracts, agreements, and understandings relating to the ownership and operation of the Marbles Furnace.

Q. “Marbles Furnace Operational Areas” means the:

1. areas appurtenant to and used in the operation of the Marbles Furnace including, but not limited to, loading and unloading areas, storage areas for inputs and inventory, at the OC Anderson Facility;
2. areas for the use of employees working at or on the Marbles Furnace at the OC Anderson Facility, similar to those areas available to Owens Corning employees working at the OC Anderson Facility, including, but not limited to, exits and entrances, parking areas, machine rooms, work rooms, break rooms, bathrooms, and locker rooms;
3. existing easements and rights of way relating to the Marbles Furnace;
4. related facilities required for the storage of Marbles produced at the OC Anderson Facility.

R. “Marbles Inventory” means Respondent’s supply of Marbles at the OC Anderson Facility and Respondent’s warehouse in Commerce, South Carolina in existence at the time of the AGY Acquisition Agreement.

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- S. “Marbles Raw Materials” means the raw materials necessary for the manufacture of Marbles.
- T. “OC Acquirer” means either AGY or any other entity that receives the prior approval of the Commission to acquire the OC North American CFM Business pursuant to Paragraphs II or IV of this Order.
- U. “OC Anderson Facility” means the Owens Corning manufacturing facility, located at Highway 81 S, Anderson, South Carolina, 29624, which includes approximately 178 acres of land on which the manufacturing facility sits.
- V. “OC Battice Facility” means the Owens Corning glass fiber reinforcements manufacturing facility, located at Rue de Maestricht, Battice, Leige 4641.
- W. “OC Bushing Fabrication Business” means the fabrication of bushings conducted by OC in Concord, NC, Rio Claro, Brazil, and Ibaraki, Japan.
- X. “OC CFM Divestiture Agreement” means either the AGY Acquisition Agreement or any other agreement that receives the prior approval of the Commission between Respondent and an OC Acquirer (or between a Divestiture Trustee and an OC Acquirer), as well as all amendments, exhibits, attachments, agreements, and schedules thereto, related to the divestiture of the OC North American CFM Business pursuant to Paragraphs II or IV of this Order.
- Y. “OC CFM Intellectual Property” means all Intellectual Property relating to the design, manufacture, and sale of CFM designed, manufactured, or sold by, or on behalf of, Owens Corning, even where such Intellectual Property has

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not been reduced to practice or commercialized including, but not limited to:

1. manufacturing process technology and technology for equipment used in the manufacturing process, such as bushings and windings;
2. all United States and foreign patents, trademarks, trade names, domain names, service marks and copyrights and any applications for and registrations of such patents, trademarks, trade names, domain names, service marks and copyrights and any renewal, derivation, divisions, reissues, continuation, continuations-in part, modifications or extensions thereof or, if the patents have already been issued on the basis of said applications, the resulting patents;
3. Intellectual Property relating to applications in which CFM products produced by Owens Corning are used;
4. all plans (including proposed and tentative plans, whether or not adopted), specifications, drawings, and other assets (including the non-exclusive right to use patents, know-how, and other Intellectual Property relating to such plans);
5. any other Intellectual Property used in the past by Owens Corning in the design, manufacture, and sale of CFM.

Provided, however, OC CFM Intellectual Property does not include Intellectual Property related to Advantex™ glass, oxygen-firing processes, advanced glass melting, furnace designs, and OC Furnace Technology.

Z. “OC Furnace Technology” means:

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1. all Intellectual Property related to Owens Corning's furnaces located at, and furnace technology and furnace processes used in the OC Guelph Facility and the OC Battice Facility;
 2. a copy of all plans (including proposed and tentative plans, whether or not adopted), specifications, drawings, and other assets (including the non-exclusive right to use patents, know-how, and other Intellectual Property relating to such plans) related to Owens Corning's furnaces located at, and furnace technology and furnace processes used in the OC Guelph Facility and the OC Battice Facility.
- AA. "OC Guelph Facility" means the Owens Corning glass fiber reinforcements manufacturing facility located in Guleph, Ontario, NIH6P6, Canada.
- BB. "OC Huntingdon Facility" means the Owens Corning glass fiber continuous filament mat manufacturing facility, located at 1200 Susquehanna Ave., Huntingdon, Pennsylvania, 16652, which includes approximately 19 acres of land on which the manufacturing facility sits.
- CC. "OC North American CFM Business" means the Owens Corning North American glass fiber continuous filament mat business including, but not limited to:
1. the OC Huntingdon Facility and:
 - a. all tangible and real assets used in the operation of the OC Huntingdon Facility, including any leasehold, ownership, fee, or any other interest in real estate at the OC Huntingdon Facility grounds in Huntingdon, Pennsylvania, and in the production or

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distribution of the products produced at the facility, and includes, but is not limited to,

- (1) the main plants;
 - (2) rail cars, trucks, and other vehicles owned by Respondent Owens Corning related to the transportation and distribution of products produced or used in the OC Huntingdon Facility; and
 - (3) raw materials including, but not limited to, alloy metals currently used at the OC Huntingdon Facility, or stored at and designated for use at the OC Huntingdon Facility, or held elsewhere on account for use at the OC Huntingdon Facility, work-in-process inventories, stores and spares, inventories, packaging materials, finished goods inventories, finished goods in transit to offsite storage or to customers, and offsite inventory, *provided, however*, Respondent may, at the OC Acquirer's option and with the Commission's approval, not sell all or some of the alloy metals to the OC Acquirer;
- b. all books, records, and documents, including but not limited to electronically stored documents and records produced in an electronically readable form, together with all necessary instructions and software, or access to software licenses to the OC Acquirer, relating to the OC Huntingdon Facility and to the production, marketing, distribution, or sale of products produced at the facility; *provided, however*, that if any such books, records, or documents also include matters not related to the OC Huntingdon Facility or products produced at the OC Huntingdon Facility, then only those portions of the books

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records and documents that relate to the OC Huntingdon Facility or the products produced at the facility may be included;

- c. all Intellectual Property used solely in the operation of the OC Huntingdon Facility or in the production, marketing, distribution, or sale of the products produced at the OC Huntingdon Facility, and a non-exclusive right for the purpose of the production, marketing, distribution or sale of CFM to all other Intellectual Property used in the operation of the OC Huntingdon Facility and in the production, marketing, distribution, or sale of the products produced at the OC Huntingdon Facility;
- d. all contracts, agreements, and understandings, relating to the manufacture, transportation, storage, marketing, distribution, or sale of the products produced at the OC Huntingdon Facility, which includes but is not limited to:
 - (1) agreements under which the OC Huntingdon Facility receives electricity, natural gas, or other inputs at or for the OC Huntingdon Facility; *provided, however*, any current or future supply contract for Marbles is excluded and prohibited unless a separate contract for Marbles is expressly agreed to as part of the OC CFM Divestiture Agreement;
 - (2) agreements for services provided to the OC Huntingdon Facility, including, but not limited to, rail, trucking, capital maintenance, and technology;

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- (3) agreements and contracts with customers for products produced exclusively by the OC Huntingdon Facility;
 - e. all joint ventures relating to the operation of the OC Huntingdon Facility and the production, marketing, distribution, or sale of the products produced at the OC Huntingdon Facility;
 - f. all plans (including proposed and tentative plans, whether or not adopted), specifications, drawings, and other assets (including the non-exclusive right to use patents, know-how, and other Intellectual Property relating to such plans) related to the operation of the OC Huntingdon Facility including, but not limited to bushing designs;
 - g. existing easements and rights of way;
 - h. related facilities required for the operation or the storage of products produced or used at the OC Huntingdon Facility;
 - i. all licenses, permits, contracts, agreements, and understandings relating to the ownership and operation of the OC Huntingdon Facility;
- 2. the Marbles Furnace;
 - 3. a twenty (20) year lease for the Marbles Furnace Operational Areas, *provided, however*, such lease shall include terms that allow the OC Acquirer to terminate such lease at any time, without penalty, with at least five (5) days prior notice to Respondent Owens Corning;
 - 4. an agreement for the acquisition of Marbles Inventory.

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Provided, however, the OC North American CFM Business does not include the OC Bushing Fabrication Business or the OC Guelph Facility.

DD. “Person” means any individual, partnership, association, company or corporation.

EE. “Plastic Reinforcements Products” means products which are manufactured by melting quarry inputs (combinations of silica, clay, and other materials) in a refractory-lined furnace to create molten glass which is drawn through a surface with one or more holes to create filaments. The filaments are then treated by various chemical and physical processes to alter their properties so that these products can be used in a wide variety of reinforcement applications to provide, among other things, strength, thermal or chemical resistance.

II.

IT IS FURTHER ORDERED that:

A. Within ten (10) days after the Acquisition Date:

1. Respondent shall divest the OC North American CFM Business in good faith to AGY, pursuant to and in accordance with the AGY Acquisition Agreement (which agreement shall not vary or contradict, or be construed to vary 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 AGY or to reduce any obligations of Respondent under such agreements), and such agreement, if approved by the Commission as the OC CFM Divestiture Agreement, is incorporated by reference into this Order and made a part hereof as Confidential Appendix C.

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Provided, however, with respect to assets that are to be divested or agreements entered into pursuant to this paragraph at the Acquirer's option, Respondent need not divest such assets or enter into such agreements only if the Acquirer chooses not to acquire such assets or enter into such agreements and the Commission approves the divestiture without such assets or agreements.

2. Respondent shall grant to the Acquirer a worldwide, royalty-free, fully paid-up, perpetual, irrevocable, license to or copies of, where appropriate, the OC CFM Intellectual Property for the purpose of the production, marketing, distribution or sale of CFM. *Provided, however,* Respondent shall have up to sixty (60) days following the grant of such OC CFM Intellectual Property license to deliver documents or information from locations other than the OC Huntingdon Facility and the OC Anderson Facility.
 3. Respondent shall grant to the Acquirer a royalty-free, fully paid-up, perpetual, irrevocable license to or copies of, where appropriate, the OC Furnace Technology for the purpose of the production, marketing, distribution or sale of CFM. *Provided, however,* Respondent shall have up to sixty (60) days following the grant of such OC Furnace Technology license to deliver documents or information from locations other than the OC Huntingdon Facility and the OC Anderson Facility.
- B. If, at the time the Commission determines to make this Order final, the Commission notifies Respondent that AGY is not an acceptable acquirer of the OC North American CFM Business or that the manner in which the divestiture was accomplished is not acceptable, then, after receipt of such written notification:

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1. Respondent shall immediately notify AGY of the notice received from the Commission and shall as soon as practicable effect the rescission of the AGY Acquisition Agreement; and
2. Respondent shall, within six (6) months from the date this Order becomes final, divest the OC North American CFM Business absolutely and in good faith, at no minimum price, to an acquirer that receives the prior approval of the Commission and in a manner that receives the prior approval of the Commission. *Provided, however,* with respect to assets that are to be divested or agreements entered into pursuant to this paragraph at the OC Acquirer's option, Respondent need not divest such assets or enter into such agreements only if the OC Acquirer chooses not to acquire such assets or enter into such agreements and the Commission approves the divestiture without such assets or agreements.
3. The Commission may appoint a Monitor pursuant to Paragraph III of this Order to assist Respondent in:
 - a. effectuating modifications to the OC CFM Divestiture Agreement or manner of divestiture of the OC North American CFM Business (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; and
 - b. taking such actions as are necessary to maintain the full economic viability, marketability and competitiveness of the OC North American CFM Business, including, but not limited to, monitoring the exchange of Confidential Business Information about the OC North American CFM Business to and between Respondent, to minimize any risk of loss of

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competitive potential for the businesses associated with the OC North American CFM Business, and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the OC North American CFM Business except for ordinary wear and tear.

- C. Any OC CFM Divestiture Agreement that has been approved by the Commission between the Respondent (or a Divestiture Trustee) and an OC Acquirer of the OC North American CFM Business shall be deemed incorporated into this Order, and any failure by Respondent to comply with any term of such OC CFM Divestiture Agreement shall constitute a failure to comply with this Order.
- D. Respondent shall not enter into any agreement with Saint Gobain for Plastic Reinforcements Products that would, directly or indirectly, affect the viability, marketability and competitiveness of the Saint Gobain businesses and assets that are not sold to Respondent pursuant to the Acquisition.
- E. Until the Effective Date of OC Glass Fiber Divestiture, Respondent shall:
 - 1. take such actions as are necessary to maintain the viability and marketability of the OC North American CFM Business and to prevent the destruction, removal, wasting, deterioration, or impairment of the OC North American CFM Business except for ordinary wear and tear; and
 - 2. not sell, transfer, encumber or otherwise impair the full economic viability, marketability, or competitiveness of the OC North American CFM Business.

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- F. For the length of time during which Respondent leases the Marbles Furnace Operational Area to the OC Acquirer, Respondent shall:
1. except as requested by the OC Acquirer, take such actions as are necessary to prevent the destruction, removal, wasting, deterioration, or impairment of the Marbles Furnace and the Marbles Furnace Operational Area, *provided, however*, Respondent shall not be responsible for changes to or problems of the Marbles Furnace or the Marbles Furnace Operational Area caused by the OC Acquirer; *provided, further, however*, Respondent shall not be responsible for the maintenance, upkeep, rebuilding or replacement of the Marbles Furnace; *provided, further, however*, Respondent shall give the OC Acquirer sixty (60) days prior notice of any facility maintenance, including ordinary and regular maintenance, when such maintenance may affect the operation of the Marbles Furnace or the OC Acquirer's access to the Marbles Furnace Operational Area; *provided, further, however*, in the event Respondent cannot give the OC Acquirer sixty (60) days prior notice, then Respondent must notify the OC Acquirer as soon as it first notifies any persons at the OC Anderson Facility regarding maintenance or problems that may affect the operation of the Marbles Furnace or the OC Acquirer's access to the Marbles Furnace Operational Area; and
 2. maintain the Marbles Furnace and Marbles Furnace Operational Area in the same general way in which it maintains the other furnaces owned by Respondent and common areas of the OC Anderson Facility (to the extent the OC Acquirer complies with the lease terms) including, but not limited to, the uninterrupted provision of utilities and services, and Respondent shall allow access to the OC Anderson Facility.

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G. No later than the Effective Date of OC Glass Fiber Divestiture, Respondent shall:

1. secure all assignments, consents, and waivers, including rights of approval and rights of first refusal, from all private and Governmental Entities that are necessary for the divestiture of the OC North American CFM Business; and
2. remove all non-compete agreements or other agreements as may be necessary to accomplish the divestiture of the OC North American CFM Business.

H. Respondent shall, at the option of the Acquirer, no later than the Effective Date of OC Glass Fiber Divestiture, and as part of the OC CFM Divestiture Agreement, enter into one or more transition agreements for the short-term provision of services provided by Respondent to the OC Acquirer.

1. Such agreements may include, but are not limited to, an agreement for the supply of Marbles Raw Materials.
2. Respondent shall not terminate any transition agreement early:
 - a. without 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 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 only be given after the parties:
 - (1) have attempted to settle the dispute between themselves, and

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(2) engaged in arbitration and received an arbitrator's decision, or

(3) received a final court decision after all appeals.

- I. After divestiture of the OC North American CFM Business, Respondent and Respondent's employees shall not receive, or have access to, or use or continue to use any Confidential Business Information about the OC North American CFM Business or about the production, transportation, delivery, storage, distribution, marketing, and sale of products of the OC Acquirer from the OC Huntingdon Facility except:
1. As otherwise allowed in this Order;
 2. As provided for in a transition services agreement;
 3. As consented to by the OC Acquirer for provision to Respondent Owens Corning;
 4. As required by law;
 5. To the extent that necessary information is exchanged in the course of consummating the Acquisition;
 6. In negotiating agreements to divest assets pursuant to this Order and engaging in related due diligence;
 7. In complying with this Order;
 8. To the extent necessary to allow Respondent to comply with the requirements and obligations of the laws of the United States and other countries;

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9. In defending legal claims, investigations or enforcement actions threatened or brought against or related to the OC North American CFM Business; and
10. In obtaining legal advice.

Respondent shall require any Persons with access to Confidential Business Information to immediately enter into agreements with the Respondent and OC Acquirer not to disclose any Confidential Business Information to the Respondent or to any third party except for the purposes set forth in this paragraph.

- J. The purposes of this Paragraph II of the Order are: (1) to ensure the continuation of the OC North American CFM 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. At any time after Respondent signs the Consent Agreement in this matter, the Commission may appoint a Monitor to assure that Respondent expeditiously complies with all of its obligations and performs all of its responsibilities as required by this Order;
- B. The Commission shall select the Monitor, subject to the consent of Respondent, which consent shall not be unreasonably withheld. If the Respondent 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 of the identity of

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any proposed Monitor, Respondent shall be deemed to have consented to the selection of the proposed Monitor.

- C. Not later than ten (10) days after appointment of the Monitor, Respondent 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's compliance with the relevant terms of the Order in a manner consistent with the purposes of the Order.
- D. If a Monitor is appointed pursuant to this Paragraph III, Respondent 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 the Respondent's compliance with the terms of the Order, 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 expeditiously complies with all of its obligations and performs all of its responsibilities as required by the Decision and Order in this matter; and
 - b. Monitoring any transition services agreements.
 - 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

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access to Respondent'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's compliance with its obligations under the Order. Respondent 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's compliance with the Order.

4. The 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 Monitor shall have authority to employ, at the expense of the 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.
5. Respondent 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.
6. The Monitor Agreement shall state that within one (1) month from the date the Monitor is appointed pursuant to this paragraph, and every sixty (60) days thereafter, the

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Monitor shall report in writing to the Commission concerning performance by Respondent of its obligations under the Order.

7. Respondent 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 III.
- 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.

IV.

IT IS FURTHER ORDERED that:

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- A. If Respondent has not fully complied with the obligations to divest the OC North American CFM Business as required by Paragraph II of this Order, the Commission may appoint a Divestiture Trustee to divest the OC North American CFM Business in a manner that satisfies the requirements of Paragraph II.

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 OC North American CFM Business. Neither the appointment of a Divestiture Trustee nor a decision not to appoint a Divestiture Trustee under this Paragraph IV 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.
- 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

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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 IV, 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 divest the OC North American CFM Business.
 2. The Divestiture Trustee shall have one (1) year after the date the Commission approves the trust agreement described herein to divest the OC North American CFM Business absolutely and in good faith, at no minimum price, to an Acquirer 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 shall develop such financial or other

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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 IV 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'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 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

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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 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 misfeasance, 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 and to the Commission every sixty (60) days concerning the Divestiture Trustee's efforts to accomplish the divestiture.

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10. 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.
 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 IV.
 - 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.
 - G. The Divestiture Trustee(s) appointed pursuant to Paragraph IV of this Order may be the same Person appointed as the Monitor pursuant to Paragraph III of this Order.

V.

IT IS FURTHER ORDERED that:

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- A. Beginning from the date the Respondent signs the Consent Agreement until sixty (60) days after the Effective Date of OC Glass Fiber Divestiture, Respondent shall:
1. facilitate employment interviews between each Designated OC Employee and the OC Acquirer, including providing the names and contact information for such employees and allowing such employees reasonable opportunity to interview with the OC Acquirer, and shall not discourage such employee from participating in such interviews;
 2. not interfere in employment negotiations between each Designated OC Employee and the OC Acquirer;
 3. with respect to each Designated OC Employee who receives an offer of employment from the OC Acquirer:
 - a. not prevent, prohibit, or restrict, or threaten to prevent, prohibit, or restrict the Designated OC Employee from being employed by the OC Acquirer, and shall not offer any incentive to the Designated OC Employee to decline employment with the OC Acquirer;
 - b. cooperate with the OC Acquirer in effecting transfer of the Designated OC Employee to the employ of the OC Acquirer, if the Designated OC Employee accepts an offer of employment from the OC Acquirer;
 - c. eliminate any contractual provisions or other restrictions entered into or imposed by Respondent that would otherwise prevent the Designated OC Employee from being employed by the OC Acquirer;

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- d. eliminate any confidentiality restrictions that would prevent the Designated OC Employee who accepts employment with the OC Acquirer from using or transferring to the Acquirer any information relating to the operation of the OC North American CFM Business;
 - e. pay, for the benefit of any Designated OC Employee who accepts employment with the OC Acquirer, all accrued bonuses, vested pensions, and other accrued benefits;
- B. Respondent shall, for a period of two (2) years following the Effective Date of OC Glass Fiber Divestiture, not, directly or indirectly, solicit, induce, or attempt to solicit or induce any Designated OC Employee who is employed by the OC Acquirer to terminate his or her employment relationship with the OC Acquirer, unless that employment relationship has already been terminated by the OC Acquirer; *provided, however,* Respondent may make general advertisements for employees including, but not limited to, in newspapers, trade publications, websites, or other media not targeted specifically at the OC Acquirer's employees; *provided, further, however,* Respondent may hire Designated OC Employees who apply for employment with Respondent as long as such employees were not solicited by Respondent in violation of this Paragraph.

VI.

IT IS FURTHER ORDERED that for a period of ten (10) years from the date this Order becomes final, Respondent shall not:

- A. without the prior approval of the Commission, acquire, directly or indirectly, any assets divested pursuant to this Order, *provided, however,* prior approval shall not be required by Respondent to take possession of or reacquire

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the Marbles Furnace, or what remains of the Marble Furnace, if and only if the OC Acquirer: (1) terminates the lease to the Marbles Furnace Operational Area, and (2) notifies Respondent that it is abandoning all of its rights to the Marbles Furnace. In such a situation, Respondent shall provide written notification to the Commission of the timing and terms of the termination and abandonment as soon as possible after Respondent receives notice from the OC Acquirer; and

- B. without providing advance written notification to the Commission in the manner described in this Paragraph VI, directly or indirectly, acquire any stock, share capital, equity or other interest in any Person, corporate or non-corporate that produces, or assets used in the design, manufacture, production or sale of, glass fiber reinforcements or composite fabrics.

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 and not of any other party to the transaction. Respondent 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 shall not consummate the transaction until thirty days after submitting such additional

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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 for an acquisition, if Respondent acquires no more than one percent of the outstanding securities or other equity interest in an entity described in this Paragraph VI.

VII.**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 has fully complied with Paragraphs II, IV, and V.A 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. Respondent shall submit at the same time a copy of its report concerning compliance with this Order to the Divestiture Trustee or the Monitor, if any Divestiture Trustee or Monitor has been appointed pursuant to this Order. Respondent 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 related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent shall include in its report copies of all written

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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 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 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.

VIII.

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

- A. proposed dissolution of the Respondent;
- B. proposed acquisition, merger or consolidation of each 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 the purpose of determining or securing compliance with this Order, and subject to any legally recognized privilege, and upon written request with

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reasonable notice, 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 related to compliance with this Order; 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.

X.

IT IS FURTHER ORDERED that this Order shall terminate on December 4, 2017.

By the Commission.

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CONFIDENTIAL APPENDIX A

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

DESIGNATED OC EMPLOYEES

Those persons listed in Sections 1.1(d) as Retained Employees and 1.1(e) as Transferred Employees of the Seller Disclosure Schedule to the AGY Acquisition Agreement.

CONFIDENTIAL APPENDIX B**OC CFM DIVESTITURE 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 from Owens Corning (“Respondent”). The Consent Agreement is intended to resolve anticompetitive effects stemming from Owens Corning’s proposed acquisition of certain glass fiber reinforcements and composite fabric assets from Compagnie de Saint Gobain (“Saint Gobain”). The Consent Agreement includes a proposed Decision and Order which requires Respondent Owens Corning to divest its North American Continuous Filament Mat (“CFM”) Business, which includes the CFM production facility in Huntingdon, Pennsylvania, the Marbles Furnace in Anderson, South Carolina, which supplies the Huntingdon facility, and related technology and other assets used in the CFM business. The proposed Decision and Order also requires the licensing of all Owens Corning intellectual property related to the production of CFM and certain CFM furnace technology.

Owens Corning and Saint Gobain originally planned to combine their respective glass fiber reinforcement businesses in a new entity to be called Owens Corning Vetrotex Reinforcements. The new entity was to be owned 60 percent by Owens Corning and 40 percent by Saint Gobain. In response to antitrust concerns, the parties restructured the transaction and entered into an acquisition agreement whereby Owens Corning will acquire Saint Gobain’s glass fiber reinforcements and composite fabric business assets worldwide with several important exclusions. Owens Corning will not acquire Saint Gobain’s glass fiber reinforcements assets located in the United States. Additionally, certain assets located in Europe will be divested pursuant to an agreement entered into between the parties and the European Commission. However, under the proposed acquisition, Owens Corning will still acquire Saint Gobain’s assets used in the design, manufacture, and sale of CFM, a

Analysis to Aid Public Comment

unique glass fiber reinforcement product. Saint Gobain competes in CFM in the United States using CFM produced at its facility in Besana, Italy. The proposed Consent Agreement and Decision and Order are designed to address competition concerns in the CFM market.

The Decision and Order calls for divestiture of Owens Corning's CFM Business to AGY Holding Company ("AGY"), or another Commission-approved buyer in the event that AGY is determined not to be acceptable. The Consent Agreement, if finally accepted by the Commission, would settle charges that the proposed acquisition may substantially lessen competition in the market for CFM. The Commission has reason to believe that Respondent's proposed acquisition 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.

II. The Proposed Complaint

According to the Commission's proposed complaint, the relevant product market in which to analyze the effects of Saint Gobain's sale of assets to Owens Corning is the market for the development, manufacture, and sale of CFM and related technology. CFM is an input in the production of non-electrical laminate, marine parts and accessories, and other products where its strength and other desirable characteristics make it the most cost effective material to use. The relevant product is used to increase mechanical performance, such as stiffness and strength, as well as chemical resistance. The relevant geographic market is North America, including imports.

The proposed complaint alleges that the market for CFM is highly concentrated and that Saint Gobain and Owens Corning have been the primary competitors in these markets for many years. According to the proposed complaint, Owens Corning and Saint Gobain account for more than 90 percent of the CFM sold in North

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America. The only other substantial supplier is PPG Industries, a firm that accounted for less than 10 percent of the CFM sold in the United States last year.

The proposed complaint alleges that the proposed acquisition would reduce competition by eliminating direct competition between these two companies. The proposed complaint further alleges that entry into the relevant market would not be timely, likely, or sufficient to deter or offset the proposed joint venture's adverse competitive effects.

III. Terms of the Proposed Order

Under the proposed Decision and Order, Owens Corning will divest its CFM business to AGY within ten (10) days after acquiring certain worldwide glass fiber reinforcements and composite fabric assets from Saint Gobain. AGY, based in Aiken, South Carolina, develops, manufactures, and markets a wide range of glass fiber yarns and reinforcement materials. As an existing participant in the glass fiber reinforcement business, AGY is well-positioned to compete effectively in the CFM business.

The proposed Decision and Order requires Owens Corning to divest its Huntingdon Facility that produces CFM. In addition, Owens Corning is required to divest the Marbles Furnace located in Anderson, South Carolina, that currently supplies the Huntingdon Facility with essential glass fiber marbles used in the production of CFM at Huntingdon. Also, Owens Corning is required to grant AGY two licenses. The first license is to Owens Corning intellectual property, wherever located, related to the production, marketing, and distribution of CFM. The second license is to Owens Corning furnace technology used in the Owens Corning Guelph and Owens Corning Battice facilities related to CFM. The purpose of the divestiture and licensing is to give AGY all assets and know-how necessary for the production and sale CFM products.

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The proposed Decision and Order also allows for the parties to enter into transition agreements for the short term provision of services, including an agreement for the supply of the raw materials for the production of Marbles. Moreover, the proposed Decision and Order precludes Owens Corning and Saint Gobain from entering into any agreement that would impair the value of the assets retained by Saint Gobain. The proposed Decision and Order contains a provision requiring prior notice for the acquisition of certain CFM assets.

IV. Opportunity for Public Comment

The proposed Decision and Order has been placed on the public record for thirty (30) days to receive comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will review the Consent Agreement and comments received and decide whether to withdraw its agreement or make final the Consent Agreement's proposed Order.

The purpose of this analysis is to facilitate public comment on the proposed Decision and Order. This analysis is not intended to constitute an official interpretation of the Consent Agreement and the proposed Decision and Order.

Complaint

IN THE MATTER OF

SCHERING-PLOUGH CORPORATIONCONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATIONS
OF SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE FEDERAL
TRADE COMMISSION ACT*Docket C-4211; File No. 071 0132**Complaint, December 28, 2007 – Decision, December 28, 2007*

This consent order addresses the \$14.4 billion acquisition by Schering-Plough Corporation (“Schering-Plough”) of Organon BioSciences N.V. from Akzo-Nobel N.V. The complaint alleged that the proposed 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. market for the manufacture and sale of certain live vaccines used in poultry. The consent order requires Schering-Plough to divest or license all of the assets relating to Schering-Plough’s live vaccine for the Georgia 98 strain of infectious bronchitis (Avimune IB98); Intervet’s live fowl cholera vaccine (CHOLERV AC-PM-I); and Schering-Plough’s live MG vaccine (F V AX-MG) to Wyeth’s Fort Dodge division. Schering-Plough must also divest research and development; customer, supplier and manufacturing contracts; and certain intellectual property, including existing licenses, to Wyeth so that they can effectively compete in the live vaccines market.

Participants

For the *Commission*: *Michael R. Barnett, Daniel P. Ducore, Mark Frankena, Jacqueline K. Mendel, Michael R. Moiseyev, Aylin Ozyildirim, Robert Pickett, David Schmidt, and Michael Vita.*

For the *Respondent*: *William Henry, Ethan Litwin, and Stephen Weissman, Howrey 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 Schering-Plough Corporation (“Schering-Plough”), a corporation

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subject to the jurisdiction of the Commission, has agreed to acquire certain assets and voting securities of Akzo Nobel N.V. (“Akzo Nobel”), 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. RESPONDENT SCHERING-PLOUGH CORPORATION

1. Respondent Schering-Plough is a corporation organized, existing, and doing business under and by virtue the laws of the state of New Jersey, with its headquarters address at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-1310.

2. Respondent Schering-Plough is engaged in, among other things, the research, development, manufacture, distribution, and sale of animal health products, including live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

3. Respondent Schering-Plough 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.

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II. THE ACQUIRED COMPANY

4. Akzo Nobel is a for-profit corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its headquarters address at Velperweg 76, 6824 BM Arnhem, The Netherlands. Its principal place of business in the U.S. at 120 White Plains Road, Suite 300, Tarrytown, New York 10591-5522.

5. Organon Biosciences N.V. (“Organon Biosciences”) is a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its offices and principal place of business located at Wethouder van Eschstraat 1, 5342 AV Oss, The Netherlands. Organon Biosciences is a wholly owned subsidiary of Akzo Nobel.

6. Akzo Nobel, through its wholly-owned subsidiary, Organon Biosciences, is engaged in, among other things, the research, development, manufacture, distribution, and sale of animal health products, including live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

III. THE PROPOSED ACQUISITION

7. Pursuant to the terms of a Letter of Intent dated March 12, 2007 (the “Agreement”), Schering-Plough proposes to acquire 100 percent of the Organon BioSciences voting stock in a transaction valued at approximately \$14.4 billion (the “Acquisition”).

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IV. THE 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 research, development, manufacture, and sale of: (a) live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (b) live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (c) live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

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 each of the relevant lines of commerce.

V. THE STRUCTURE OF THE MARKET

10. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index (“HHI”). Respondent Schering-Plough and Akzo Nobel are the only suppliers of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States. Schering-Plough is the market leader with Avimune IB98, while Intervet competes with its MILDVAC GA-98 product. The acquisition would create a monopoly by combining the only two companies with products on the market.

11. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index (“HHI”). Respondent Schering-Plough and Akzo Nobel are two of only three suppliers of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United

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States. Akzo Nobel is the market leader with its CHOLERVAC-PM-1 product, while Schering-Plough is the second leading supplier with its PM-ONEVAC-C and M-NINEVAX products. Together, Schering-Plough and Akzo Nobel account for over eighty percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, leaving Schering-Plough as the dominant supplier.

12. The relevant market for the manufacture, distribution, and sale of live *Mycoplasma gallisepticum* vaccines in the United States is highly concentrated when measured by the Herfindahl-Hirschman Index (“HHI”). Respondent Schering-Plough and Akzo Nobel are two leading suppliers of live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States. Akzo Nobel is the market leader with its MYCOVAC-L product, while Schering Plough competes with its MYCOVAC-L product. Together, they account for over seventy-two percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry, leaving Schering-Plough as the dominant supplier.

VI. ENTRY CONDITIONS

13. Entry into any relevant line of commerce would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition set forth in Paragraph 14 below. Entry into any of these markets would require overcoming three major obstacles: lengthy development periods, USDA approval requirements, and customer acceptance. As a result, new entry into any of these markets sufficient to achieve a significant market impact within two years is unlikely.

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VII. EFFECTS OF THE ACQUISITION

14. 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 Schering-Plough and Akzo Nobel for the research, development, manufacture, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States;

b. by increasing the ability of the merged entity to raise prices unilaterally of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States; and

c. by reducing the merged entity's incentives to improve service or product of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry, live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry, and live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States.

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VIII. VIOLATIONS CHARGED

15. The Acquisition described in Paragraph 7 constitutes a violation of Section 5 of the FTC Act, as amended, 15 U.S.C. § 45.

16. The Acquisition described in Paragraph 7, 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 twenty-eighth day of December, 2007, issues its Complaint against said Respondent.

By the Commission.

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The Federal Trade Commission (“Commission”) having initiated an investigation of the acquisition by Respondent Schering-Plough Corporation (“Schering-Plough”) of Organon Biosciences N.V. from Akzo Nobel N.V., and Respondent having been furnished thereafter with a copy of a draft of a 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 Order (“Consent Agreement”), containing an admission by Respondent of

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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 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 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 Schering-Plough Corporation is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its headquarters address at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-1310.

2. Akzo Nobel N.V. is a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its headquarters address at Velperweg 76, 6824 BM Arnhem, The Netherlands and its principal place of business in the U.S. at 120 White Plains Road, Suite 300, Tarrytown, New York 10591-5522.

3. Organon BioSciences N.V., with its headquarters address at Wethouder van Eschstraat 1, 5342 AV OSS, The Netherlands, includes Intervet.

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4. 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. “Schering-Plough” means Schering-Plough Corporation, its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Schering-Plough Corporation, and the respective directors, officers, employees, agents, representatives, successors, and assigns of each. After the Acquisition, Schering-Plough Corporation shall include Organon BioSciences and Intervet.
- B. “Akzo Nobel” means Akzo Nobel N.V., its directors, officers, employees, agents, representatives, predecessors, successors, and assigns; its joint ventures, subsidiaries, divisions, groups and affiliates controlled by Akzo Nobel and the respective directors, officers, employees, agents, representatives, successors, and assigns of each.
- C. “Organon BioSciences” means Organon BioSciences N.V., a corporation organized, existing and doing business under and by virtue of the laws of The Netherlands, with its offices and principal place of business located at Wethouder van Eschstraat 1, 5342 AV Oss, The Netherlands. Organon Biosciences is a wholly owned subsidiary of Akzo Nobel.
- D. “Intervet” means Intervet Inc, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters located at

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29160 Intervet Lane, Millsboro, Delaware 19966. Intervet is a wholly owned indirect subsidiary of Organon BioSciences.

- E. “Respondent” means Schering-Plough.
- F. “Commission” means the Federal Trade Commission.
- G. “Acquirer” means the following:
 - 1. Wyeth; or
 - 2. an entity that is approved by the Commission to acquire particular assets that the Respondent is required to assign, grant, license, divest, transfer, deliver or otherwise convey pursuant to this Order. There may be one or more Acquirers under this Order.
- H. “Acquisition” means the Respondent Schering-Plough’s acquisition of one hundred percent (100%) of the voting stock of Organon BioSciences N.V. from Respondent Akzo Nobel N.V. pursuant to a letter of intent dated March 12, 2007.
- I. “Agency(ies)” means any governmental regulatory authority or authorities 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 Divestiture Product in the Territory. The term “Agency” includes, but is not limited to, the United States Department of Agriculture (“USDA”).
- J. “Avimune IB98” means any Schering-Plough poultry Product that includes an antigen avirulent live modified strain 2820 of Georgia 98 infectious bronchitis virus which is manufactured, marketed or sold by Schering-Plough pursuant to USDA License No. 1231.1J.

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K. “Avimune IB98 Assets” means all of Respondent’s rights, title and interest not acquired in the Acquisition in and to all assets related to the business of Schering-Plough in the Territory related to Avimune IB98, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of Avimune IB98, including, without limitation, the following:

1. all Product Intellectual Property;
2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
3. the Master Seed;

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4. the Challenge Material;
5. the Reagents;
6. the Product Regulatory File;
7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
8. a list of all of the NDC Numbers related to the Product;
9. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
10. at the Acquirer's option, each of the Product Assumed Contracts;
11. all Product Marketing Materials;
12. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;

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13. Product Scientific and Regulatory Material;
14. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
15. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
16. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and labels, which shall include the grant of a license to use

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Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and

17. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for Avimune IB98 from January 1, 2000, through the Closing Date, and quality control histories pertaining to Avimune IB98 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the Avimune IB98 Assets contain information that (i) relates both to Avimune IB98 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to Avimune IB98, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have 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 Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than Avimune IB98;

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provided further, however, the term “Avimune IB98 Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-17 above as used in the conduct of Respondent’s business outside the Territory.

- L. “Asset Purchase Agreement” or “Agreement” means the Amended and Restated Asset Purchase Agreement between Schering-Plough Animal Health Corporation and Intervet Inc., and Wyeth, acting through its Fort Dodge Animal Health division, dated October 18, 2007, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the Divestiture Assets to be divested, that have been approved by the Commission to accomplish the requirements of this Order. The Asset Purchase Agreement is attached to this Order as non-public Appendix I.
- M. “Challenge Material” means the materials (other than Retained Challenge Material) used to confirm the immunogenicity of each Divestiture Product and the media formula to propagate the challenge organism.
- N. “CHOLERVAC PM-1” means any Intervet poultry Product that includes as an antigen avirulent live PM-1 strain of *Pasteurella multocida* which is manufactured, marketed or sold by Intervet pursuant to USDA License No. 1871.04.

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O. "CHOLERVAC PM-1 Assets" means all of Respondent's rights, title and interest acquired in the Acquisition in and to all assets related to the business of Organon and Intervet in the Territory, related to CHOLERVAC PM-1, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of CHOLERVAC PM-1, including, without limitation, the following:

1. all Product Intellectual Property;
2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

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3. the Master Seed;
4. the Challenge Material;
5. the Reagents;
6. the Product Regulatory File;
7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
8. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
9. at the Acquirer's option, each of the Product Assumed Contracts;
10. all Product Marketing Materials;
11. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent Schering-Plough (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;

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12. Product Scientific and Regulatory Material;
13. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
14. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
15. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and

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labels, which shall include the grant of a license to use Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and

16. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for CHOLERVAC PM-1 from January 1, 2000, through the Closing Date, and quality control histories pertaining to CHOLERVAC PM-1 owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

provided, however, that in cases in which documents or other materials included in the CHOLERVAC PM-1 Assets contain information that (i) relates both to CHOLERVAC PM-1 and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to CHOLERVAC PM-1, Respondent shall be required only to provide copies of the documents and materials containing this information. In instances where such copies are provided to the Acquirer, the Acquirer shall have 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 Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than CHOLERVAC PM-1;

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provided further, however, the term “CHOLERVAC PM-1 Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-16 above as used in the conduct of Respondent’s business outside the Territory.

- P. “Closing Date” means the date on which Respondent (or a Divestiture Trustee) and an Acquirer close on a transaction to divest, license, or otherwise convey relevant assets pursuant to this Order.
- Q. “Confidential Business Information” means all information owned by, or in the possession or control of, Respondent that is not in the public domain and that is directly related to the research, Development, manufacture, marketing, commercialization, distribution, importation, exportation, cost, pricing, supply, sales, sales support, or use of a Divestiture Product; *provided, however*, that the restrictions contained in this Order regarding the 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 Respondent;

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2. Information related to Divestiture Products that Respondent can demonstrate it obtained without the assistance of Akzo Nobel, Organon BioSciences, or Intervet prior to the Acquisition;
 3. Information that is required by Law to be publicly disclosed;
 4. Information that does not directly relate to the Divestiture Product(s);
 5. Information relating to 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 Product(s); or
 6. Information specifically excluded from the Avimune IB98 Assets, F VAX-MG Assets and CHOLERVAC PM-1 Assets.
- R. "Contract Manufacture" means the manufacture of a Divestiture Product to be supplied by Respondent or a Designee specifically identified in this Order for sale to an Acquirer.
- S. "Designee" means any entity other than the Respondent that will manufacture a Divestiture Product for an Acquirer.
- T. "Develop" means to engage in Development.
- U. "Development" means, to the extent applicable for a veterinary vaccine Product, 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

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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 Divestiture Product (including any governmental price or reimbursement approvals), Divestiture Product approval and registration, and regulatory affairs related to the foregoing.

- V. “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 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.
- W. “Divestiture Assets” means the Avimune IB98 Assets, the CHOLERVAC PM-1 Assets, and the F VAX-MG Assets.
- X. “Divestiture Product Core Employees” means the Product Manufacturing Employee(s), Product Marketing Employee(s), Product Sales Employee(s) and Product Research and Development Employee(s) related to each of the Divestiture Products.
- Y. “Divestiture Products” means any one or more of the following Products: Avimune IB98, CHOLERVAC PM-1, and F VAX-MG.

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- Z. “Divestiture Trustee” means a trustee appointed by the Commission pursuant to the relevant provisions of this Order.
- AA. “Effective Date” means the date the Respondent and Akzo Nobel close on the Acquisition.
- BB. “Employee Access Period” means a period of twelve (12) months from the Closing Date.
- CC. “Employee Notification” means the “Notice of Divestiture and Requirement for Confidentiality” attached to this Order as public Appendix II.
- DD. “F VAX-MG” means any Schering-Plough Product that includes as an antigen live F strain of *Mycoplasma gallisepticum* which is manufactured, marketed or sold by Schering-Plough pursuant to USDA License No. 1751.00.
- EE. “F VAX-MG Assets” means all of Respondent’s rights, title and interest not acquired in the Acquisition in and to all assets related to the business of Schering-Plough in the Territory related to F VAX-MG, to the extent legally transferable, including the research, Development, manufacture, distribution, marketing or sale of F VAX-MG, including, without limitation, the following:
1. all Product Intellectual Property;
 2. license(s) to all Product Licensed Intellectual Property:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;

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- (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,
 - (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);
3. the Master Seed;
 4. the Challenge Material;
 5. the Reagents;
 6. the Product Regulatory File;
 7. License(s) to use the Product Registrations to the extent required for the distribution, marketing, promoting, offering for sale and selling of the Divestiture Products in the Territory, which license(s) shall be royalty-free, non-exclusive, transferable and sublicensable; *provided however*, that such license(s) shall terminate upon Acquirer's receipt of all Divestiture Product approvals in accordance with Paragraph II.C.5 of this Order;
 8. a list of all of the NDC Numbers related to the Product;

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9. the existing lists of all current customers for the Divestiture Product and the pricing of the Divestiture Product for such customers;
10. at the Acquirer's option, each of the Product Assumed Contracts;
11. all Product Marketing Materials;
12. rights of reference (if such rights exist) to information similar to the Product Regulatory File submitted to any Agency other than the USDA and relating to the Divestiture Product except as may be retained by Respondent (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order, or (2) for the purposes of conducting Respondent's business related to such Product outside the Territory;
13. Product Scientific and Regulatory Material;
14. all unfilled customer orders for the Divestiture Product as of the Closing Date (a list of such orders is to be provided to the Acquirer within two days after the Closing Date);
15. license(s) to all Product Manufacturing Technology:
 - (i) to make and have made the Divestiture Product anywhere in the world, which license(s) shall be perpetual, transferable, fully paid-up and royalty-free, and co-exclusive with Respondent within the Territory and non-exclusive outside the Territory, and;
 - (ii) to use, distribute, offer for sale, promote, advertise, sell, or import, or to have used, distributed, offered

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for sale, promoted, advertised, sold, or imported such Divestiture Product, in and into the Territory, which license(s) shall be perpetual, fully paid-up and royalty-free, and exclusive (even as to Respondent); and,

- (iii) all of which licenses shall include the right to use to make improvements or modifications to such Divestiture Product (including, but not limited to, the preparation of new or modified Products by combining components, antigens, or ingredients of such Divestiture Product with one or more other components, antigens, ingredients, or Products);

- 16. at the Acquirer's option, all inventories for the Territory in existence as of the Closing Date, including, but not limited to, raw materials, goods in process, finished goods, and Divestiture Product specific packaging and labels, which shall include the grant of a license to use Product Trademarks and Product Trade Dress for the purposes of marketing and selling such inventories in the Territory; and
- 17. all Respondent's books, records and files related to the foregoing that are not included in the Product's Regulatory File, including all correspondence with the USDA and other Agencies, all validation documents and data; all market studies; all sales histories, including, without limitation, clinical data, and sales force call activity, for F VAX-MG from January 1, 2000, through the Closing Date, and quality control histories pertaining to F VAX-MG owned by, or in the possession or control of, Respondent, or to which Respondent has a right of access, in each case such as is in existence as of the Closing Date;

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provided, however, that in cases in which documents or other materials included in the F VAX-MG Assets contain information that (i) relates both to F VAX-MG and to other Products or businesses of Respondent (including the business outside the Territory), and (ii) cannot be segregated in a manner that preserves the usefulness of the information as it relates to F VAX-MG, Respondent shall be required only to provide copies of the documents and materials containing this information.

In instances where such copies are provided to the Acquirer, the Acquirer shall have 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 Respondent provide the Acquirer with the above-described information without requiring Respondent completely to divest itself of information that, in content, also relates to Products and businesses other than F VAX-MG;

provided further, however, the term “F VAX-MG Assets” does not include: (i) Retained Master Seed; (ii) Retained Challenge Material; (iii) Retained Reagents; (iv) manufacturing equipment and facilities, business permits and licenses, research and Development expertise, professional services, trade and distribution networks, personnel, manufacturing facilities, factories, laboratories and other real property, administrative, systems and processing infrastructure, sales, promotion and marketing expertise, regulatory expertise, financing, and items of a similar nature generally necessary to conduct an animal health business; (v) those assets listed in 1-17 above as used in the conduct of Respondent’s business outside the Territory.

FF. “Government Entity” means any Federal, state, local or non-U.S. government or any court, legislature, government

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agency or government commission, or any judicial or regulatory authority of any government.

- GG. “Interim Monitor” means a monitor appointed by the Commission pursuant to the relevant provisions of this Order.
- HH. “Law” means all laws, statutes, rules, regulations, ordinances and other pronouncements having the effect of law by any Government Entity.
- II. “Master Seed” means the following (other than Retained Master Seed): (i) the isolated strain of organism selected and permanently stored by Respondent from which all other seed passages are derived within permitted levels for each Divestiture Product and (ii) the isolated strain of organism for the Divestiture Products produced by, and permanently stored by, Respondent from master seed identical to the seed set forth in clause (i) from which all other seed passages are derived within permitted levels for each Divestiture Product.
- JJ. “Patents” means all patents, patent applications and statutory invention registrations, in each case existing as of the Effective Date (except where this Order specifies a different time), and includes all reissues, divisions, continuations, continuations-in-part, supplementary protection certificates, extensions and reexaminations thereof, all inventions disclosed therein, all rights therein provided by international treaties and conventions, and all rights to obtain and file for patents and registrations thereto in the Territory, related to any Divestiture Product of or owned by Respondent as of the Closing Date.
- KK. “Poultry Business” means the business within Respondent’s Animal Health Corporation responsible for the research, Development, manufacture, distribution, marketing,

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promotion, sale, or after sales support of any product sold for use with poultry as of the Closing Date.

LL. “Product” means any pharmaceutical, biological, or genetic composition containing any formulation or dosage of a compound referenced as its pharmaceutically, biologically or genetically active ingredient.

MM. “Product Assumed Contracts” means all of the following contracts or agreements related to the Territory:

1. pursuant to which any Third Party purchases any Divestiture Product from the Respondent;
2. pursuant to which the Respondent purchases any materials from any Third Party for use in connection with the manufacture of any Divestiture Product;
3. relating to any clinical trial involving any Divestiture Product;
4. constituting the material transfer agreements involving the transfer of any Divestiture Product;
5. relating to the marketing of any Divestiture Product or educational matters relating to any Divestiture Product;
6. relating to the manufacture of any Divestiture Product;
7. constituting confidentiality agreements involving any Divestiture Product;
8. involving any royalty, licensing or similar arrangement involving any Divestiture Product;
9. pursuant to which any services are provided with respect to any Divestiture Product or any Divestiture Product business, including consultation arrangements; and/or

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10. pursuant to which any Third Party collaborates with the Respondent in the performance of research or Development of any Divestiture Product or any Divestiture Product business.

provided, however, that where any such contract or agreement also relates to a Product of Respondent other than any Divestiture Product, Respondent shall assign the Acquirer all such rights in the Territory under the contract or agreement as are related to the Product required to be divested pursuant to this Order, but concurrently may retain similar rights for the purposes of the other Product.

NN. “Product Copyrights” means rights to all original works of authorship of any kind related to any Divestiture Product and any registrations and applications for registrations thereof, including, but not limited to, the following: educational materials for the sales force; copyrights in all pre-clinical, clinical and process development data and reports relating to the research and Development of any Divestiture Product or of any materials used in the research, Development, manufacture, marketing or sale of any Divestiture Product, including all raw data relating to clinical trials of any 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; customer information, promotional and marketing materials, any Divestiture Product sales forecasting models, medical education materials, sales training materials, website content and advertising and display materials; all records relating to employees that accept employment with the Acquirer

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(excluding any personnel records the transfer of which is prohibited by applicable Law); all 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 data contained in laboratory notebooks relating to any Divestiture Product or relating to its biology; all adverse experience reports and files related thereto (including source documentation) and all periodic adverse experience reports and all data contained in electronic data bases relating to adverse experience reports and periodic adverse experience reports; all analytical and quality control data; and all correspondence with the USDA.

OO. "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 relevant employee from ninety (90) days prior to Closing Date through the Closing Date. This list shall be organized by the relevant respective employee categories defined in this Order, (*i.e.*, "Product Manufacturing Employee(s)," "Product Marketing Employee(s)," "Product Research and Development Employee(s)," or "Product Sales Employee(s)," as applicable);
2. with respect to each such employee:
 - 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 Divestiture Product; provided, however, in lieu of this description,

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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 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
 - 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.

PP. "Product Intellectual Property" means all of the following (regardless of whether physically located in or outside the Territory) related to a Divestiture Product that is sold in the Territory (other than Retained Product Licensed Intellectual Property):

- 1. Patents;
- 2. Product Copyrights;
- 3. trade secrets, know-how, techniques, data, inventions, practices, methods and other confidential or proprietary technical, business, research, Development and other

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information, other than Product Licensed Intellectual Property;

4. rights to obtain and file for Patents and registrations thereof; and
5. 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” does not include the corporate names or corporate trade dress of “Schering-Plough,” “Akzo Nobel,” “Intervet” or the corporate names or corporate trade dress of any other corporations or companies owned by Respondent or related logos.

QQ. “Product Licensed Intellectual Property” means all of the following (regardless of whether physically located in or outside of the Territory):

1. Patents that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by either Respondent or Organon BioSciences or Intervet (whichever is relevant to such Divestiture Product) for a Retained Product(s); 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 Territory to limit the use or disclosure thereof, that are related to a Divestiture Product that Respondent can demonstrate have been routinely used, prior to the Effective Date, by Respondent or Organon BioSciences or Intervet (whichever is relevant to such Divestiture Product) for a Retained Product(s).

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RR. “Product Manufacturing Employee(s)” means all salaried employees of Respondent who directly participated (irrespective of the portion of working time involved) in the manufacture of the Divestiture Product for the Territory, including, but not limited to, those involved in the quality assurance and quality control of the Divestiture Product for the Territory, within the eighteen (18) month period immediately prior to the Closing Date

SS. “Product Manufacturing Technology” means all technology, trade secrets, know-how, and proprietary information related to the manufacture, validation, packaging, release testing, stability and shelf life of the Divestiture Product, including the Divestiture Product’s formulation, in existence and in the possession of Respondent as of the Closing Date, including, but not limited to, the percentages and specifications of ingredients, the manufacturing processes and flow diagrams thereof, the Production Outlines, specifications, technology, inventions, assays, quality control and testing procedures, know-how, trade secrets and trade art, whether tangible or intangible and used to manufacture, formulate, test and package the Divestiture Products for sale, marketing and distribution in the Territory.

TT. “Product Marketing Employee(s)” means all management level employees of Respondent who directly participated (irrespective of the portion of working time involved) in the marketing, contracting, or promotion of the Divestiture Product in the Territory within the eighteen (18) month 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 and market research, but excluding administrative assistants.

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- UU. “Product Marketing Materials” means the content of all marketing materials used in the Territory related to the Divestiture Product as of the Closing Date, including, without limitation, all tangible copies of all advertising materials, training materials, product data, price lists, mailing lists, sales materials (e.g., detailing reports; vendor lists; sales data; reimbursement 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 sales information; sales forecasting models; medical educational materials; website content and advertising and display materials; speaker lists), promotional and marketing materials, artwork for the production of packaging components, television masters and other similar materials related to the Divestiture Product.
- VV. “Product Registrations” means all 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 or sale of the Divestiture Product in the Territory.
- WW. “Product Regulatory File” means all data submitted to and all correspondence with the USDA and other Agencies related to the Divestiture Product except as may be retained by Respondent (in which case, Acquirer will receive a copy from Respondent) (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order or (2) for the purposes of Respondent’s business related to such Product outside the Territory.
- XX. “Product Research and Development Employee(s)” means all employees of Respondent who directly participated (irrespective of the portion of working time involved) in the research, Development, regulatory approval process, or

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clinical studies of the Divestiture Product for the Territory within the eighteen (18) month period immediately prior to the Closing Date.

YY. “Product Sales Employee(s)” means all employees of Respondent who directly participated (irrespective of the portion of working time involved) in the detailing, marketing or promotion of the Divestiture Product directly in the Territory within the eighteen (18) month period immediately prior to the Closing Date.

ZZ. “Product Scientific and Regulatory Material” means all technological, scientific, chemical, biological, pharmacological, toxicological, regulatory and clinical trial materials and information related to the Divestiture Product, and all rights thereto, (regardless of whether physically located in or outside of the Territory) in the Territory except as may be retained by Respondent (in which case, Acquirer will receive a copy from Respondent) (1) in order to comply with its obligations to Contract Manufacture under Paragraph II.D.1 of this Order or (2) for the purposes of Respondent’s business related to such Product outside the Territory.

AAA. “Product Trade Dress” means the current trade dress of the Divestiture Product, including, but not limited to, product packaging associated with the sale of the Divestiture Product and the lettering of the Divestiture Product’s trade name or brand name.

BBB. “Product Trademark(s)” means all trademarks, 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 in the Territory.

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CCC. "Production Outline" means all Respondent's production instructions and processes for each Divestiture Product for the Territory.

DDD. "Proposed Acquirer" means an entity proposed by Respondent (or a Divestiture Trustee) to the Commission and submitted for the approval of the Commission as the acquirer for particular assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by Respondent pursuant to this Order.

EEE. "Reagents" means all of the reagents (other than the Retained Reagents) that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory.

FFF. "Remedial Agreement(s)" mean:

1. The agreement between Respondent and Wyeth, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets 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;
2. Any agreement between Respondent and a Third Party to effect the assignment of assets or rights of Respondent related to a Divestiture Product to the benefit of an Acquirer that is specifically referenced in or attached to this Order, including all amendments, exhibits,

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attachments, agreements, and schedules thereto, 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;

3. Any agreement between 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, and all amendments, exhibits, attachments, agreements, and schedules thereto, related to the relevant assets 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; or,
4. Any agreement between Respondent and a Third Party to effect the assignment of assets or rights of 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.

GGG. "Retained Challenge Material" means the quantities of materials used to confirm the immunogenicity of each Divestiture Product and the media formula to propagate the challenge organism, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.

HHH. "Retained Master Seed" means the quantities of isolated strain of organism selected and permanently stored by Respondent from which all other seed passages are derived within permitted levels for each Divestiture Product, which are not conveyed to Acquirer as Divestiture Assets and are

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retained by Respondent for the conduct of its business outside the Territory.

- III. “Retained Product” means any Product(s) other than a Divestiture Product.
- JJJ. “Retained Reagents” means the quantities of the reagents that are proprietary or unavailable from commercial sources used in the research, Development, manufacture, distribution, marketing or sale of any one or more of the Divestiture Products to confirm the identification of the Master Seed and to perform the potency tests of the Divestiture Products, including the reference vaccine for each Divestiture Product for the Territory, which are not conveyed to Acquirer as Divestiture Assets and are retained by Respondent for the conduct of its business outside the Territory.
- KKK. “Supply Cost” means a cost not to exceed the manufacturer’s average direct unit cost of manufacturing the Divestiture Product for the twelve (12) month period immediately preceding the Effective Date. “Supply Cost” shall expressly exclude any intracompany business transfer profit; *provided, however*, that in each instance where: (1) an agreement to Contact 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.
- LLL. “Territory” means the United States of America and its territories and possessions.
- MMM. “Third Party(ies)” means any private entity other than: (1) the Respondent, or (2) the Acquirer for the affected assets, rights and Divestiture Products.

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NNN. “Wyeth” means Wyeth, a corporation organized, existing and doing business under and by virtue of the laws of the State of Delaware, with its headquarters address at Five Giralda Farms, Madison, New Jersey 07940-0874.

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

- A. Not later than ten (10) days after the Effective Date, Respondent shall assign, grant, license, divest, transfer, deliver or otherwise convey the Divestiture Assets, absolutely and in good faith, to Wyeth pursuant to and in accordance with the Asset Purchase Agreement (which Agreement shall not vary or contradict, or be construed to vary 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 Wyeth or to reduce any obligations of Respondent under such Agreement), and such Agreement, if it becomes the Remedial Agreement for one or more of the Divestiture Assets, is incorporated by reference into this Order and made a part hereof. If Respondent does not divest the Divestiture Assets to Wyeth within ten (10) days after the Effective Date, the Commission may appoint a Divestiture Trustee to divest the Divestiture Assets;

provided, however, that if Respondent has divested the Divested Assets to Wyeth prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that Wyeth is not an acceptable purchaser of any one or more of the Divestiture Assets, then Respondent shall immediately rescind the transaction with Wyeth, in whole or in part, as directed by the Commission, and shall divest any one or more of the Divestiture Assets within six (6) months from the date the Order becomes final, absolutely and in

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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 Respondent has divested the Divested Assets to Wyeth prior to the date this Order becomes final, and if, at the time the Commission determines to make this Order final, the Commission notifies Respondent that the manner in which the divestiture was accomplished is not acceptable, the Commission may direct the Respondent, or appoint a Divestiture Trustee, to effect such modifications to the manner of divestiture to Wyeth of any one or more of the Divestiture Assets (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 Third Parties that are necessary to permit Respondent to divest the assets required to be divested pursuant to this Order to the relevant Acquirer, and/or to permit such Acquirer to continue the research, Development, manufacture, sale, marketing, or distribution of the Divestiture Products;

provided, however, that Respondent may satisfy this requirement by certifying that the relevant Acquirer has obtained fully executed consents and waivers directly with each of the relevant Third Parties.

- C. Respondent shall transfer the Product Manufacturing Technology related to each Divestiture Product to the Acquirer in an organized, comprehensive, complete, useful, timely, and meaningful manner. Respondent shall, *inter alia*:

1. Designate employees of Respondent knowledgeable with respect to Product Manufacturing Technology for each

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Divestiture Product to a committee for the purposes of communicating directly with the Acquirer and the Interim Monitor for the purposes of effecting such transfer;

2. Prepare technology transfer protocols and transfer acceptance criteria for both the processes and analytical methods related to the relevant Divestiture Product, 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 transfer of all relevant information, all appropriate documentation, all other materials, and projected time lines for the delivery of all Product Manufacturing Technology to the Acquirer;
4. Upon reasonable notice and request from the Acquirer to Respondent, provide in a timely manner, at no greater than Direct Cost, assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to:
 - a. Manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities;
 - b. Obtain any product approvals necessary for the Acquirer to manufacture, sell, market or distribute the Divestiture Products; and,
 - c. Receive, integrate, and use such Product Manufacturing Technology to achieve the Order's purposes; and,
5. Provide consultation with knowledgeable employees of Respondent and training, at the request of the Acquirer

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and at a facility chosen by the Acquirer, until the Acquirer (or the Designee of the Acquirer) obtains all Divestiture Product approvals to manufacture the Divestiture Products in the same quality achieved by the Respondent and in commercial quantities, and in a manner consistent with the rules and regulations set forth by USDA in the code of Federal Regulations Title 9 and current industry good manufacturing practices for animal health products, independently of Respondent and sufficient to satisfy the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products.

- D. Respondent shall include in any Remedial Agreement related to the Divested Assets the following provisions:
1. At the option of the Acquirer, Respondent shall Contract Manufacture and deliver to the Acquirer, in a timely manner and under reasonable terms and conditions, a supply of any one or more of the Divestiture Products at Respondent's Supply Cost, for a period of time sufficient to allow the Acquirer (or the Designee of the Acquirer) to obtain any Agency or Government Entity approvals necessary to manufacture the Divestiture Products.
 2. After Respondent commences delivery of any one or more of the Divestiture Products to the Acquirer pursuant to a Remedial Agreement to Contract Manufacture any one or more of the Divestiture Products, Respondent will make inventory of any one or more of the Divestiture Products available for sale or resale in the Territory only to the Acquirer.
 3. Respondent shall make representations and warranties to the Acquirer that the Divestiture Products supplied through Contract Manufacture pursuant to the Remedial Agreement meet any Agency or Government Entity

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specifications. 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 Divestiture Products supplied to the Acquirer pursuant to the Remedial Agreement by the Respondent to meet any Agency or Government Entity specifications. This obligation shall be contingent upon the Acquirer giving Respondent prompt, adequate notice of such claim and cooperating fully in the defense of such claim. The Remedial Agreement shall be consistent with the obligations assumed by Respondent under this Order; *provided, however*, Respondent 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 the Respondent's responsibilities to supply the Divestiture Products in the manner required by this Order; *provided further, however*, this obligation shall not require Respondent to be liable for any negligent act, omission or willful misconduct 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.

4. Respondent shall make representations and warranties to the Acquirer that Respondent will hold harmless and indemnify the Acquirer for any liabilities or loss of profits resulting from the failure by Respondent to deliver any one or more of the Divestiture Products in a timely manner as required by the Remedial Agreement unless Respondent can demonstrate that its failure was entirely beyond the control of the Respondent and in no part the result of negligence or willful misconduct by Respondent

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5. During the term of the Contract Manufacture between Respondent and the Acquirer, upon request of the Acquirer or Interim Monitor (if applicable), Respondent shall make available to the Acquirer or the Interim Monitor all records that relate to the manufacture of the Divestiture Products for the Territory that are generated or created after the Closing Date
6. Upon reasonable notice and request from the Acquirer to the Respondent, Respondent shall provide in a timely manner at no greater than Direct Cost:
 - a. assistance and advice to enable the Acquirer (or the Designee of the Acquirer) to obtain all necessary permits and approvals from any Agency or Government Entity to manufacture and sell the Divestiture Products in the Territory;
 - b. assistance to the Acquirer (or the Designee of the Acquirer) to manufacture the Divestiture Products in substantially the same manner and quality employed or achieved by Respondent in the Territory; and
 - c. consultation with knowledgeable employees of Respondent and training, at the request of the Acquirer and at a facility chosen by the Acquirer, until the Acquirer (or the Designee of the Acquirer) obtains all Agency or Government Entity approvals necessary to manufacture the Divestiture Products independently of the Respondent and sufficient to satisfy management of the Acquirer that its personnel (or the Designee's personnel) are adequately trained in the manufacture of the Divestiture Products.

E. Respondent shall:

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1. Submit to the Acquirer, at Respondent's expense, all Confidential Business Information related to the Divestiture Products;
2. Deliver such Confidential Information as follows:
 - a. In good faith;
 - b. As soon as practicable, avoiding 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 the Acquirer, provide the Acquirer and the Interim Monitor 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 in the Territory 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 in the Territory other than as necessary to comply with the following:
 - a. The requirements of this Order;
 - b. Respondent's obligations to the Acquirer under the terms of the Remedial Agreement related to Divestiture Products; or

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- c. Applicable Law;
 - 5. Not disclose or convey any such Confidential Business Information, directly or indirectly, to any person except the Acquirer or other persons specifically authorized by the Acquirer to receive such information, and only if authorized to do so by Acquirer; 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 in the Territory to the employees associated with business related to those Retained Products that are approved by any Agencies for the same or similar indications or purposes as the Divestiture Products.
- F. At the Acquirer's option and upon written notice to Respondent from the Acquirer, delivered at Closing:
- 1. Respondent shall provide the Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees during the Employee Access Period.
 - 2. Respondent shall provide any Proposed Acquirer with the opportunity to enter into employment contracts with the Divestiture Product Core Employees in connection with the divestiture of the Divestiture Assets; *provided, however*, that any such employment contracts entered into prior to the Closing Date shall be contingent upon the Commission's approval of the Asset Purchase Agreement and the other Remedial Agreements.
 - 3. Not later than the earlier of the following dates: (1) ten (10) days after notice by staff of the Commission to Respondent to provide the Product Employee

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Information or (2) ten (10) days after the relevant Closing Date, Respondent shall provide the Acquirer or the Proposed Acquirer the Product Employee Information related to the Divestiture Product Core Employees. Failure by Respondent to provide the Product Employee Information related to the Divestiture Product Core Employees within the time provided herein shall extend the Employee Access Period with respect to that employee in an amount equal to the delay or seven (7) days, whichever is greater.

4. During the Divestiture Product Core Employee Access Period, Respondent shall not interfere with the hiring or employing by the Acquirer of any Divestiture Product Core Employees, and shall remove any impediments within the control of Respondent that may deter any Divestiture Product Core Employee from accepting employment with the Acquirer, including, but not limited to, any non-compete provisions of employment or other contracts with Respondent that would affect the ability or incentive of those individuals to be employed by the Acquirer. In addition, Respondent shall not make any counteroffer to a Divestiture Product Core Employee who receives a written offer of employment from the Acquirer;

provided, however, that these requirements shall not prohibit the Respondent from making offers of employment to or employing any Divestiture Product Core Employee during the Divestiture Product Core Employee Access Period where the Acquirer has notified the Respondent in writing that the Acquirer does not intend to make an offer of employment to that employee;

provided further, that if the Respondent notifies the Acquirer in writing of its desire to make an offer of

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employment to a particular Divestiture Product Core Employee and the Acquirer does not make an offer of employment to that employee within twenty (20) days of the date the Acquirer receives such notice, the Respondent may make an offer of employment to that employee.

5. Respondent shall provide all Divestiture Product Core Employees with reasonable financial incentives to continue in their positions until the Closing Date. Such incentives shall include a continuation of all employee benefits offered by Respondent until the Closing Date has occurred, including regularly scheduled raises, bonuses, and vesting of pension benefits (as permitted by Law);

provided, however, that nothing in these requirements or in this Order requires or shall be construed to require the Respondent to terminate the employment of any employee.

6. For a period of one (1) year from the Closing Date, Respondent shall not:
 - (a) directly or indirectly, solicit or otherwise attempt to induce any employee of the Acquirer with any amount of responsibility related to the Divestiture Products (“Divestiture Product Employee”) to terminate his or her employment relationship with the Acquirer; *provided, however,* a violation of this provision will not occur by any of the following actions: (i) Respondent advertises for employees in newspapers, trade publications or other media not targeted specifically at the Divestiture Product Employees, or (ii) a Divestiture Product Employee contacts Respondent on his or her own initiative

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without any direct or indirect solicitation or encouragement from the Respondent; or

- (b) hire any Divestiture Product Employee; *provided, however,* Respondent may hire any former Divestiture Product Employee whose employment has been terminated by the Acquirer or who independently applies for employment with the Respondent, as long as such employee was not solicited in violation of the non-solicitation requirements contained herein.

- G. Respondent shall require, as a condition of continued employment post-divestiture, that each Divestiture Product Core Employee sign a confidentiality agreement pursuant to which such employee shall be required to maintain all Confidential Business Information related to Divestiture Products strictly confidential, including the nondisclosure of such 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 Effective Date, Respondent shall provide written notification of the restrictions on the use of the Confidential Business Information related to Divestiture Products by Respondent's personnel to all of Respondent's employees who (i) are or were involved in the research, Development, manufacturing, distribution, sale or marketing of any one or more of the Divestiture Products; (ii) are directly involved in the research, Development, manufacture, distribution, sale or marketing of Retained Products that are approved by any Agencies for the same or similar indications or purposes as the Divestiture Products; and/or (iii) may have Confidential Business Information related to the Divestiture Products. Such notification shall be in substantially the form set forth

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in the Employee Notification attached to this Order as non-public Appendix II. Respondent shall give such notification by email 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 corporate headquarters 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.

- I. Upon reasonable notice and request by the Acquirer, Respondent shall make available to the Acquirer, at no greater than Direct Cost, such personnel, assistance and training as the Acquirer might reasonably need to transfer the Divestiture Assets, and shall continue providing until the Acquirer (or the Designee of the Acquirer) is fully validated, qualified, and approved by all Agencies, and able to manufacture the Divestiture Products independently of the Respondent.
- J. Pending divestiture of the Divestiture Assets, Respondent shall take such actions as are necessary to maintain the viability and marketability of the Divestiture Assets and to prevent the destruction, removal, wasting, deterioration, or impairment of any of the Divestiture Assets except for ordinary wear and tear.
- K. Respondent shall maintain manufacturing facilities for production of the Divestiture Products that are ready, validated, qualified and approved by the Agency and Government Entities, and fully capable of producing Divestiture Products for the Territory until the Acquirer (or the Designee of the Acquirer) is fully validated, qualified

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and approved by the Agency and Government Entities and able to manufacture Divestiture Products for the Territory independently of Respondent; *provided, however*, the Commission may eliminate, or limit the duration of, the Respondent's obligation under this provision should the Commission determine that the Acquirer is not using commercially reasonable best efforts to secure the Agency and Government Entities approvals necessary to manufacture Divestiture Products for the Territory independently of Respondent.

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

- A. Any Remedial Agreement shall be deemed incorporated into this Order.
- B. Any failure by Respondent to comply with any term of such Remedial Agreement shall constitute a failure to comply with this Order. Notwithstanding any paragraph, section, or other provision of the Remedial Agreement, any failure to meet any condition precedent to closing (whether waived or not) without the prior approval of the Commission shall constitute a failure to comply with this Order.
- C. Respondent shall include in each Remedial Agreement related to a Divestiture Product, a specific reference to this Order, the remedial purposes thereof, and the provisions to reflect the full scope and breadth of Respondent's obligations to the Acquirer pursuant to this Order.
- D. Respondent shall include in each Remedial Agreement a representation from the Acquirer that the Acquirer shall use commercially reasonable efforts to secure from Agencies all approvals necessary to manufacture, or to have

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manufactured by Third Parties, in commercial quantities, each Divestiture Product, and to have any such manufacture to be independent of Respondent, as soon as reasonably practicable.

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

IV.

IT IS FURTHER ORDERED that the purpose of the divestiture of the Divestiture Assets, the transfer of the Product Manufacturing Technology related to the Divestiture Products, and the related obligations imposed on the Respondent by this Order, is:

- A. To ensure the continued use of the Divestiture Assets in the research, Development, and manufacture of each of the Divestiture Products for the Territory;
- B. To provide for the future use of the Divestiture Assets in the distribution, sale and marketing of each of the Divestiture Products in the Territory;
- C. To create a viable and effective competitor, who is independent of the Respondent, in the research, Development, manufacture, distribution, sale, and marketing of each of the Divestiture Products in the Territory; and,
- D. To remedy the lessening of competition resulting from the Acquisition as alleged in the Commission's Complaint in a timely and sufficient manner.

V.

IT IS FURTHER ORDERED that:

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Respondent shall assure that, in any instance wherein counsel (including in-house counsel under appropriate confidentiality arrangements) either retains unredacted copies of documents or other materials provided to the Acquirer or accesses original documents (under circumstances where copies of documents are insufficient or otherwise unavailable) provided to the Acquirer, that Respondent's counsel does so only in order to do the following:

- A. Comply with any Remedial Agreement, this Order, any Law (including, without limitation, any requirement to obtain regulatory licenses or approvals), any data retention requirement of any Government Entity, or any taxation requirements; or,
- B. 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 assets and businesses associated with those Products; *provided, however*, that Respondent may disclose such information as necessary for the purposes set forth in this Paragraph pursuant to an appropriate confidentiality order, agreement, or arrangement;

provided, 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 Acquirer (but shall not be deemed to have violated this requirement if the Acquirer withholds such agreement unreasonably); and, (2) uses its best efforts to obtain a protective order to protect the confidentiality of such information during any adjudication;

provided further, however, that Respondent may continue to use that portion of those documents retained by Respondent that does not relate to the Divestiture Products.

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

- A. Dr. David A. Espeseth of Espeseth Consulting shall serve as the 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 and the Remedial Agreements. In lieu of or as a replacement to Dr. Espeseth, the Commission may appoint one or more Interim Monitors to assure Respondent’s compliance with the requirements of the Order and the related Remedial Agreements.
- B. If Dr. Espeseth fails to serve, or if a new Interim Monitor must be selected, 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. Respondent shall consent to the following terms and conditions regarding the powers, duties, authorities, and responsibilities of the Interim Monitor:

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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 later of:
 - a. the completion by Respondent of the divestiture of all relevant assets required to be divested pursuant to this Order in a manner that fully satisfies the requirements of the Order and notification by the Acquirer to the Interim Monitor that it is fully capable of producing the relevant Product acquired pursuant to a Remedial Agreement independently of Respondent; or
 - b. the completion by Respondent of the last obligation under the Order pertaining to the Interim Monitor's service.

provided, however, 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,

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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 Respondent's compliance with its obligations under the Order, including, but not limited to, its obligations related to the Divestiture 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 misfeasance, 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/or as otherwise provided in any agreement approved by the

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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 obligations under the Order or the Remedial Agreement. Within one (1) month from the date the Interim Monitor receives these reports, the Interim Monitor shall report confidentially 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.
 9. 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 or non-disclosure agreement related to Commission materials and information received in connection with the performance of the Interim Monitor's duties.
- E. If the Commission determines that the Interim Monitor has ceased to act, failed to act diligently, or for other good cause, the Commission may appoint a substitute Interim Monitor in the same manner as provided in this Paragraph.
- F. 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.

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- G. 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.

VII.**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 relevant assets as required by this Order, the Commission may appoint a trustee or trustees (“Divestiture Trustee(s)”) to assign, grant, license, divest, transfer, deliver or otherwise convey the assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed pursuant to each of the relevant Paragraphs in a manner that satisfies the requirements of each such Paragraph. 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 the relevant 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

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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 the 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-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 may be extended by the Commission, or, in the case of a court-appointed

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Divestiture Trustee, by the court; *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 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. Each 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

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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 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 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

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from misfeasance, gross negligence, willful or wanton acts, or bad faith by the Divestiture Trustee.

7. In the event that the Divestiture Trustee determines that he or she is unable to assign, grant, license, divest, transfer, deliver or otherwise convey the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed in a manner that preserves their marketability, viability and competitiveness and ensures their continued use in the research, Development, manufacture, distribution, marketing, promotion, sale, or after-sales support of the relevant Product, the Divestiture Trustee may assign, grant, license, divest, transfer, deliver or otherwise convey such additional assets of the Poultry Business of Respondent and effect such arrangements as are necessary to satisfy the requirements of this Order.
8. The Divestiture Trustee shall have no obligation or authority to operate or maintain the relevant assets required to be assigned, granted, licensed, divested, transferred, delivered or otherwise conveyed by this Order.
9. 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.
10. 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.

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- E. If the Commission determines that a Divestiture Trustee has ceased to act, failed to act diligently, or for other good cause, 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.
- G. 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.

VIII.**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 has fully complied with Paragraph II (including the performance of all obligations under any Remedial Agreements), 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 description of all substantive contacts or negotiations related to the divestiture of the relevant assets and the identity of all parties contacted. Respondent shall include in its reports

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copies of all written communications to and from such parties, all internal memoranda, and all reports and recommendations concerning completing the obligations.

- B. One (1) year after the date this Order becomes final, annually for the next nine (9) years on the anniversary of the date this Order becomes final, 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 this Order.

IX.

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 and the creation of or dissolution of subsidiaries, if such change might affect compliance obligations arising out of the Order.

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 and upon five (5) days notice to Respondent made to its principal United States office or its headquarters address, Respondent shall, without restraint or interference, permit any duly authorized representative of the Commission:

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- 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 the Respondent related to compliance with this 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. To interview officers, directors, or employees of Respondent, who may have counsel present, regarding such matters.

XI.

IT IS FURTHER ORDERED that this Order will terminate on December 28, 2017.

By the Commission.

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Nonpublic Appendix I

Asset Purchase Agreement

[Redacted From Public Record Version
But Incorporated By Reference]

Nonpublic Appendix II

Notice of Divestiture and Requirement for Confidentiality

[Redacted From Public Record Version
But Incorporated By Reference]

Analysis to Aid Public Comment

**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 Schering-Plough Corporation (“Schering-Plough”), which is designed to remedy the anticompetitive effects of its acquisition of Organon BioSciences N.V. (“Organon BioSciences”) from Akzo-Nobel N.V. (“Akzo-Nobel”). Under the terms of the proposed Consent Agreement, Schering-Plough would be required to divest to Wyeth: (1) the Schering-Plough rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (2) the rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (3) the rights and assets necessary to develop, manufacture, and market live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* (“MG”) in poultry.

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”).

Pursuant to the terms of a Letter of Intent dated March 12, 2007, Schering-Plough proposes to acquire from Akzo Nobel 100 percent of the outstanding shares of Organon BioSciences voting stock. 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

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Commission Act, as amended, 15 U.S.C. § 45, by lessening competition in the U.S. markets for the manufacture and sale of the following poultry vaccines: (1) live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry; (2) live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry; and (3) live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry. The proposed Consent Agreement will remedy the alleged violations by replacing the lost competition that would result from the acquisition in each of these markets.

The Products and Structure of the Markets

The markets for the Georgia 98 strain of infectious bronchitis, fowl cholera, and live MG vaccines are highly concentrated, with Schering-Plough and Intervet accounting for significant market shares in each of these markets. The proposed acquisition would create a monopolist in the live Georgia 98 vaccine market and would give Schering-Plough shares of approximately eighty-five percent and seventy-two percent in the markets for live fowl cholera and live MG vaccines, respectively.

The Georgia 98 strain of infectious bronchitis is a highly contagious respiratory disease in poultry spread by contact with infected respiratory discharge and feces. Live Georgia 98 vaccines are the only vaccines that can effectively prevent and treat the Georgia 98 strain of infectious bronchitis virus. Other infectious bronchitis virus vaccine strains, administered either individually or in multiple-antigen combination vaccines, do not provide adequate protection against the Georgia 98 serotype to act as a sufficient alternative to the live Georgia 98 vaccines. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious bronchitis virus in poultry in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are the only suppliers of live vaccines for the prevention and treatment of the Georgia 98 strain of infectious

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bronchitis virus in poultry in the United States. Schering-Plough's Avimune IB98 product is the market leader with an estimated seventy-nine percent market share, while Intervet competes with its MILDVAC GA-98 product, selling the remaining twenty-one percent in the United States. The acquisition would create a monopoly by combining the only two companies with products on the market.

Live fowl cholera vaccines prevent an infectious bacterial disease in poultry caused by a common pathogenic bacterium, *Pasteurella multocida*. The relevant market for the manufacture, distribution, and sale of live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are two of only three suppliers of live fowl cholera vaccines, and the only providers of a PM-1 strain of the vaccine. Organon BioSciences is the market leader with its CHOLERVAC-PM-1 product, accounting for approximately fifty-three percent of the live fowl cholera vaccines sold in the United States. Schering-Plough is the second leading supplier with its PM-ONEVAC-C and M-NINEVAX products, accounting for thirty-two percent of sales in the market. Together, Schering-Plough and Organon BioSciences account for approximately eighty-five percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of fowl cholera due to *Pasteurella multocida* in poultry.

MG is a respiratory disease that is transmitted laterally between chickens or through infected eggs. The relevant market for the manufacture, distribution, and sale of live *Mycoplasma gallisepticum* vaccines in the United States is highly concentrated. Respondent Schering-Plough and Organon BioSciences are the two leading suppliers of live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry in the United States. Akzo

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Nobel is the market leader with its MYCOVAC-L product, while Schering Plough competes with its F-VAX MG. Together, they account for over seventy-two percent of the sales in this highly concentrated market. Accordingly, the Acquisition would significantly increase the concentration levels in the United States in the market for live vaccines for the prevention and treatment of *Mycoplasma gallisepticum* in poultry.

Entry

Entry into any relevant line of commerce would not be timely, likely, or sufficient to deter or counteract the anticompetitive effects of the Acquisition. Entry into any of these markets would require overcoming three major obstacles: lengthy development periods, USDA approval requirements, and customer acceptance. As a result, new entry into any of these markets sufficient to achieve a significant market impact within two years is unlikely.

Effects

The markets for the Georgia 98 strain of infectious bronchitis, fowl cholera, and MG live vaccines are highly concentrated, with Schering-Plough and Intervet accounting for substantial shares of sales in each of these markets. The proposed acquisition would create a monopolist in the live Georgia 98 vaccine market and would give Schering-Plough shares of approximately eighty-five percent and seventy-two percent in the markets for live fowl cholera vaccine and live MG vaccines, respectively.

The competitive concerns can be characterized as unilateral in nature. Schering-Plough and Organon BioSciences are each other's closest competitors in all of the relevant markets. Consumers have benefitted from the price competition between Schering-Plough and Organon BioSciences. If unremedied, the proposed acquisition would likely cause higher prices and reduce incentives to improve service or product quality, resulting in significant harm to consumers in the U.S. markets for these vaccines.

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The Consent Agreement

The proposed Consent Agreement remedies the competitive harm caused by the proposed transaction. Pursuant to the Consent Agreement, Schering-Plough must divest or license all of the assets relating to Schering-Plough's live vaccine for the Georgia 98 strain of infectious bronchitis (Avimune IB98), Intervet's live fowl cholera vaccine (CHOLERVAC-PM-1) and Schering-Plough's live MG vaccine (F VAX-MG) ("the assets to be divested"), to the Fort Dodge division of Wyeth, within ten days after the date Schering-Plough acquires Organon BioSciences. The assets to be divested include research and development, customer, supplier and manufacturing contracts and any intellectual property including existing licenses, but excluding trademarks. Fort Dodge plans to bring all manufacturing of the three vaccines in-house to its own manufacturing facilities and to add the three to its own portfolio of poultry vaccines. While Fort Dodge undertakes the process of obtaining USDA regulatory approvals and bringing vaccine production in-house, Schering-Plough will provide Fort Dodge with the vaccines pursuant to a supply and transition services agreement with a term of two years, and an option to extend it another year, individually for each of the three vaccines, if required.

The 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 itself present competitive problems.

Wyeth, headquartered in Madison, New Jersey, is a global leader in pharmaceuticals, consumer health care products and animal health care products. In 2006, it had net sales of \$20 billion. Wyeth's Fort Dodge Animal Health division offers a broad range of biological and pharmaceutical products for the companion animal, equine,

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livestock, swine and poultry industries. Significantly, Wyeth already has an established poultry vaccine line comprised of internally developed vaccines as well as several vaccines that it has acquired and transferred to its manufacturing facilities. Fort Dodge has its own distribution network and an experienced sales force with existing relationships with major poultry producers. The three vaccines being divested to Fort Dodge are all established products that have been on the market for at least two years. Fort Dodge has its own manufacturing facilities with excess capacity and intends to bring the manufacturing of all of the products it is acquiring from Schering-Plough in-house. For these reasons, Wyeth is a strong buyer that appears well positioned to replace the competition lost by the acquisition.

If the Commission determines that Wyeth is not an acceptable acquirer of the assets to be divested, 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 Schering-Plough to provide transitional services to enable the Commission-approved acquirer to obtain all of the necessary approvals from the USDA. These transitional services include technology transfer assistance to manufacture the Products in substantially the same manner and quality employed or achieved by Schering-Plough and Akzo-Nobel.

The Commission has appointed Dr. David A. Espeseth to oversee the implementation of the Order as the Interim Monitor Trustee. Dr. Espeseth retired in 1998 from a career at the USDA, where his last position was as Special Assistant to the Deputy Administrator of Veterinary Services and where he spent the majority of his 37 years regulating veterinary biologic products (vaccines). Today, he is a consultant to animal health companies, assisting with regulatory issues before the USDA and technology

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transfers. Dr. Espeseth's strengths are his strong regulatory background, his experience overseeing technology transfers, and experience resolving disputes between companies and the USDA.

Dr. Espeseth is an excellent candidate to handle the expected duties and responsibilities of the Interim Monitor Trustee in this matter. He has the requisite capability and applicable knowledge to ensure the proper transfer of the divested assets, oversee the transfer of the relevant technology, monitor the critical manufacturing and supply activities of the Respondent, ensure the Respondent's compliance with the Order and related agreements, respond to Commission needs, and perform other related services as may be required. Accordingly, the Commission has appointed Dr. Espeseth as the Interim Monitor Trustee.

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**

IN THE MATTER OF

**KONINKLIJKE AHOLD N.V.,
AND
BRUNO'S SUPERMARKETS, INC.**

Docket No. C-4027. Order, July 10, 2007

Order approving respondents request to reopen and terminate the Commission's Decision and Order, dated January 16, 2002 as it applies to Bruno's, BI-LO, LLC, and their ultimate parent entity, Lone Star Fund V (U.S.), L.P.

ORDER REOPENING AND MODIFYING ORDER

On March 29, 2007, respondent Bruno's Supermarkets, Inc. ("Bruno's"), its owner BI-LO, LLC ("BI-LO"), BI-LO Holding, LLC ("BI-LO Holding"), the direct parent of BI-LO and Bruno's, and BI-LO's and BI-LO Holding's ultimate parent entity, Lone Star Fund V (U.S.), L.P. (collectively "Lone Star" or "Bruno's Respondents"), filed a Petition requesting the Commission to reopen and set aside the order in this matter ("Order") insofar as it applies to respondent Bruno's.¹ In its Petition, Lone Star states that the Bruno's Respondents have exited the relevant markets and that the Order should therefore be set aside as to Bruno's.

Lone Star's Petition was filed pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), and Section 2.51

¹ Petition of Lone Star to Reopen and Modify Decision and Order ("Petition") at 1. In 2005, Lone Star became a successor to respondent Koninklijke Ahold N.V. ("Ahold") under the Order after Ahold sold all of its interests in BI-LO and BI-LO Holding to Lone Star. Subsequently, in response to a petition filed by Ahold, the Commission reopened and set aside the Order as it applies to Ahold. In the matter of Koninklijke Ahold, N.V. and Bruno's Supermarkets, Inc., Docket No. C-4027, Order Reopening and Modifying Order (July 21, 2006).

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of the Commission's Rules of Practice and Procedure, 16 C.F.R. § 2.51. In its Petition, Lone Star asserts that changed circumstances eliminate the continuing need for the Order as it relates to Bruno's. Lone Star also contends the requested modification is in the public interest.² The Petition was placed on the Public Record and the thirty-day comment period closed on May 9, 2007. No comments were received. The Commission has reviewed Lone Star's Petition and has determined to reopen and set aside the Order as to Bruno's.

The Order that Lone Star seeks to modify resulted from Ahold's acquisition of Bruno's in 2001. The acquisition raised competitive concerns in the retail sale of food and grocery products in supermarkets located in "areas in and near Sandersville, Georgia and Milledgeville, Georgia."³ At the time, Ahold and Bruno's were direct competitors in Sandersville and Milledgeville and the Complaint alleged, among other things, that the acquisition would eliminate direct competition between Ahold and Bruno's in these areas.⁴ To remedy the competitive concerns raised by the acquisition, the Order required Ahold to divest its BI-LO supermarket in Milledgeville, Georgia (located in Baldwin County), and its BI-LO supermarket in Sandersville, Georgia (located in Washington County).⁵ Ahold divested the two supermarkets on December 14, 2001, and December 17, 2001, respectively. In 2005, Ahold sold BI-LO Holding to Lone Star. As a result, Ahold no longer owned or operated supermarkets in Baldwin and Washington Counties, Georgia, the relevant areas subject to the remaining compliance obligations under the Order, and the Bruno's Respondents became the successor to Ahold's compliance obligations under the remaining operative provisions of the Order.

² Petition at 2.

³ Complaint, Docket No. C-4027, ¶¶ 9-13.

⁴ *Id.* ¶ 17.

⁵ Order ¶ II.

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The Order's remaining operative provisions prohibit Bruno's, for a ten-year period ending on January 21, 2012, from (1) acquiring any supermarket in Baldwin or Washington Counties without providing advance written notice to the Commission; (2) entering into or enforcing any agreement that restricts the ability of any person acquiring any location used as a supermarket to operate a supermarket at that site if the supermarket was formerly owned or operated by Ahold or Bruno's in either Baldwin or Washington Counties; and (3) with certain exceptions, removing any fixtures or equipment from any property owned or leased by Ahold or Bruno's in Baldwin and Washington Counties that no longer operates as a supermarket.⁶ Bruno's is also required to file annual reports of its compliance with the Order until 2012, notify the Commission prior to any corporate changes that may affect compliance obligations arising out of the Order, and permit the Commission access, upon reasonable request, to all records and employees.⁷

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), provides that the Commission shall reopen an order to consider whether it should be modified if the respondent "makes a satisfactory showing that changed conditions of law or fact" require such modification.⁸ A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of it inequitable or

⁶ Id. ¶¶ IV and V.

⁷ Id. ¶¶ VI, VII and VIII.

⁸ Section 5(b) provides, in part:

[T]he Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part.

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harmful to competition.⁹ The Commission may also modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest requires such action.¹⁰ Thus, Section 2.51 of the Commission's Rules of Practice and Procedure, as amended, invites respondents in petitions to reopen to show how the public interest warrants the modification. In the case of a request for modification based on public interest grounds, a petitioner must make a *prima facie* "satisfactory showing" of a legitimate public interest reason or other reasons justifying the requested modification.¹¹ In this instance, however, we do not need to assess the sufficiency of Bruno's public interest showing because Bruno's has made the requisite satisfactory showing that changed conditions of fact require the Order to be reopened and set aside as to the Bruno's Respondents.

The record shows that on April 22, 2005, Lone Star entered into a Master Store Purchase Agreement with C&S Wholesale Grocers, Inc. ("C&S"), and its affiliate Southern Family Markets Acquisition LLC, pursuant to which the Bruno's Respondents sold certain supermarkets to C&S. As part of the sale, Bruno's sold its remaining two BI-LO supermarkets in Baldwin County, Georgia to C&S.¹² Bruno's also sold its one remaining Washington County, Georgia BI-LO supermarket to South Harris Street Partners. That store, however, had been closed since March 12, 2004, and was not

⁹ See S. Rep. No. 96-500, 96th Cong., 2nd Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished); see also *United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) ("A decision to reopen does not necessarily entail a decision to modify the order. Reopening may occur even where the petition itself does not plead facts requiring modification.").

¹⁰ See *United States v. Louisiana-Pacific Corp.*, 967 F.2d at 1376-77.

¹¹ See Requests to Reopen, Supplementary Information, 65 Fed. Reg. 50,636, 50,637 (Aug. 21, 2001) amending 16 C.F.R. § 2.51(b).

¹² Petition at 6.

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an operating concern at the time of the sale to South Harris Street Partners.¹³ As a result, Bruno's no longer owns or operates supermarkets in Baldwin and Washington Counties, Georgia, the relevant areas that are the subject of the Order's remaining operative provisions.¹⁴ C&S, through its counsel, has acknowledged and agreed that it would continue to comply with the obligations of the Order as Bruno's successor to those requirements. Further, Bruno's has stated that it has no present intention to re-enter Baldwin County or Washington County.¹⁵

Bruno's exit from the relevant markets eliminates the continuing need for the Order's remaining requirements to apply to Bruno's and thus is a sufficient changed circumstance to support setting aside the Order as to Bruno's.¹⁶ Setting aside Paragraph IV. of the Order (the prior notification provision) as to Bruno's is also consistent with the *Statement of the Federal Trade Commission Policy Concerning Prior Approval and Prior Notice Provisions*, issued June 21, 1995 ("Prior Approval Policy Statement").¹⁷ There is no evidence that a

¹³ *Id.* at 6.

¹⁴ Order ¶¶ IV-VIII.

¹⁵ Supplemental Affidavit of Marc L. Lipshy, Vice President of Bruno's Supermarkets, Inc. (June 18, 2007). See also Supplemental Affidavit of Brian Carney, Chief Financial Officer, BI-LO Holding, LLC (June 15, 2007).

¹⁶ *Koninklijke Ahold, N.V. and Bruno's Supermarkets, Inc.*, Docket No. C-4027, Order Reopening and Modifying Order (July 21, 2006) ("Ahold no longer owns or operates supermarkets in Baldwin and Washington Counties, Georgia, the relevant areas that are subject of the Order's remaining operative provisions"). See also *Entergy Corporation, et al.*, Docket No. C-3998, Order Reopening and Setting Aside Order (July 1, 2005) ("the factual premise underlying the concerns that led to entry of the Order, . . . arose specifically from the acquisition of Entergy's ownership interest in Gulf South The sale of Gulf South constitutes a substantial change that eliminates the continuing need for the Order's requirements"); *Union Carbide Corporation*, 108 F.T.C. 184 (1986) (order modified because respondent had clearly exited a business covered by the order and had demonstrated it had no intention of re-entering the business).

¹⁷ 60 Fed. Reg. 39,745-47 (August 3, 1995); 4 Trade Reg. Rep. (CCH) ¶ 13,241, at 20,991 (June 21, 1995).

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prior notification provision is needed as to Bruno's as Bruno's and its related entities do not own any interest in any supermarket operation in the relevant markets identified in the Order. Although Bruno's remains in the supermarket business in areas that are not addressed by the Order, an acquisition by Bruno's of any competitively significant supermarket operation in the relevant markets likely would be reportable under the Hart-Scott-Rodino Act, 15 U.S.C. 18a.¹⁸

Accordingly, **IT IS ORDERED** that this matter be, and it hereby is, reopened; and that the Commission's Order issued on January 16, 2002 be, and it hereby is, set aside as to Bruno's Respondents as of the effective date of this Order, but will continue in effect with respect to Bruno's successor, C&S Wholesale Grocers, Inc.

By the Commission.

¹⁸ In its Prior Approval Policy Statement, the Commission states that it will "henceforth rely on the HSR process as its principal means of learning about and reviewing mergers by companies as to which the Commission had previously found a reason to believe that the companies had engaged or attempted to engage in an illegal merger . . . [and that as a general matter] Commission orders in such cases will not include prior approval or prior notification requirements." *Id.* at 2. See *KKR Associates, L.P.*, 120 F.T.C. 879 (October 31, 1995) (setting aside order containing prior approval provision pursuant to Prior Approval Policy Statement).

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IN THE MATTER OF

**WHOLE FOODS MARKET, INC.,
AND
WILD OATS MARKETS, INC.**

Docket No. 9324. Order, August 7, 2007

Order staying the Commission action during the pendency of other federal court proceedings.

ORDER STAYING ADMINISTRATIVE PROCEEDINGS

On June 6, 2007, the Commission filed a complaint and motions for a temporary restraining order and a preliminary injunction against Respondents in the United States District Court for the District of Columbia. On June 7, 2007, the District Court issued a Temporary Restraining Order preventing Respondent Whole Foods Market, Inc., from consummating any acquisition of any stock, assets, or other interest, directly or indirectly, in Respondent Wild Oats Markets, Inc., pending the District Court's decision on the Commission's motion for a preliminary injunction.

On June 28, 2007, Commission issued the complaint in this administrative action. The Commission retained adjudicative responsibility for the matter. Rule 3.42(a), 15 C.F.R. § 3.42(a). On July 17, 2007, the Respondents in this matter filed their respective Answers to the Complaint.

In light of the pendency of the federal court proceedings, the Commission, as a matter of discretion, has determined to stay these proceedings pursuant to Rule 3.51, 16 C.F.R. § 3.51.

Accordingly,

IT IS ORDERED THAT this administrative proceeding is stayed pending the proceedings in the collateral federal district court

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case (Case Number 07-cv-01021-PLF) and further order of the Commission.

By the Commission.

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IN THE MATTER OF

**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.**

Docket No. C-4174. Order, August 9, 2007

Letter approving the petitions filed by SCI to divest certain assets to Wilson Family Funeral Chapel, Inc. and EMCR, LLC.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestiture to EMCR, LLC (“EMCR”), filed by Service Corporation International (“SCI”) and received on May 11, 2007 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to EMCR.

After consideration of SCI’s Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI and EMCR in connection with SCI’s Petition and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.**

Docket No. C-4174. Order, August 16, 2007

Order approving the petition of SCI to divest certain assets to Griffin Funeral Home, Inc.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestiture to Griffin Funeral Home, Inc. (“Griffin”), filed by Service Corporation International (“SCI”) and received on June 18, 2007 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to Griffin.

After consideration of SCI’s Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI and Griffin in connection with SCI’s Petition and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

SERVICE CORPORATION INTERNATIONAL

Docket No. C-3869. Order, August 29, 2007

Commission letter approving the petition of SCI to divest certain assets to JCAM, L.L.C.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Clanton and Mr. Johnson:

This is in reference to the Petition for Approval of Proposed Divestiture to JCAM, L.L.C. ("JCAM") filed by Trustee Thomas Johnson and received on May 30, 2007 ("Petition"). Pursuant to the Decision and Order, as modified by the Order to Show Cause and Order Modifying Order, in Docket No. C-3869, the Trustee requests prior Commission approval of his proposal to divest certain assets to JCAM.

After consideration of the Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by the Trustee, SCI and JCAM in connection with the Petition and has assumed them to be accurate and complete.

Further, the Commission has extended the divestiture period contained in the Order to Show Cause and Order Modifying Order issued in the above-referenced matter to August 31, 2007. This action is being taken pursuant to Paragraphs VIII.E and VIII.F.2.d of the Order.

By direction of the Commission.

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IN THE MATTER OF
RAMBUS INCORPORATED

Docket No. 9302. Order, August 29, 2007

Letter approving Rambus' Application for Approval of Compliance Officer filed pursuant to the Commission's final Order.

COMMISSION LETTER APPROVING COMPLIANCE OFFICER

Dear Mr. Stone and Mr. Melamed:

This letter responds to the *Application for Approval of Compliance Officer* filed by respondent Rambus Inc. ("Rambus") on July 11, 2007. In that application, Rambus has sought, pursuant to Paragraph III.A.1 of the Commission's Final Order in the above matter ("*Order*"), Commission approval of the employment by Rambus of Chirag R. Asaravala in the position of Compliance Officer.

After considering Rambus's application, the Commission has determined to approve Rambus's employment of Chirag R. Asaravala as Compliance Officer. In according its approval, the Commission has relied upon the information submitted and representations made in connection with the filings and has assumed them to be accurate and complete.

This approval does not relieve Rambus from liability for any violations of the Order, including any violations for which the Compliance Officer is responsible. *See Order* at ¶ III.C. (as modified by *Order Granting in Part and Denying in Part Respondent's Petition for Reconsideration of the Final Order and Granting Complaint Counsel's Petition for Reconsideration of Paragraph III.C. of the Final Order* at ¶ 2 (April 27, 2007)).

By direction of the Commission.

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IN THE MATTER OF

**EVANSTON NORTHWESTERN HEALTHCARE
CORPORATION
AND
ENH MEDICAL GROUP, INC.**

Docket No. 9315. Order, September 10, 2007

Order granting Respondent's request for an extension of time to file their proposal for implementing the injunctive relief ordered by the Commission.

ORDER GRANTING MOTION FOR EXTENSION OF TIME

On August 2, 2007, the Commission issued an Order in this matter that, *inter alia*, requires Respondent Evanston Northwestern Healthcare Corporation to file with the Commission, on or before September 10, 2007, a detailed proposal for implementing the type of injunctive relief that the Commission has selected, as described by the Opinion of the Commission and the Commission Order; that requires Complaint Counsel to file with the Commission any objections to or comments on that proposal within thirty calendar days thereafter; and that requires Respondent to file any response to Complaint Counsel's filing within ten calendar days thereafter.

Respondent has now filed a Motion requesting an extension of the deadline for filing its detailed proposal until September 17, 2007. Respondent advises that its counsel have received input from numerous officers and employees of Evanston Northwestern Healthcare Corporation, in order to assist counsel in preparing the proposal; that certain persons whose input is necessary have not been available throughout the period since issuance of the Commission Order, as a consequence of previously-scheduled summer travel; and that one additional week is therefore requested in order to complete client input. Respondent further advises that Complaint Counsel do not oppose the Motion, provided that

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Complaint Counsel will still have thirty days within which to file their response after Respondent has filed its proposal.

The Commission has determined to grant the Motion. Accordingly,

IT IS ORDERED that the deadline prescribed in the Third Ordering Paragraph in the Commission Order issued in this matter on August 2, 2007, be, and it hereby is, extended until September 17, 2007; and

IT IS FURTHER ORDERED THAT the deadlines prescribed in the Sixth and Seventh Ordering Paragraphs in the August 2, 2007 Order remain unchanged.

By the Commission.

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IN THE MATTER OF

**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.**

Docket No. C-4174. Order, September 19, 2007

Letter approving the petition of SCI to divest certain assets to Found, LLC

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestiture to Found, LLC (“Found”), filed by Service Corporation International (“SCI”) and received on July 3, 2007 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to Found.

After consideration of SCI’s Petition and other available information, the Commission has determined to approve the proposed divestiture as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI and Found in connection with SCI’s Petition and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.***Docket No. C-4174. Order, September 19, 2007*

Letter approving the petition of SCI to divest certain assets to Janssen Funeral Homes, Inc. and Janssen-Eastman Properties, LLC.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestitures to Janssen Funeral Homes, Inc., and Janssen-Eastman Properties, LLC (collectively “Janssen”), filed by Service Corporation International (“SCI”) and received on July 3, 2007 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to Janssen.

After consideration of SCI’s Petition and other available information, the Commission has determined to approve the proposed divestitures as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI and Janssen in connection with SCI’s Petition and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

**DUKE ENERGY CORPORATION,
PHILLIPS PETROLEUM COMPANY,
AND
DUKE ENERGY FIELD SERVICES L.L.C.**

Docket No. C-3932. Order, September 26, 2007

Order approving the petition of Duke Energy Company, Spectra Energy Corp. and DCP Midstream, LLC to reopen the Decision and Order in this matter and vacate the Order as it applies to Duke Energy. Petitioners present evidence that Duke Energy has exited the relevant markets, and argue that this constitutes a changed condition of fact that justifies the release of Duke Energy from the Order.

ORDER REOPENING AND MODIFYING ORDER

On May 31, 2007, Duke Energy Company (“Duke Energy”), Spectra Energy Corp. (“Spectra Energy”),¹ and DCP Midstream, LLC² (collectively, “Petitioners”) submitted a petition requesting that the Commission reopen and set aside the order in this matter (“Order”) insofar as the Order applies to respondent Duke Energy.³ Petitioners’ stated reason for setting aside the Order as to Duke Energy is that Duke Energy has exited the relevant markets.

The Petition was filed pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), and Section 2.51 of the Commission’s Rules of Practice and Procedure, 16 C.F.R. § 2.51. Petitioners assert that changed circumstances eliminate the

¹ Spectra Energy has become the successor to Duke Energy in this matter through its acquisition of Duke Energy’s assets in the relevant markets. *See infra*.

² DCP Midstream, LLC, a respondent in this matter, was known as “Duke Energy Field Services L.L.C.” at the time the Order was issued.

³ *Petition of Duke Energy Company, Spectra Energy Corp., and DCP Midstream, LLC to Reopen and Modify Decision and Order* (“Petition”) at 1.

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continuing need for the Order as it relates to Duke Energy.⁴ Petitioners also contend that the requested modification is in the public interest.⁵

The Petition was placed on the Public Record on June 5, 2007. The thirty-day comment period closed on July 5, 2007. No public comments were submitted. The Commission has reviewed the Petition and has determined to reopen and set aside the Order as to Duke Energy.

The Order that Petitioners seek to modify resulted from (a) the merger by Duke Energy and Phillips Petroleum Company of their natural gas gathering and processing businesses into Duke Energy Field Services L.L.C., and (b) the acquisition by Duke Energy of certain gas gathering and processing assets located in central Oklahoma and owned by Conoco Inc. These transactions raised competitive concerns regarding markets for natural gas gathering and processing in certain areas of Kansas, Oklahoma, and Texas.⁶ The Order required Duke Energy and the other respondents to divest certain gas gathering pipelines in those areas.⁷

The Order's remaining operative provisions require that Duke Energy and the other respondents (1) give the Commission prior notice of their mergers and acquisitions in the relevant markets,⁸ (2) file annual reports of their compliance with the Order,⁹ (3) notify the

⁴ Petition at 6-7.

⁵ *Id.* at 7-9.

⁶ Complaint, Docket No. C-3932, at ¶¶ 12, 13, 20, 21, 28, 29, 36, 37, 44, 45, 52, 53, 61 and 62.

⁷ Order, at ¶ II.

⁸ *Id.* at ¶¶ IV and V.

⁹ *Id.* at ¶ VI.B

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Commission prior to any corporate changes that may affect compliance obligations arising out of the Order,¹⁰ and (4) permit the Commission access, upon reasonable request, to their records and employees.¹¹ The Order expires on May 5, 2010.¹²

Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. § 45(b), provides that the Commission shall reopen an order to consider whether it should be modified if the respondent “makes a satisfactory showing that changed conditions of law or fact” require such modification.¹³ A satisfactory showing sufficient to require reopening is made when a request to reopen identifies significant changes in circumstances and shows that the changes eliminate the need for the order or make continued application of it inequitable or harmful to competition.¹⁴ The Commission may also modify an order when, although changed circumstances would not require reopening, the Commission determines that the public interest

¹⁰ *Id.* at ¶ VII.

¹¹ *Id.* at ¶ VIII.

¹² *Id.* at ¶ IX.

¹³ Section 5(b) provides, in part:

(T)he Commission shall reopen any such order to consider whether such order (including any affirmative relief provision contained in such order) should be altered, modified, or set aside, in whole or in part, if the person, partnership, or corporation involved files a request with the Commission which makes a satisfactory showing that changed conditions of law or fact require such order to be altered, modified, or set aside, in whole or in part.

¹⁴ See S. Rep. No. 96-500, 96th Cong., 2nd Sess. 9 (1979) (significant changes or changes causing unfair disadvantage); *Louisiana Pacific Corp.*, Docket No. C-2956, Letter to John C. Hart (June 5, 1986), at 4 (unpublished); see also *United States v. Louisiana-Pacific Corp.*, 967 F.2d 1372, 1376-77 (9th Cir. 1992) (“A decision to reopen does not necessarily entail a decision to modify the order. Reopening may occur even where the petition itself does not plead facts requiring modification.”).

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requires such action.¹⁵ Thus, Section 2.51 of the Commission's Rules of Practice and Procedure, as amended, invites respondents in petitions to reopen to show how the public interest warrants the modification. In the case of a request for modification based on public interest grounds, a petitioner must make a *prima facie* "satisfactory showing" of a legitimate public interest reason or other reasons justifying the requested modification.¹⁶ In this instance, however, we do not need to assess the sufficiency of Petitioners' public interest showing because Petitioners have made the requisite satisfactory showing that changed conditions of fact require the Order to be reopened and set aside as to Duke Energy.

The record shows that in January 2007, Duke Energy divested most of its natural gas business to Spectra Energy.¹⁷ As a result of that transaction, Duke Energy no longer has any gas gathering or processing assets in the relevant markets.¹⁸ Spectra Energy, through its counsel, has acknowledged and agreed that it would continue to comply with the obligations of the Order as Duke Energy's successor to the requirements of the Order.¹⁹ Further, Duke Energy has stated that it has no present intention to re-enter the relevant markets.²⁰

The exit of Duke Energy from the relevant markets eliminates the continuing need for the Order's remaining requirements to apply

¹⁵ See *United States v. Louisiana-Pacific Corp.*, 967 F.2d at 1376-77.

¹⁶ See Requests to Reopen, Supplementary Information, 65 Fed. Reg. 50,636, 50,637 (Aug. 21, 2001) *amending* 16 C.F.R. § 2.51(b).

¹⁷ See Petition at Appendix 3 (Spectra Energy News Release).

¹⁸ Declaration of Marc Manly at ¶ 5 (Appendix 4 to Petition) ("Manly Declaration"); Declaration of Brent Backes at ¶ 5 (Appendix 5 to Petition).

¹⁹ See *also* Petition at 2.

²⁰ Manly Declaration, at ¶ 6.

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to Duke Energy, and, thus, is a changed circumstance sufficient to support the setting aside of the Order as to Duke Energy.²¹ Setting aside Paragraph IV and V of the Order (the prior notification requirement) as to Duke Energy is also consistent with the *Statement of the Federal Trade Commission Policy Concerning Prior Approval and Prior Notice Provisions*, issued June 21, 1995 (“Prior Approval Policy Statement”).²² There is no evidence that a prior notification provision is needed as to Duke Energy as Duke Energy does not own any gas gathering and processing assets in the relevant markets identified in the Order.

Accordingly, **IT IS ORDERED** that this matter be, and it hereby is, reopened; and that the Commission’s Order issued on May 5, 2000, be, and it hereby is, set aside as to respondent Duke Energy as of the effective date of this Order, but will continue in effect with respect to Duke Energy’s successor Spectra Energy and with respect to the other respondents.

By the Commission, Commissioner Rosch recused.

²¹ *Koninklijke Ahold, N.V.*, Dkt. No. C-4027, Order Reopening and Modifying Order (July 10, 2007) (“Bruno’s no longer owns or operates supermarkets in Baldwin and Washington Counties, Georgia, the relevant areas that are the subject of the Order’s remaining operative provisions.”); *Koninklijke Ahold, N.V.*, Docket No. C-4027, Order Reopening and Modifying Order (July 21, 2006) (“Ahold no longer owns or operates supermarkets in Baldwin and Washington Counties, Georgia, the relevant areas that are subject of the Order’s remaining operative provisions”). See also *Entergy Corporation, et al.*, Docket No. C-3998, Order Reopening and Setting Aside Order (July 1, 2005) (“the factual premise underlying the concerns that led to entry of the Order, . . . arose specifically from the acquisition of Entergy’s ownership interest in Gulf South. . . . The sale of Gulf South constitutes a substantial change that eliminates the continuing need for the Order’s requirements”); *Union Carbide Corporation*, 108 F.T.C. 184 (1986) (order modified because respondent had clearly exited a business covered by the order and had demonstrated it had no intention of re-entering the business).

²² 60 Fed. Reg. 39,745-47 (August 3, 1995); 4 Trade Reg. Rep. (CCH) ¶ 13,241, at 20,991 (June 21, 1995).

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IN THE MATTER OF

**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.**

Docket No. C-4174. Order, September 26, 2007

Letter approving the petitions of SCI to divest certain assets to O'Hair & Riggs Funeral Services, Inc., Ivers & Alcorn Atwater Funeral Services, Inc., and Ivers & Alcorn Merced Funeral Services, Inc.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestitures to O'Hair & Riggs Funeral Services, Inc. ("ORFS"), filed by Service Corporation International ("SCI") and received on June 8, 2007 ("Petition"), and the Petition for Approval of Proposed Divestitures to Ivers & Alcorn Atwater Funeral Services, Inc. ("I&AAFS") and Ivers & Alcorn Merced Funeral Services, Inc. ("I&AMFS"), filed by SCI and received on June 18, 2007. Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to ORFS, I&AAFS, and I&AMFS.

After consideration of SCI's Petitions and other available information, the Commission has determined to approve the proposed divestitures as set forth in both of these Petitions. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI, ORFS, I&AAFS, and I&AMFS in connection with SCI's Petitions and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

**PAUL L. FOSTER,
WESTERN REFINING, INC.,
AND
GIANT INDUSTRIES, INC.**

Docket No. 9323. Order, October 2, 2007

Order returning this matter to adjudication for the purpose of dismissing the complaint in light of the district court's refusal to grant a preliminary injunction enjoining the merger of Western Refining and Giant Industries.

**ORDER RETURNING MATTER TO ADJUDICATION AND
DISMISSING COMPLAINT**

On June 7, 2007, the Secretary issued an Order withdrawing this matter from adjudication pursuant to Rule 3.26(c) of the Commission Rules of Practice, 16 C.P.R. § 3.26(c) (2007) --and staying all proceedings before the Chief Administrative Law Judge-- in order to permit the Commission to assess the public interest in further litigation, and to allow the Respondents and Complaint Counsel the opportunity to discuss the matter with the Commission. For the reasons discussed in the attached Statement of the Commission, the Commission has now determined to return this matter to adjudication for the sole purpose of dismissing the complaint. Accordingly,

IT IS ORDERED that this matter be, and it hereby is, returned to adjudication; and

IT IS FURTHER ORDERED that the complaint in this matter be, and it hereby is, dismissed.

By the Commission, Commissioner Harbour and Commissioner Rosch dissenting.

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**STATEMENT OF THE COMMISSION CONCERNING
DISMISSAL OF THE ADMINISTRATIVE COMPLAINT**

As the Commission has stated repeatedly, no other industry's performance is more deeply felt than that of the petroleum sector, and no other industry is more carefully scrutinized by the FTC.¹ The Commission's vigorous efforts to identify, prosecute, and prevent unlawful anticompetitive mergers and practices in the oil industry are longstanding and ongoing.

The Commission brought this case as part of that effort. On May 29, 2007, however, following a four and one-half day hearing and consideration of the evidence presented, the United States District Court for the District of New Mexico denied the Commission's Petition for a Preliminary Injunction to enjoin the merger of two petroleum industry companies, Western Refining, Inc. and Giant Industries, Inc.² The Commission now faces the difficult decision whether to remand this matter for further administrative proceedings or to dismiss the complaint. If the only consideration were whether we agree with the district court's decision and reasoning, we would remand. As our colleagues explain in their dissenting statement, the district court made a number of questionable findings. Here, as in all cases that staff files, before authorizing the district court complaint, the Commission determined that it had reason to believe that the effect of the defendants' proposed merger "may be substantially to lessen competition, or to tend to create a monopoly."³ But the Commission must account for factors beyond disagreement with the district court's decision. After weighing all relevant factors -

¹ E.g., Prepared Statement of the Federal Trade Commission, *Petroleum Industry Consolidation*, presented by Dr. Michael A. Salinger, Director, Bureau of Economics, Federal Trade Commission, before the Joint Economic Committee, United States Congress (May 23, 2007), available at: <http://www.ftc.gov/os/testimony/070523PetroleumIndustryConsolidation.pdf>.

² *FTC v. Foster*, 2007 WL 1793441 (D.N.M. Apr. 29, 2007) (public version).

³ 15 U.S.C. § 18.

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and recognizing that this is a close call - we conclude that continuing to pursue the case would not be in the public interest, as required by Commission Rule 3.26(d).⁴ Accordingly, the Commission has determined to dismiss the complaint in this matter, rather than to remand for further proceedings.

**THE PUBLIC INTEREST STANDARD OF COMMISSION
RULE 3.26(D)**

Commission Rule 3.26(d)⁵ directs that, following the denial of a preliminary injunction, further administrative proceedings should not be pursued if “the public interest does not warrant further litigation.”⁶ Although the rule itself does not set out what constitutes the “public interest,” the Commission Policy Statement issued contemporaneously explains the Commission’s intent. It provides five factors that the Commission considers in determining whether to dismiss an administrative complaint after unsuccessfully seeking a preliminary injunction: (1) the factual findings and legal conclusions of the district court or any appellate court; (2) any new evidence developed during the course of the preliminary injunction proceeding; (3) whether the transaction raises important issues of fact, law, or merger policy that need resolution in administrative proceedings; (4) an overall assessment of the costs and benefits of further proceedings; and (5) any other matter that bears on whether it would be in the public interest to proceed with the merger challenge.⁷ These factors are applied on a case-by-case basis.⁸

⁴ 16 C.F.R. § 3.26(d).

⁵ 16 C.F.R. § 3.26(d).

⁶ Policy Statement Regarding Administrative Merger Litigation Following the Denial of a Preliminary Injunction (Jun. 21, 1995), *republished at* 60 Fed. Reg. 39741, 39742 (Aug. 3, 1995) (“Policy Statement”).

⁷ 60 Fed. Reg. at 39743.

⁸ *Id.*

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1. The Factual Findings and Legal Conclusions of the District Court

Although this matter was litigated in a short period of time, the district court received into evidence live testimony as well as numerous documents, declarations, and deposition transcripts. In a fact-intensive, 116-page opinion, the district court found that the Commission, based upon a concentration level that was on the low end of the highly concentrated range of the Merger Guidelines, made only a “weak” *prima facie* case that the defendants then rebutted.⁹

We do not agree with the district court’s view of the facts of this case. We believe that the factual and legal showing that the FTC made before the district court at least should have persuaded that court to conclude that our staff had “raised questions going to the merits so serious, substantial, difficult and doubtful as to make them fair ground for thorough investigation, study, deliberation and determination by the FTC in the first instance and ultimately by the Court of Appeals.”¹⁰ Furthermore, we agree with the dissenting Commissioners that the court made numerous factual and legal errors that contributed to what we believe was an erroneous decision. These are not, however, the only issues to be considered under this factor of the Policy Statement.

Because an important benefit from administrative litigation is the creation of an enhanced record, it is essential to understand whether the court’s errors resulted from a flawed record or simply from a mistaken view of a sufficient record. Before the Commission engages in potentially lengthy and resource-intensive administrative litigation in this context, there must be support for the conclusion that the additional expense will improve the

⁹ *Foster*, 2007 WL 1793441 at *28, ¶ 264; *55-*56, ¶¶ 20-22, 28.

¹⁰ *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 715 (D.C. Cir. 2001) (quoting *FTC v. Beatrice Foods Co.*, 587 F.2d 1225, 1229 (D.C. Cir.1978) (Appendix to Statement of MacKinnon & Robb, JJ.).

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evidentiary record. That does not appear to be the case here. In particular, it does not appear that the record before the district court was deficient in any serious respect. The record before the district court, although short of a fully developed trial record, is extensive, and it does not appear that the Commission was prevented from presenting any important evidence regarding the potential impact of the merger.

2. New Evidence Developed During the Course of the Preliminary Injunction Proceeding

As is often the case, some new facts came to light during discovery leading to the preliminary injunction hearing; in this case, the new information militates against continuing in administrative litigation. For example, new information suggests that the Plains Pipeline, which runs from El Paso, Texas to Albuquerque, New Mexico, may begin work on a capacity expansion project more quickly than previously thought.¹¹ A cornerstone of FTC staff's case at the hearing was that the Plains Pipeline was capacity-constrained and fully utilized, preventing some competitors and potential competitors from being able to respond to an anticompetitive post-merger price increase by Western. If, as appears likely, the Plains Pipeline expansion leads to increased gasoline supply and allows new bulk suppliers to deliver gasoline to the Albuquerque area, we would expect more competition and lower gasoline prices in Northern New Mexico, notwithstanding the merger.

¹¹ *Foster*, 2001 WL 1793441 at *36, ¶¶ 341-43.

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3. Whether the Transaction Raises Important Issues of Fact, Law, or Merger Policy That Need Resolution in Administrative Proceedings

The transaction does not raise important issues of fact, law, or merger policy that need resolution in administrative proceedings. The district court's preliminary injunction ruling was highly fact-driven, and its discussion of the law generally did little more than recite established principles of competition law. The district court's opinion, therefore, should have little precedential value beyond the specific facts of this case.

As the dissenting Commissioners' statement notes, the district court's opinion referred three times to matters that should have no weight in merger adjudications. We doubt, however, that these flaws made a difference in the court's analysis or materially limit the Commission's ability to prosecute merger cases in the future.

First, in assessing whether Western was a competitor in the Northern New Mexico bulk gasoline supply market despite its neither owning nor having long-term access to a terminal there, the court cited to "inconsistencies" between the Commission's position on terminals in the case before it and the Commission's position with respect to terminals in *Aloha Petroleum*¹² and in the Commission's Bureau of Economics' August 2004 study entitled, *The Petroleum Industry: Mergers, Structural Change and Antitrust Enforcement*.¹³ In *Aloha*, the Commission asserted a narrow bulk supply market that included only local indigenous refiners, terminal operators, and firms with long-term contractual access to terminals. For its part, the section of the FTC staff economists' report cited by the court merely states that terminal access is one possible "factor" in determining whether a bulk supplier is a competitor in a particular geographic market.¹⁴

¹² *FTC v. Aloha Petroleum*, No. CV 05-00471 (D. Haw. 2005).

¹³ *Foster*, 2007 WL 1793441 at *18-19, ¶¶ 173-81.

¹⁴ Federal Trade Commission, Bureau of Economics, *The Petroleum Industry*:

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Although we disagree with the court's characterizations of such positions as inconsistent with those taken in *Foster*, that is beside the point. In fact, the terminal issue ultimately was not significant in *Foster* because the court concluded that - even without terminal access - Western was a bulk supply competitor to Giant.¹⁵ Nevertheless, we note that the court's reliance on *Aloha* and the FTC staff economists' report in this context was improper because, while courts and agencies follow established antitrust principles, the bases for challenging mergers are individual and highly fact-specific.

Second, in one passage of its opinion, the district court noted that the Commission's 2006 report to Congress entitled *Gasoline Price Manipulation and Post-Katrina Gasoline Price Increases* concluded that the Commission staff had found no evidence of collusion in the petroleum industry in general, and no specific evidence of collusion in the Albuquerque market.¹⁶

We believe that the Court erred in treating this part of the report as support for its conclusion that the merger should not be enjoined. As stated above, a merger challenge must be decided on the facts of each case. In contrast, a report to Congress such as the *Gasoline Price Manipulation* report provides a broad evaluation of the competitive conditions in numerous markets at a particular time. Such a report generally does not analyze the potency of particular competitors or post-merger combinations of competitors in particular defined antitrust markets. As a result, the *Gasoline Price Manipulation* report provides no probative insight as to how the merger of Giant and Western would affect the Northern New

Mergers, Structural Change, and Antitrust Enforcement (Aug. 2004) 23-24, available at <http://www.ftc.gov/os/2004/08/040813mergersinpetrolberpt.pdf>.

¹⁵ *Foster*, 2007 WL 1793441 at *18, ¶ 172.

¹⁶ *Id.* at *49, ¶ 457.

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Mexico market, either in 2007 or in the years to come. Because the court separately found that the Commission did not present any evidence that coordinated behavior between competitors existed in the Albuquerque market or would exist prospectively post-merger,¹⁷ however, we do not believe that consideration of the *Gasoline Price Manipulation* report was dispositive.

Third, the district court's opinion referred to Bureau of Economics working papers analyzing some oil company transactions that the Commission did not challenge, as well as to a summary of Commission horizontal merger investigation data indicating that the Commission has not challenged any "8 to 7" mergers since 2001.¹⁸ We agree with our dissenting colleagues that this is not evidence that the Western/Giant merger was not anticompetitive. The transactions analyzed in the working papers were based on the specific facts of those transactions. The observation concerning the Commission's decision not to challenge relatively recent "8 to 7" mergers is too generalized to provide guidance on the specific facts of this case. Viewed in context, however, the court used these working papers and the merger investigation data simply to bolster its point that the Commission's *prima facie* showing was "weak," as the court had already independently concluded without reference to these materials.¹⁹

In addition, the dissenting Commissioners are concerned that the court's ruling establishes conclusively that the elimination of a "maverick" cannot violate merger law unless the transaction would increase the likelihood of coordinated conduct by the remaining competitors in the market. At the time the Commission authorized its staff to file a complaint in district court, we believed that the evidence suggested that an independent Giant, as the output at its Four Corners refineries rose, would increase the amount of gasoline that it would supply to the Northern New Mexico market,

¹⁷ *Id.* at *48, ¶¶ 454-56

¹⁸ *Id.* at *29, ¶¶ 268-71.

¹⁹ *Id.* at *28, ¶ 264; *see also id.* at *55-56, ¶¶ 20-21.

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and that this likely would cause gasoline prices in this market to decrease. Giant, thereby, would act as a maverick as that term is used in the Merger Guidelines.²⁰

The district court, however, found that defendants presented substantial evidence that an independent Giant would have used part of its additional output to reduce the amount that it purchased for resale in this market - leaving its supply to the market roughly constant - and would have sent its remaining additional output to other markets more profitable than Northern New Mexico.²¹ We disagree with the dissenting Commissioners that the district court, on the facts presented, reached any conclusion other than that an independent Giant would not have acted as a maverick to thwart the coordinated anticompetitive behavior of its competitors.²² The district court did not address, much less resolve, the more general legal question of whether a competitor unilaterally can act as a maverick even in the absence of coordinated behavior by its competitors.

In sum, the court's anomalous references to and conclusions about Giant's likely behavior should not establish discernable rules of law that could serve as precedent for future merger analysis. Moreover, we note that there are many established, well-reasoned, and well-articulated recent merger cases, to which courts considering future merger challenges by the Commission may look for guidance.²³

²⁰ United States Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines* (Apr. 8, 1997 rev.) at § 2.12, available at <http://www.usdoj.gov/atr/public/guidelines/hmg.htm>.

²¹ *Foster*, 2007 WL 1793441 at *44-45, ¶¶ 425-27, 429, 435, 438.

²² See *Foster*, 2007 WL 1793441 at *49, ¶ 458.

²³ E.g., *Heinz*, *supra*; *FTC v. Swedish Match*, 131 F. Supp. 2d 151 (D.D.C. 2000); *FTC v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34 (D.D.C. 1998); *FTC v. Staples, Inc.*, 970 F. Supp. 1066 (D.D.C. 1997).

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4. Overall Assessment of the Costs and Benefits of Further Proceedings

The use of *FTC* resources is always an important consideration in determining whether to continue in administrative litigation. Further administrative proceedings will consume significant Commission resources. In appropriate situations, the Commission should expend those resources. The modern history of the FTC's competition programs underscores the Commission's willingness to apply substantial resources to cases and studies involving gasoline and other energy markets.

In this matter, the Commission devoted considerable resources to assessing the competitive effects of the Western/Giant merger and - after concluding that it was likely to substantially lessen competition - to proving this harm. Given the district court's finding that the Commission failed to define a geographic market,²⁴ and its negative assessment of our two experts' analyses,²⁵ we believe that an administrative proceeding would require substantially more resources, which should instead be reallocated to new competition matters, including in particular other gasoline matters.

5. Other Matters That Bear on Whether It Would Be in the Public Interest to Proceed with the Merger Challenge

The fact that the merger of Western and Giant has combined two petroleum refining companies necessitates that the Commission give the matter the utmost scrutiny in determining whether further administrative proceedings are in the public interest.²⁶ Indeed, the Commission's authority to pursue an

²⁴ *Foster*, 2007 WL 1793441 at *40-43, ¶¶ 386-415.

²⁵ *Id.* at *17-18, ¶¶ 160-71.

²⁶ The FTC's aggressive enforcement stance is evident in the results of a review of merger investigation data that the agency released last January. From fiscal year 1996 to fiscal year 2005, the Commission brought more merger cases at lower levels of concentration in the petroleum industry than in any other industry.

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administrative proceeding after the denial of a preliminary injunction by a district court is an important and potent tool. But, due to the significant ramifications to both the Commission and the Respondents that arise in such situations, it is crucial that the Commission exercise this authority judiciously. We conclude that this is not an appropriate case in which to continue administrative litigation following the district court's denial of the Commission's request for a preliminary injunction.

For all of the foregoing reasons, the Commission has determined to issue the attached Order dismissing the administrative complaint in this matter.

Unlike in other industries, the Commission has brought enforcement actions (and, in many cases, has obtained merger relief) in petroleum markets that are only moderately concentrated. Federal Trade Commission Horizontal Merger Investigation Data, Fiscal Years 1996-2005 (Jan. 25, 2007), Table 3.1, *et seq.*, available at <http://www.ftc.gov/os/2007/01/P035603horizmergerinvestigationdata1996-2005.pdf>; see also FTC Horizontal Merger Investigations Post-Merger HHI and Change in HHI for Oil Markets, FY 1996 through FY 2003 (May 27, 2004), available at <http://www.ftc.gov/opa/2004/05/040527petrolactionsHHIdeltachart.pdf>.

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**DISSENTING STATEMENT OF COMMISSIONER
PAMELA JONES HARBOUR AND COMMISSIONER J.
THOMAS ROSCH**

We would submit to a Part 3 plenary trial complaint counsel's claim that this transaction violated Section 7 because it eliminated Giant as a potential maverick who had the ability and intent to reduce gasoline prices in Albuquerque.¹

First, we emphatically reject the district court's conclusion that even assuming Giant increased supply to Albuquerque as a result of its new crude oil source (as Giant represented to state and local officials that it would do in order to secure their approval for that plan),² that expansion would have had a *de minimus* effect on Albuquerque gasoline prices.³ There is substantial evidence that the loss of Giant's incremental production would cost Albuquerque

¹ Giant's ability and willingness to increase gasoline supply to Albuquerque and Santa Fe, despite causing lower prices, makes it a "maverick" in antitrust terms. *See* U.S. Dep't of Justice & Federal Trade Comm'n, Horizontal Merger Guidelines § 2.12 (1992) *reprinted in* 4 Trade Reg. Rep. (CCH)13,104 ("Horizontal Merger Guidelines").

² *See* Federal Trade Commission v. Foster, et al., 2007-1 Trade Cas. (CCH) ¶ 75,670 (D.N.M. 2007) (In granting the Commission's TRO motion, the court noted that "The FTC's Exhibit 5 is styled 'New Mexico Crude Oil Pipeline Fact Sheet' and indicates that Giant prepared the document. The document indicates that Giant believes additional product marketed to Albuquerque and Santa Fe will spur price competition. The fact sheet states: 'Price Competition. Additional production of petroleum products will help spur price competition in northern New Mexico markets, including Albuquerque and Santa Fe.' Exhibit 5."); *see also* Wendy Brown, The Whys Behind the 'Highs', Santa Fe New Mexican, May 7, 2006 ("Gould said gasoline prices are currently higher in northwest New Mexico because both of Giant's refineries are running at 50 percent capacity.").

³ *See* Federal Trade Commission v. Foster et al., 2007-1 Trade Cas. (CCH) ¶ 75,725, *80 (D.N.M. 2007) (Finding of Fact ¶ 286 "The amount of gasoline that the FTC alleges would be diverted from Albuquerque is small and would have little or no significant impact on price. *See id.* at 881:11-15 (Stevens).") Finding of Fact ¶ 287 "The Court does not believe these few additional barrels will significantly impact the market, or reduce the price as much as the FTC projects.").

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consumers millions of dollars annually. In this sensitive area of the economy that is a substantial injury to consumers.

Second, we also reject the district court's view that, as a matter of law, the elimination of a maverick cannot violate Section 7 unless the transaction would enhance the likelihood of coordinated conduct by the remaining competitors in the market.⁴ No court has ever held that the elimination of a maverick is only a concern in coordinated effects cases, and there is no support for that conclusion in the language of Section 7. To be sure, the Horizontal Merger Guidelines treat the elimination of a maverick as most apt to cause anti-competitive effects when the maverick would disrupt coordination among competitors in a highly concentrated market.⁵ However, the Guidelines do not say those are the only circumstances in which the elimination of a maverick may increase prices significantly. Indeed, as the Commentary to the Merger Guidelines make clear "the Guidelines were never intended to detail how the Agencies would assess every set of circumstances that a proposed merger may present. As the Guidelines themselves note, the specific standards set forth therein must be applied to a broad range of possible factual circumstances."⁶

⁴ See Foster, 2007-1 Trade Cas. (CCH) ¶ 75,725, *124 (Finding of Fact ¶ 458 "Under the Merger Guidelines, the concept of a maverick is used in cases premised on tacit or coordinated behavior to describe competitors that, because of structural conditions or unique incentives, can prevent or limit anti-competitive coordinated interaction by other firms and 'are unusually disruptive and competitive influences in the market.' Defendants' Hearing Exhibits, CG at § 2.12. The FTC has not, however, presented evidence of past competitor coordination or the ability of firms to coordinate in the future.").

⁵ See *supra* note 1, Horizontal Merger Guidelines § 2.12.

⁶ FED. TRADE COMM'N AND U.S. DEP'T OF JUSTICE, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES, at p.3 (2006), available at <http://www.ftc.gov/os/2006/03/CommentaryontheHorizontalMergerGuidelinesMarch2006.pdf>.

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Third, these fundamental errors are compounded by the court's references to prior Commission actions and inactions vis-a-vis the petroleum industry. For example, the court infers that competitive effects are unlikely from the Commission's decisions not to challenge two prior refiner mergers that court said were similar.⁷ That is error both as a matter of fact and as a matter of law. Even if one were to assume that the market conditions in those earlier cases were similar to those in northern New Mexico, there is no evidence that the acquired party was a putative maverick in either of the earlier cases.⁸ Moreover, and most fundamentally, as a matter of law no inference respecting the legal merits of the agency's legal challenge in this matter can be drawn from an exercise of its discretion not to challenge other transactions.⁹

⁷ See Foster, 2007-1 Trade Cas. (CCH) ¶ 75,725, *73-74 (Finding of Fact ¶ 268 "While Professor White's concentration analysis satisfies the minimum levels set out in the Merger Guidelines, his findings, based on recent studies by the FTC and the FTC's recent enforcement record, do not appear to represent substantial proof of anti-competitive effect. For example, two FTC Bureau of Economics working papers analyzed two petroleum industry mergers that the FTC did not challenge to determine whether the mergers adversely affected gasoline prices and consumers. See Defendants' Hearing Exhibits, CV (Economic Effects of the Marathon-Ashland Joint Venture, dated May 7, 2007); Defendants' Hearing Exhibits, CW (Michigan Gasoline Pricing and the Marathon-Ashland and Ultramar Diamond Shamrock Transaction, dated July 2005).").

⁸ See John Simpson and Christopher T. Taylor, Michigan Gasoline Pricing and the Marathon-Ashland and Ultramar Diamond Shamrock Transaction, at p. 5 (July 2005) available at <http://www.ftc.gov/be/workpapers/wp278.pdf> ("Given the environment described above, MAP's acquisition of UDS's Michigan gasoline stations could lead to higher prices in several ways: The acquisition could eliminate localized competition between gasoline stations supplied by MAP and gasoline stations supplied by UDS; the acquisition could also facilitate coordinated interaction by reducing the number of competitors; and the acquisition could lead to higher prices by prompting the combined firm to restrict access to its terminals thereby raising the costs of its independent rivals."); John Simpson and Christopher T. Taylor, The Economic Effects of the Marathon-Ashland Joint Venture: The Importance of Industry Supply Shocks and Vertical Market Structure (May 7, 2004) available at <http://www.ftc.gov/be/workpapers/wp270.pdf>.

⁹ See, e.g., *United States v. Cinemette Corp. of Am.*, 687 F. Supp. 976, 982 (W.D. Pa. 1988) ("[T]he government is under no obligation to pursue a history of

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Conversely, the district court implied that the Court's inclusion of Western as a competitor was inconsistent with the position it took in *FTC v. Aloha Petroleum* that terminal ownership was critical to competition in bulk supply of gasoline in Oahu.¹⁰ That compares apples and oranges too. Even assuming that the market conditions in Oahu and Albuquerque were similar, the challenge here was not focused on Western's acquisition of Giant's Albuquerque terminal but on the elimination of Giant as a potential maverick in the northern New Mexico market. Beyond that, again as a matter of law, the Commission's exercise of prosecutorial discretion - this time to challenge the terminal acquisition in Aloha - creates no inference respecting the merits of its challenge in this case.¹¹

Indeed, the district court even drew an inference that anticompetitive effects were unlikely here from the Commission's Report to Congress as to whether "price-gouging" occurred in the wake of Hurricane Katrina.¹² That report had nothing to do with

civil enforcement proceedings in a particular industry in advance of bringing criminal prosecutions for anti-competitive conduct.").

¹⁰ See Foster, 2007-1 Trade Cas. (CCH) ¶ 75,725, *46-48 (Finding of Fact ¶ 174 "In *Aloha Petroleum*, the FTC asserted a narrow bulk supply market that included only local indigenous refiners, terminal operators, and firms with long-term contractual access to terminals. The FTC represented to the United States District Court for the District of Hawaii that access to a local product terminal was indispensable to bulk supply competition. "[O]wnership of a [local] refinery or ownership of, or unfettered access to, a terminal on Oahu is necessary to make a bulk sale of gasoline." Defendants' Hearing Exhibits, CK (Petroleum: Plaintiffs' Aloha Proposed Findings of Fact) ¶ 21, at 11.)").

¹¹ See *supra* note 9.

¹² See Foster, 2007-1 Trade Cas. (CCH) ¶ 75,725, *124 (Finding of Fact ¶ 457 "In 2006, the FTC represented to Congress that the bulk petroleum supply markets within the United States were operating in a competitive manner. See Defendants' Hearing Exhibits, EJ (FTC, Investigation of Gasoline Price Manipulation and Post-Katrina Gasoline Price Increases, dated Spring 2006) at vi. To support its investigation, the FTC analyzed a large volume of wholesale and retail pricing

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Giant's unique incentives in the northern New Mexico market or whether this transaction violated Section 7 by eliminating Giant as a potential maverick. It was concerned with whether there was questionable pricing (as defined by the authorizing legislation) by refiners or retailers in the wake of Katrina. Using (or, more accurately, misusing) that Report to ascertain the likelihood of success in this merger case goes beyond drawing illegitimate inferences from exercises of prosecutorial discretion. It has the potential to chill the kind of unfettered communication that Congress -and the public -expect from this agency.

Fourth, these errors cannot be shrugged off as harmless dicta. The district court would not have included them in his opinion if he did not consider them relevant to his ultimate ruling denying the preliminary injunction. Moreover, it is hard to explain the numerous anomalies in the court's opinion on any other basis. For example, the court seemed to opine at one point that Western did not even compete with Giant before the merger.¹³ That conclusion was apparently influenced by the court's finding that Western did not have rights to an Albuquerque terminal.¹⁴ Although the court reversed itself in this regard,¹⁵ the court's doubts on this score are apparent.

Similarly, the district court took complaint counsel's economic expert to task for not considering alternatives to his relevant geographic market and even opined at one point that he did not

data, including data on gasoline prices in the Albuquerque area. See *id.* at v, 95-96, 125, 131, 134, 136. The FTC's investigation concluded that there was no evidence suggesting that any refiner was manipulating prices by any of the means the FTC's staff investigated. See *id.* at viiii.”).

¹³ Foster, 2007-1 Trade Cas. (CCH) ¶ 75,725, *53 (Finding of Fact ¶ 195 “[t]he FTC has not provided evidence that Western and Giant compete in the relevant market.”).

¹⁴ For example, the court noted in finding of fact 178 that “[w]ithout its own terminal in Albuquerque, Western can only deliver gasoline over the Plains pipeline with the consent of its existing customers.” *Id.* *49.

¹⁵ *Id.* *50 (Finding of Fact ¶ 182 “Giant and Western are competitors”).

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support any relevant geographic market.¹⁶ However, the expert defined the relevant geographic market in accordance with the Horizontal Merger Guidelines, which provide that alternatives need not be considered once the SSNIP test is satisfied.¹⁷ Again, the court ultimately reversed himself, holding that the record established a relevant geographic market.¹⁸ Indeed, the court found that complaint counsel established a prima facie case that the transaction would likely result in anti-competitive effects in the

¹⁶ The court's found that "[t]he FTC's economic expert did not endorse the relevant geographic market alleged in the FTC's Complaint. Instead, he defined a different geographic market: the Albuquerque MSA, which encompasses four counties." Id. *44 (Finding of Fact ¶ 163).

¹⁷ See *Federal Trade Commission v. Foster et al.*, Trial Transcript at 550:13-551:14 (May 9, 2007). Testimony of Dr. Hal White:

A: My conclusion was that the relevant antitrust market is the supply of bulk delivery of gasoline in the Albuquerque MSA.

Q: Did you look at other candidate markets?

A: I didn't have time or data to look at other candidate markets. Instead, I found that was a -- I'm not saying it was the only, but it was a relevant product in geographic market for this study.

//

Q: And how does -- How does finding a relevant market square with your understanding of the [Guidelines]

A: My understanding is that once one finds a relevant market one can then proceed to analyze the likely antitrust impact in that market.

¹⁸ "While the Court agrees with the FTC that the relevant geographic market is limited to firms that provide bulk supply in northern New Mexico, the FTC's proposed market does not include all current suppliers of bulk supply of gasoline to Albuquerque." See *Foster*, 2007-1 Trade Cas. (CCH) ¶ 75,725, *144-45 (Conclusion of Law ¶ 23).

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market for gasoline in northern New Mexico.¹⁹ However, having done so and despite recognizing that respondents had the burden of producing evidence to dispel that presumption, the court engaged in a relatively uncritical analysis of respondents' evidence.

For example, the district court concluded that Giant was unlikely to act as a maverick because it believed it would have been contrary to Giant's self-interest to do so.²⁰ The court not only dismissed Giant's internal planning documents in reaching that conclusion but it also ignored the representations that Giant made to governmental officials and the press about its intentions to increase price competition for gasoline sales in Albuquerque. In contrast, the court concluded that, if Western diverted Giant's incremental production to other markets instead of distributing it in Northern New Mexico post-transaction, Flying J and/or other suppliers would have trucked enough extra gasoline in from Texas to make up the difference.²¹ That conclusion, however, was contrary to the logic of the court's earlier conclusion: if it made no sense for Giant to act as a maverick, it would make no sense for Flying J to do so (especially since, as the court elsewhere recognized, the cost of trucking gasoline from Texas generally

¹⁹ *Id.* *146 (Conclusion of Law ¶ 127 "The FTC attempted to establish a likelihood of success on the merits by submitting evidence demonstrating that the proposed merger would have an anti-competitive impact through unilateral effects. The Court finds that the FTC made a prima facie showing that the market is presently concentrated and that the proposed merger would result in an increase in market concentration.").

²⁰ *Id.* *117 (Finding of Fact ¶ 438 "Chasing customers in Albuquerque at a deep discount-- as the FTC asserts Giant will do -- is inconsistent with Giant's business practices. Giant seeks to sell its refinery production, not to resell products that others refine. *See* Hearing Transcript at 845:1-4 (Matthew)("I'm in the refining business."). Giant has no economic incentive to purchase product from Western at market prices and then resell the same barrels at a discounted price. *See id.* at 973:17-19 (Kalt)").

²¹ *Id.* *35-37 (Finding of Fact ¶ 135-141 discussing the ability of Flying J and other firms to truck gasoline to the Albuquerque market from Texas).

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made that supposed alternative unfeasible).²² Similarly, the court concluded that existing suppliers such as Holly, ConocoPhillips, and Valero had the same incentives as Giant to act as a maverick in the relevant market. However, the court failed to explain their incentives to ship additional amounts of gasoline in the market or address the undisputed fact that those refiners had historically failed to increase their shipments to the market in response to sustained price increases.²³

The district court's analysis of the incentives of the other suppliers to act as a maverick in the relevant market was flawed. It focused on whether entry or expansion was possible, not on whether it was profitable or likely.²⁴ For example, the court cited the fact that firms were already trucking into the market to support his conclusion that these firms could discipline future price increases post-merger. Yet the court did not analyze the relative costs of these various producers. In this market the marginal suppliers were those who could truck product into the market. Giant's location placed it in a unique position to serve this market—the geographic proximity of its refineries to the northern New Mexico market gave it a cost advantage over other firms trucking product. That gave it a greater ability-and incentive-to discipline a price increase or in the alternative disrupt the market equilibrium than those other firms.

²² *Id.* at *37 (Finding of Fact ¶ 141 “For Flying J, the added costs of trucking product are eight cents per gallon when trucking to Albuquerque from El Paso, and ten to thirteen cents per gallon when trucking from El Paso to Phoenix or to Tucson. Additional costs place Flying J at an economic and competitive disadvantage relative to firms transporting from and to the same locations via pipeline. See Plaintiff’s Hearing Exhibits, PX04011 (Declaration of J. Phillip Adams, executed April 26, 2007) ¶ 8, at 2.”)).

²³ *Id.* at *82-83 (discussing ConocoPhillips), *87 (discussing Valero).

²⁴ *See supra* note 1, Horizontal Merger Guidelines § 3 (“Entry is easy if entry would be timely, likely, and sufficient in its magnitude, character and scope to deter or counteract the competitive effects of concern.”).

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Fifth, these flaws in the opinion of a distinguished federal district judge are not surprising. As Justice Ginsburg has observed, there is a vast difference between a preliminary injunction hearing and a plenary trial. The former is necessarily truncated and is followed by issuance of an opinion that must be crafted quickly out of fairness to the parties.²⁵ It is because of these differences and because of the paramount importance of “getting it right” when gasoline refinery mergers are at issue that we believe a full plenary trial, at which complaint counsel’s claim that this transaction threatened anti-competitive effects can be thoroughly analyzed, is warranted.

We consider such a plenary trial to be essential for several reasons. For one thing, regardless of how that trial was to come out, we are concerned with letting the district court’s flawed opinion stand as the last word in this case. Moreover, we have pledged vigorous merger enforcement in this area of the economy generally and with respect to refinery mergers specifically. We do not consider a preliminary injunction hearing to be any substitute for a plenary trial in this respect.

Finally, we know that a plenary trial requires the commitment of significant Commission resources. However, the Commission’s decision to issue the complaint was unanimous. Nothing in the district court’s opinion gives us reason to second-guess that decision.

²⁵ See *FTC v. Weyerhaeuser Co.*, 665 F.2d 1072, 1083 (D.C.Cir. 1981) (observing that the district court’s ruling in a preliminary injunction case “must be made under time pressure and on incomplete evidence” and “the risk of an erroneous assessment is therefore higher than it is after a full evidentiary presentation.”).

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IN THE MATTER OF

**EVANSTON NORTHWESTERN HEALTHCARE
CORPORATION**

AND

ENH MEDICAL GROUP, INC.*Docket No. 9315 Order, October 3, 2007*

Order granting Complaint Counsel's motion for an extension of the deadline for filing any objections or comments on Respondent's Proposed Final Order.

ORDER GRANTING MOTION FOR EXTENSION OF TIME

On August 2, 2007, the Commission issued an Order in this matter that, *inter alia*, requires Respondent Evanston Northwestern Healthcare Corporation to file with the Commission, on or before September 10, 2007, a detailed proposal for implementing the type of injunctive relief that the Commission has selected, as described by the Opinion of the Commission and the Commission Order; that requires Complaint Counsel to file with the Commission any objections to or comments on that proposal within thirty calendar days thereafter; and that requires Respondent to file any response to Complaint Counsel's filing within ten calendar days thereafter. On September 10, 2007, the Commission issued an Order granting Respondent an extension until September 17, 2007, by which to file its proposal, and Respondent filed its Submission In Explanation and Support of Its Proposed Final Order, and the Proposed Final Order itself, on that date.

Complaint Counsel have now filed a Motion requesting an extension of the deadline for filing any objections or comments on Respondent's Proposed Final Order from October 17, 2007, until October 29, 2007. Complaint Counsel advise that, as a consequence of previously-scheduled travel, lead Complaint Counsel will be out of the office until two days before the current filing deadline, and that

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an extension will permit a thorough review of Respondent's Proposed Final Order, and the preparation of objections and comments that may assist the Commission in developing a Final Order. Complaint Counsel further advise that Respondent does not oppose the Motion, provided that Respondent will still have ten days within which to file its response after Complaint Counsel effect their filing.

The Commission has determined to grant the Motion. Accordingly,

IT IS ORDERED that the deadline prescribed in the Sixth Ordering Paragraph in the Commission Order issued in this matter on August 2, 2007, be, and it hereby is, extended until October 29, 2007; and

IT IS FURTHER ORDERED THAT the deadline prescribed in the Seventh Ordering Paragraphs in the August 2, 2007 Order remains unchanged.

By the Commission.

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IN THE MATTER OF
**SERVICE CORPORATION INTERNATIONAL
AND
ALDERWOODS GROUP, INC.**

Docket No. C-4174. Order, December 19, 2007

Letter approving the petition of SCI to divest certain assets to Kent Care, LLC.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Mr. Schwartz:

This is in reference to the Petition for Approval of Proposed Divestitures to Kent Care, LLC (“Kent Care”) filed by Service Corporation International (“SCI”) and received on May 29, 2007 (“Petition”). Pursuant to the Decision and Order in Docket No. C-4174, SCI requests prior Commission approval of its proposal to divest certain assets to Kent Care.

After consideration of SCI’s Petitions and other available information, the Commission has determined to approve the proposed divestitures as set forth in the Petition. In according its approval, the Commission has relied upon the information submitted and the representations made by SCI and Kent Care in connection with SCI’s Petition and has assumed them to be accurate and complete.

By direction of the Commission.

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IN THE MATTER OF

**KYPHON, INC.,
DISC-O-TECH MEDICAL TECHNOLOGIES
LTD.,
AND
DISCOTECHORTHOPEDIC TECHNOLOGIES
INC.**

Docket No. C-4201. Order, December 19, 2007

Letter approving the petition of Kyphon, Inc. to divest the Confidence Assets to DePuy Spine, Inc.

COMMISSION LETTER APPROVING DIVESTITURE

Dear Ms. Feinstein:

This letter responds to the November 6, 2007, Petition of Kyphon Inc. For Approval of Proposed Divestiture (“Petition”) requesting that the Commission approve Kyphon’s divestiture of the Confidence Assets to DePuy Spine, Inc., a subsidiary of Johnson & Johnson (“DePuy”), pursuant to the order in this matter. The Petition was placed on the public record for comments for thirty days, until December 12, 2007, and no comments were received.

After consideration of the proposed transaction as set forth in the Petition and supplemental documents, as well as other available information, the Commission has determined to approve the divestiture of the Confidence Assets to DePuy. In according its approval, the Commission has relied upon the information submitted and representations made in connection with Kyphon’s Petition, and has assumed them to be accurate and complete.

By direction of the Commission, Commissioner Harbour and Commissioner Kovacic recused.

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IN THE MATTER OF

**HERBS NUTRITION CORPORATION
AND
SYED M. JAFRY***Docket No. 9325. Order, December 21, 2007*

Order granting Complaint Counsel's motion to withdraw the matter from adjudication to enable the Commission to consider a proposed consent agreement.

**ORDER WITHDRAWING MATTER FROM ADJUDICATION FOR THE
PURPOSE OF CONSIDERING PROPOSED CONSENT AGREEMENT**

Complaint Counsel having moved that this matter be withdrawn from adjudication to enable the Commission to consider a proposed Consent Agreement; and

Complaint Counsel having submitted a proposed Consent Agreement containing a proposed Order, executed by the Respondents and by Complaint Counsel and approved by the Director of the Bureau of Consumer Protection, 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) (2007), that this matter in its entirety be and it hereby is withdrawn from adjudication, and that all proceedings 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 proposed Consent Agreement shall not be placed on the public record unless and until it is accepted by the Commission.

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By the Commission.

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IN THE MATTER OF

REALCOMP II, LTD.

Docket No. 9320. Order, December 28, 2007

Order granting the parties joint motion for an extension of time in part by granting an extension as to the initial brief and the answering brief.

**ORDER PARTIALLY GRANTING JOINT MOTION FOR EXTENSION
OF TIME THROUGHOUT THE APPELLATE BRIEFING SCHEDULE**

Complaint Counsel and Respondent have filed a Joint Motion for Extension of Time Throughout the Appellate Briefing Schedule (December 21, 2007) (hereinafter “Joint Motion”) requesting that the Commission extend the time for the filing of briefs on the appeal and possible cross-appeal in this matter. For the reasons discussed below, the Commission grants in part the parties’ motion for an extension of time.

Chief Administrative Law Judge McGuire filed his Initial Decision and Order in this matter on December 10, 2007, and Complaint Counsel filed a timely Notice of Appeal on December 19, 2007. If Respondent determines to file a Notice of Appeal (hereinafter “Notice of Cross-Appeal”), it must be filed on or before December 31, 2007. Pursuant to Commission Rule 3.52(g), 16 C.F.R. § 3.52(g) (2007), if such a Notice of Cross-Appeal is filed – and Respondent perfects its Cross-Appeal with the timely filing of a Cross-Appeal Brief – Complaint Counsel will be deemed the Appellant, and Respondent will be deemed the Cross-Appellant/Appellee. Because Complaint Counsel were served with the Initial Decision on December 19, 2007, Complaint Counsel must currently file their Appeal Brief on or before January 18, 2008.¹ If service of that and subsequent briefs is effected on the opposing parties on the date on which each brief is due – and if Respondent

¹ Commission Rule 3.52(b), 16 C.F.R. § 3.52 (b).

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files and perfects a Cross-Appeal² – then Respondent’s Answering and Cross-Appeal Brief would be due on or before February 20, 2008.

The time periods prescribed by the Commission Rules of Practice ordinarily should afford parties to Commission proceedings sufficient time to file pleadings and briefs of sufficient quality and detail to aid in the preparation of Commission opinions and orders. The proximity of the current briefing schedule to the holidays, however, may interfere with that process. *See* Order Granting in Part and Denying in Part Joint Motion for Extension of Time and Length of Appeal Briefs, *In re Evanston Northwestern Healthcare Corporation*, Docket No. 9315 (Nov. 18, 2005) available at <http://www.ftc.gov/os/adjpro/d9315/051205orderd9315.pdf>. The Commission has therefore determined to grant an extension as to the initial brief and the answering brief. Because the time for filing the notice of cross-appeal has not expired, the Commission will issue a subsequent order regarding further briefing and a date for the oral argument. Accordingly,

IT IS ORDERED THAT (1) Complaint Counsel shall file their Appeal Brief on or before January 25, 2008, and (2) the appeal of Complaint Counsel shall be deemed perfected “by the timely filing of an appeal brief,” for purposes of Commission Rule 3.51(a), 16 C.F.R. § 3.51(a), if Complaint Counsel file their Appeal Brief by that date;

IT IS FURTHER ORDERED THAT (1) Respondent shall file its Answering Brief (including any Cross-Appeal Brief) on or before February 29, 2008, and (2) if Respondent pursues a cross appeal, it shall be deemed perfected “by the timely filing of an appeal brief” if Respondent files its Answering and Cross-Appeal Brief by that date, whether or not Complaint Counsel have previously perfected their

² For purposes of this Order, if Respondent files a Cross-Appeal, it will be deemed to have been perfected if its initial brief contains its “arguments as to any issues [Respondent] is raising on cross-appeal . . .” Commission Rule 3.52(c), 16 C.F.R. § 3.52(c).

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appeal.

IT IS FURTHER ORDERED THAT all of the foregoing Briefs shall in all other respects conform to the requirements of Commission Rule 3.52, 16 C.F.R. § 3.52.

By the Commission.

ADVISORY OPINION

IN THE MATTER OF

ACA INTERNATIONAL

FTC File No. P064803.

Opinion, October 5, 2007

Re: Whether the Fair Debt Collection Practices Act (“FDCPA”) prohibits a debt collector from notifying a consumer who disputed a debt that the collector has ceased its collection efforts.

Dear Mr. Beato:

This is in response to ACA International’s (“ACA’s”) request for a Commission advisory opinion (“Request”) regarding whether the Fair Debt Collection Practices Act (“FDCPA”) prohibits a debt collector from notifying a consumer who disputed a debt that the collector has ceased its collection efforts. ACA submitted the Request pursuant to Sections 1.1-1.4 of the Commission’s Rules of Practice, 16 C.F.R. §§ 1.1-1.4. As explained more fully below, the Commission concludes that a debt collector providing such a notice to a consumer would not violate the FDCPA.

The Request focuses primarily on Section 809 of the FDCPA, 15 U.S.C. § 1692g. Section 809(a) provides that, within five days after its initial communication with a consumer about a debt, a debt collector must send the consumer a written notice. Among other things, this notice must state that “if the consumer notifies the debt collector in writing within [thirty days after receipt of the notice] that the debt, or any portion thereof, is disputed, the debt collector will obtain verification of the debt or a copy of a judgment against the consumer and a copy of such verification or judgment will be mailed to the consumer by the debt collector.” Section 809(b) provides that if a consumer provides such a notice, the debt collector must cease collection until it has obtained verification of the debt or a copy of the judgment and mailed it to the consumer.

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In July 2007, ACA amended its Code of Ethics and Code of Operations (“Ethics Code”). If a debt collector receives a written request for verification and is unable to verify the debt, the Ethics Code now requires “the cessation of all collection efforts, removal of the account from the consumer’s credit report or reporting the account as disputed, and prompt notification of the **creditor or legal owner** of the debt that collection activities have been terminated due to the inability to provide verification information.” Request at 3 (emphasis added). ACA “also has considered amending the Ethics Code to promote the notification of a **consumer** that collection activity has been terminated if the debt collector is unable to verify the debt following the receipt of a written request for verification.” *Id.* (emphasis added). However, ACA has not yet amended its Ethics Code to include such a provision because of “concern that communication with the consumer following a request for verification might be construed as an attempt to collect, even though the intention merely is to inform the consumer that there will no further collections.” *Id.* at 2.

We note first that courts have construed Section 809(b) as giving debt collectors two options when they receive a written dispute or a request for verification¹: (1) provide the requested verification and continue collection activities, or (2) cease all collection activities. If the debt collector ceases collection, it is not required to provide

¹ Courts interpreting Section 809(b) have used the phrases “disputing the debt,” “requesting verification,” and “requesting validation” interchangeably. *See, e.g., Jang v. A.M. Miller and Assocs.*, 122 F.3d 480, 482 (7th Cir. 1997) (collection agencies “ceased collection activities immediately upon receiving the requests for validation, in compliance with [Section 809(b)]”); *Wilhelm v. Credico Inc.*, 426 F. Supp. 2d 1030, 1036 (D.N.D. 2006) (debt collector’s Section 809(b) obligations triggered “once a debt collector receives a request for verification”); *Sambor v. Omnia Credit Servs., Inc.*, 183 F. Supp. 2d 1234, 1243 (D. Haw. 2002) (debt collector’s Section 809(b) obligations triggered “[w]hen timely asked in writing to validate a debt”); *see also Clark’s Jewelers v. Humble*, 823 P.2d 818, 821 (Kan. Ct. App. 1991) (a consumer need not use the word “dispute” to trigger the debt collector’s obligation to cease collection and provide verification of the debt, as long as the consumer’s notice makes clear that the debt is contested).

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verification. *See, e.g., Guerrero v. RJM Acquisitions LLC*, 2007 U.S. App. LEXIS 20072, at *35-36 (9th Cir. Aug. 23, 2007); *Jang v. A.M. Miller & Assocs.*, 122 F.3d 480,483 (7th Cir. 1997); *Wilhelm v. Credico Inc.*, 426 F. Supp. 2d 1030, 1036 (D.N.D. 2006); *Zaborac v. Phillips and Cohen Assocs.*, 330 F. Supp. 2d 962, 966 (N.D. Ill. 2004); *Sambor v. Omnia Credit Servs., Inc.*, 183 F. Supp. 2d 1234, 1243 (D. Haw. 2002).

The Request poses the question of whether a debt collector that discontinues debt collection activities after receiving a written request for verification can inform the consumer that it has done so without violating the FDCPA. As noted above, Section 809(b) requires a debt collector to cease collection of a debt until the collector has provided verification of the debt to the consumer if the consumer, in writing within the thirty-day window, has either disputed the debt or requested verification. If a debt collector cannot provide such verification to the consumer, merely informing the consumer that debt collection efforts have been terminated is not an attempt to collect a debt and therefore does not violate the FDCPA.²

We note that Congress enacted Section 809 to “eliminate the recurring problem of debt collectors dunning the wrong person or attempting to collect debts which the consumer has already paid.”³ The provision allows a consumer who does not believe that he or she owes a debt to require that the debt collector obtain and provide verification prior to contacting the consumer again. The purpose of Section 809 therefore is to stop further calls and letters from collectors unless the consumer incurred and continues to owe the

² The Request also raises the question whether a notice informing a consumer that collection efforts have ceased “might be construed as a ‘communication’ in furtherance of collecting the debt.” Request at 5. Regardless of whether such a notice is a “communication” under 15 U.S.C. § 1692a(2), a debt collector telling a consumer that debt collection has ceased is not “in furtherance of collecting the debt.”

³ S. Rep. No. 95-382, at 4 (1977), *reprinted in* 1977 U.S.C.C.A.N. 1695, 1698.

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debt. Interpreting Section 809 as allowing debt collectors to notify consumers that they have ceased collection efforts, without conveying any other message, is consistent with this purpose. A consumer receiving such a notice would benefit both from having the calls and letters from that collector stop and from knowing that the collector will not renew its collection efforts.⁴

The only other FDCPA provision that could be implicated by the notification that ACA proposes to require of its members is Section 805(c). That provision provides that, if a consumer notifies a debt collector in writing that he or she “refuses to pay a debtor . . . wishes the debt collector to cease further communication,” the debt collector is not permitted to communicate further with the consumer about the debt. However, Section 805(c) includes an express exception to its prohibition on communication that permits a debt collector to “advise the consumer that the debt collector’s further efforts are being terminated.” Thus, even if a consumer demands in writing that a debt collector cease communicating about a debt, the debt collector would not violate Section 805(c) if it notified the consumer that the collector’s collection efforts have ceased.⁵

After reviewing the language of the FDCPA and its legislative history as well as information contained in the Request, the Commission concludes that a debt collector does not violate the FDCPA if, after receiving written notice of a dispute, it informs the consumer that it has ceased collection efforts.

⁴ Even if, as the amended Ethics Code now requires, a debt collector that is unable to provide verification of a debt ceases collection efforts, closes the account, and notifies the credit grantor, client, or owner of legal title to the debt that collection activities have been terminated because the collector could not provide verification of the debt, the credit grantor, client, or debt owner might choose to refer the account to a different debt collector. Thus, although the consumer will no longer be contacted by the first debt collector, he or she might receive collection calls and letters from a different debt collector.

⁵ We note, however, that any such communication must not violate any other FDCPA provision.

Advisory Opinion

RESPONSES TO PETITIONS TO QUASH OR LIMIT COMPULSORY PROCESS

MONTANA REFINING COMPANY, INC.

FTC File No. 071 0163 Decision, August 6, 2007

RESPONSE TO MONTANA REFINING COMPANY, INC.'S ("MRC") PETITION TO LIMIT CIVIL INVESTIGATIVE DEMAND AND SUBPOENA DUCES TECUM

Dear Ms. Laughner:

This letter advises you of the disposition of MRC's Petition to Limit Civil Investigative Demand ("CID") and Subpoena *Duces Tecum* ("SDT"). MRC argues that its Petition to Limit should be granted because:

1. the CID and SDT seek information beyond the scope of the investigation, Petition at 2;
2. the CID and SDT provide a return date which is not reasonable under the circumstances, *id.* at 4; and
3. CID Specification 17 is overbroad, vague, ambiguous, and unduly burdensome, *id.* at 5.

For the reasons stated herein, MRC's Petition to Limit is denied. Pursuant to 16 C.F.R. § 2.7(e), MRC is ordered to comply with the CID and SDT on or before August 16, 2007, at 5:00 p.m. E.D.T.

This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission's delegate. *See* 16 C.F.R. § 2.7(d)(4). Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.¹

¹ This letter decision is being delivered by facsimile and express mail. The facsimile copy is being provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail. In accordance with the provisions of 16 C.F.R. § 2.7(f), the timely

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I. Background and Summary

The CID and SDT were issued to MRC on June 21, 2007. The record indicates that MRC received service of the CID and SDT on June 25, 2007. Pursuant to 16 C.F.R. § 2.7(d), any petition to limit or quash should have been filed on or before July 15, 2007; that is, twenty days after service. On July 12, 2007, counsel for MRC faxed a copy of the Petition to Limit to the Commission. The cover letter to that fax indicated that an original and one copy of the Petition to Limit would be delivered by first class mail; however, the Commission did not receive the original and required copies for filing until July 17, 2007. Also on July 17, 2007, the Commission received MRC's Motion to File Petition to Limit Out of Time.²

II. MRC Has Not Established That It Is Entitled to Relief.

MRC claims that the CID and SDT seek information about refined petroleum products other than gasoline, and that such other refined products are beyond the scope of the resolution authorizing the use of compulsory process. Petition at 2-4. MRC also claims that it has been given inadequate time within which to respond in light of its small size and the limited number of people available "who potentially can access files containing responsive documents. Welsh Aff. ¶ 3. Finally, MRC claims that CID Specification 17 is so overbroad, vague, and ambiguous as to impose an undue burden on MRC. *Id.* at 5-6. MRC has not established that materials and information covered by the CID and SDT are beyond the scope of

filing of a request for review of this matter by the full Commission shall not stay the return date established by this decision.

² The motion recites that MRC faxed and served its Petition to Limit on July 12, 2007, and then states that the Petition to Limit "was not filed within the 20 days of service due to an inadvertent oversight" of not having provided initially the twelve copies required by 16 C.F.R. § 4.2(c). MRC attempted to file in a timely fashion. An inadvertent failure to submit the required number of copies for filing should not prevent the Commission from reaching the merits of this Petition to Limit. Accordingly, MRC's Motion to File Petition to Limit Out of Time is granted.

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the investigation, or that timely compliance with the CID and SDT is not feasible, or that Specification 17 is in any respect improper or unduly burdensome.

A. The Information Requested Is Within the Scope of the Commission’s Resolution and Is Relevant to the Investigation.

The CID was issued pursuant to the Resolution adopted by the Commission on May 18, 2007 permitting Staff to conduct an investigation to determine whether the conduct and practices of “certain oil refiners, marketers, or others have . . . lessened competition in the refining, distribution, and supply of gasoline . . . in violation of Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, as amended.” MRC claims that this resolution limits the investigation to gasoline, and precludes inquiry regarding other refined light petroleum products produced by MRC, such as, diesel fuel, jet fuel, aviation gasoline, and heating oil. Petition at 3. This contention is wholly without merit.

As MRC’s Petition to Limit notes, the *Invention Submission Corp.* case describes the broad scope of the Commission’s investigatory reach.³ *Federal Trade Comm’n v. Invention Submission Corp.*, 965 F.2d 1086, 1089 (D.C. Cir. 1992) (“It is well established that a district court must enforce a federal agency’s investigative subpoena if the information is reasonably relevant . . . - or, put differently, not plainly incompetent or irrelevant to any lawful purpose of the [agency] . . . - and not unduly burdensome to produce.”) (citations and internal quotation marks omitted).

MRC argues that the Commission’s Resolution Authorizing Use of Compulsory Process only “authorizes the use of compulsory process to investigate gasoline, and the subject matter of the authorized investigation cannot be arbitrarily changed or improved upon by the drafters of the CID or Subpoena.” Petition at 3. That

³ Petition at 3-4.

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construction interprets the Resolution far too narrowly. The Resolution directs an inquiry into the conduct of refiners and others in order to determine what, if any, effect their conduct has had upon the supply of gasoline. Petroleum refineries produce a broad range of refined products of which gasoline is but one. Thus, refiners' production decisions regarding non-gasoline products directly affects the supply and price of gasoline. *See Investigation of Gasoline Price Manipulation and Post-Katrina Gasoline Price Increases* at 10 - 11 (May 22, 2006) (Choice of Output), available at <http://www.ftc.gov/reports/060518PublicGasolinePricesInvestigationReportFinal.pdf>. The focus of the investigation is the *conduct* of refiners and others. The Resolution clearly supports the definition of "Relevant Products" about which MRC complains. Petition at 3. The Commission, accordingly, declines MRC's invitation to impose an artificial limitation on the scope of the investigation authorized by the Resolution.

B. MRC Has Not Shown That It Needs Additional Time Within Which To Respond.

MRC claims that it is a small company and that it has only five employees who can prepare the company's responses to the CID and SDT. It also claims that it will take 300-400 person hours to comply with the CID and SDT, Petition at 4. MRC also claims that its five employees cannot work on CID and SDT production full time, and that 17-21 working days is not a sufficient amount of time in which to comply. *Id.*; Welsh Aff. ¶¶ 4-5. However, MRC's own numbers do not show an inability to meet the return date. Five people could accomplish this task, even assuming 300-400 hours would be required, in less than three weeks without having to devote full-time to the project. In these circumstances, MRC has not established that the return date is unreasonably short. Given the amount of time already lapsed, this order requires compliance with the CID and SDT within 10 days from the date it is issued. Moreover, the Commission is confident that staff will treat any future request for

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more time reasonably, if MRC demonstrates a good faith effort to comply and a genuine need for a brief additional extension.

C. Specification 17 of the CID Is Not Overbroad, Vague, Ambiguous, or Unduly Burdensome.

MRC argues that Specification 17 of the CID is overbroad, vague, and ambiguous, and that it therefore imposes on undue burden on MRC.⁴ MRC's objects to this Specification stating that it "cannot see how [the Specification] can be satisfied or practically

⁴ Specification 17 asks MCR to:

Identify all communications between July 1, 2006 and March 1, 2007, whether written, oral or electronic, between or among the Company and any competitor or other provider of any service (including consultants and industry associations) relating to any Relevant Product, which relate to (a) any specification change in any Relevant Product (including, but not limited to, the transition to ultra-low sulfur diesel ("ULSD") production) and the effect of any such specification change on the bulk, Wholesale, or retail supply or price of any Relevant Product; (b) any Refinery Interruption, pipeline capacity proration or allocation, or any other interruption or disruption in the production, transportation, distribution, or storage of any Relevant Product in any Relevant Area, and the effect of any such disruption on the bulk, wholesale, or retail supply or prices of any Relevant Product in any Relevant Area; or (c) any price, production, volume, inventory level, territorial or market allocation, or customer allocation of any Relevant Product in any Relevant Areas.

For each such communication, identify the following:

- a. the date, location and medium of the communication;
- b. all Persons participating in, observing and/or hearing such communications;
- c. the subject matter and substance of such communication;
- d. all Persons who have knowledge regarding such communication, whether or not such knowledge is based upon first-hand information; and
- e. any document that was the subject of, or records, refers, or relates to, such communication.

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answered . . . [and that] there may have been daily conversations [that] cannot be recalled.” Petition at 6. We find these objections unpersuasive.⁵

Specification 17 seeks information regarding, among other things, certain communications involving MRC employees. The language of the Specification is clear and precise. Like any other interrogatory-type question, it only requires MRC to supply information that it knows, can reconstruct or summarize, or can reasonably recall. Information regarding these communications will assist staff in determining whether increased gasoline prices are in any degree attributable to collusion among refiners, marketers, and others. This information addresses directly a primary focus of staff’s inquiry. Given the centrality of the information to the underlying investigation, MRC’s simple assertion that “it does not see how” it can “practically answer” the specification does not support its heavy burden of persuasion on this issue. *See Federal Trade Commission v. Texaco Inc.*, 555 F.2d 862, 882 (D.C. Cir. 1977) (“The burden of showing that the request is unreasonable is on the subpoenaed party. Further, that burden is not easily met where, as here, the agency inquiry is pursuant to a lawful purpose and the requested documents are relevant to that purpose.”).

⁵ The Commission has reason to believe that MRC did not discuss the scope of Specification 17 with staff prior to filing its Petition to Limit. MRC has therefore failed to comply with the meet and confer provisions of 16 C.F.R. § 2.7(d)(2).

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IV. Conclusion and Order

Accordingly, **IT IS ORDERED THAT** MRC's Motion to File Petition to Limit Out of Time should be, and it hereby is, **GRANTED**;

IT IS FURTHER ORDERED THAT MRC's Petition to Limit should be, and it hereby is, **DENIED**; and

IT IS FURTHER ORDERED THAT MRC shall respond to the CID and SDT on or before August 16, 2007, at 5:00 p.m. E.D.T.

By Direction of the Commission.

Responses to Petitions to Quash

WELLNESS SUPPORT NETWORK*FTC File No. 072 3179 Decision, October 25, 2007*

RESPONSE TO PETITION TO QUASH CIVIL INVESTIGATIVE DEMAND

Dear Mr. Fuerst:

This letter advises you of the disposition of the Petition to Quash Civil Investigative Demand (“Petition to Quash”) served on Wellness Support Network (hereinafter “Petitioner” or “WSN”) in conjunction with an investigation of WSN’s conduct by the Federal Trade Commission (hereinafter “FTC” or “Commission”). The Petition to Quash is denied for the reasons hereinafter stated. The new date for Petitioner to comply with the Civil Investigative Demand is November 5, 2007.

This ruling was made by Commissioner Pamela Jones Harbour, acting as the Commission’s delegate. *See* 16 C.F.R. § 2.7(d)(4). Petitioner has the right to request review of this matter by the full Commission. Such a request must be filed with the Secretary of the Commission within three days after service of this letter.¹

I. Background and Summary

On July 27, 2007, the Commission issued a Civil Investigative Demand (“CID”) to Petitioner in connection with the Commission’s investigation into advertising claims made by WSN regarding WSN[®] Diabetic Pack and WSN[®] Nerve Support Formula (hereinafter “WSN’s products”). Petition at 5. The CID was issued pursuant to the Commission’s Resolution of May 12, 2006. *See*

¹ This letter decision is being delivered by facsimile and express mail. The facsimile copy is being provided as a courtesy. Computation of the time for appeal, therefore, should be calculated from the date you received the original by express mail.

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Petition, Exhibit G. On August 27, 2007, WSN timely filed its Petition to Quash.

Petitioner claims that the CID should be quashed for three reasons: (1) the FTC “has neither the authority nor the expertise to make a determination as to whether a product is a drug, medical food or a dietary supplement;” Petition at 4; (2) “the CID was not properly tailored to yield information that is relevant and material to this request for information;” *id.* at 9; and (3) the “CID is unreasonably overbroad and unduly burdensome,” *id.*

II. The FTC Has Jurisdiction to Investigate Petitioner’s Advertising Claims.

This Petition to Quash proceeds from an irrelevant distinction, between medical foods and dietary supplements, to the unsupported conclusion that the FTC lacks the jurisdiction to investigate Petitioner’s advertising claims for its products. Section 5 of the FTC Act, 15 U.S.C. § 45, authorizes the FTC to prohibit “unfair or deceptive acts or practices in or affecting commerce.” Further, Section 12(a) of the FTC Act, 15 U.S.C. § 52(a), declares unlawful the dissemination of “any false advertisement . . . by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, devices, services, or cosmetics.” WSN provides no cogent reason why its products are excluded from the FTC’s jurisdiction.

WSN’s reliance on the Memorandum of Understanding (“MOU”) between the FTC and the Food and Drug Administration (“FDA”), Petition at 9, is wholly misplaced. On its face, the MOU states that the FTC has “primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs [other than prescription drugs], devices and cosmetics.” FDA MOU number 225-71-8003. WSN’s claim that its products are medical foods within the meaning of Section 5(b) of the Orphan Drug Act, 21 U.S.C. § 360ee(b)(3), Petition at 7, does not

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include any citation of authority that would oust the FTC's jurisdiction under Section 12(a) of the FTC Act over "foods, drugs, devices, services, or cosmetics." WSN's reliance on the MOU is further misplaced in that the FTC cannot by agreement with the FDA abandon jurisdiction bestowed on the FTC by Congress.

The Petitioner has "the burden of showing that an agency subpoena is unreasonable . . . and, where, as here, the agency inquiry is authorized by law and the materials sought are relevant to the inquiry, that burden is not easily met." *Securities and Exchange Commission v. Brigadoon Scotch Distributing Co.*, 480 F.2d 1047, 1056 (1973), *cert. denied*, 415 U.S. 915 (1974). This is especially so in light of the breadth of inquiry this Commission is permitted to conduct. *United States v. Morton Salt Co.*, 338 U.S. 632, 652 (1950) ("[I]t is sufficient if the inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant."). WSN did not provide sufficient factual or legal support for its claim that the FTC lacks jurisdiction to investigate WSN's advertisements, nor has it given the Commission any reason to believe that the public interest would be served by failing to exercise its jurisdiction to investigate WSN's advertising claims.² WSN's jurisdictional challenge to this CID must, therefore, be denied.

² The Commission may consider a jurisdictional challenge to its compulsory process during the course of an investigation on policy grounds even when such a challenge in the federal courts would not be appropriate. "With rare exceptions (none of which applies here), a subpoena enforcement action is not the proper forum in which to litigate disagreements over an agency's authority to pursue an investigation." *Federal Trade Commission v. Roberts*, 276 F.3d 583, 584 (D.C. Cir. 2001) ("Whatever the merit of Ken Roberts' preemption argument – and we believe they have little – appellants cannot overcome the long-standing doctrine that precludes courts from entertaining challenges to the jurisdiction of administrative agencies during subpoena enforcement proceedings."). "An agency's investigations should not be bogged down by premature challenges to its regulatory jurisdiction." *Federal Trade Commission v. Swanson*, 560 F.2d 1, 2 (1st Cir. 1977); *see Federal Trade Commission v. Monahan*, 832 F.2d 688, 689 (1st Cir. 1987) ("We, like the FTC, must wait to see the results of the investigation before we know whether, or the extent to which, the activity falls within the scope of a [particular defense].").

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III. The Information Sought Is Within the Scope of the Resolution/Investigation.

The scope of the investigation is defined by the resolution authorizing the use of compulsory process. The Petitioner mischaracterizes the resolution authorizing staff's use of compulsory process, Resolution of May 12, 2006 attached to the Petition to Quash as Exhibit G, when it claims that

The Commission is looking for information as it pertains to the advertising of a dietary supplement, and has improperly applied the standard for evaluating dietary supplements to the initial phase investigation conducted prior to the issuance of the CID. As such, it is clear that this investigation is premised on an erroneous conclusion and, therefore, cannot reasonably be tailored to yield information that is relevant or material to the investigation.

Petition at 9. Again, the distinction between dietary supplements and medical foods has no bearing on whether the information required in response to the CID is relevant to the scope of investigation authorized by the resolution. The Resolution defines the scope of the inquiry to include determining “whether unnamed persons . . . engaged directly or indirectly in the advertising or marketing of drugs, devices, dietary supplements or *any other product or service intended to provide a health benefit or to affect the structure or function of the body* have misrepresented or are misrepresenting the safety or efficacy of such products. . . .” Resolution of May 12, 2006 (emphasis supplied). Petitioner admits that its products fit the above description of the Resolution. Petition at 3 (“WSN . . . is in the business of marketing and selling medical foods designed to provide nutrients for the dietary management of Type II diabetes and neuropathy.”). The specifications of the CID are relevant to determining whether WSN has misrepresented the safety or efficacy of its products. Petitioner has not demonstrated that any information sought by the CID is legitimately beyond the

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scope of this investigation. In fact, the Commission finds that the materials sought by the CID are relevant to the scope of this investigation. Accordingly, the Petition to Quash on the ground that the CID seeks information not relevant to the investigation must be denied.

IV. The Petition Does Not Show that the CID Is Unduly Burdensome.³

Allegations of burden must be supported with specificity. *National Claims Service, Inc., Petition to Limit Civil Investigative Demand*, 1998 FTC LEXIS 192, *8 (FTC 1998) (“At a minimum, a petitioner alleging burden must (i) identify the particular requests that impose an undue burden; (ii) describe the records that would need to be searched to meet that burden; and (iii) provide evidence in the form of testimony or documents establishing the burden (e.g., the person-hours and cost of meeting the particular specifications at issue). Petitioner has failed to do any of these things.”). Likewise, Petitioner has failed to do any of these things with any reasonable degree of specificity.

The Petition is supported by an Affidavit from Robert Held, Petition, Exhibit J, which claims in summary fashion that the records sought are voluminous, Aff. ¶ 4, that Held (the CEO of WSN) and his daughter, Robyn Held, are the only two of the firm’s eleven employees who are capable of preparing the response to the CID, Aff. ¶¶ 4, 6-7, and that compliance would make them otherwise unavailable for some unknown period of time to the detriment of the firm. Aff. ¶¶ 6-7. The Petition, including the Affidavit of Held, does not satisfy Petitioner’s burden of demonstrating that compliance would impose an unreasonable burden on WSN. The Commission, therefore, finds that the burden of complying with the

³ Petitioner’s argument that the CID is overbroad was wholly redundant with its argument that the CID sought information not relevant to the investigation and need not be addressed again here.

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CID does not appear unreasonable on this record. *See Federal Trade Commission v. Rockefeller*, 591 F.2d 182, 190 (2nd Cir. 1979).

Counsel for WSN makes a further argument that compliance with the CID might result in WSN losing its suppliers of needed materials and products. Petition at 10. This argument is supported by no factual materials. It is claimed that WSN uses vitamins and minerals manufactured “under an exclusive proprietary process” by “a small group of suppliers.” *Id.* It is not clear, however, if the proprietary process at issue is that of WSN or of its suppliers. It is further argued that WSN is one of its suppliers’ smallest customers and that, therefore, the disclosure of information⁴ about this proprietary process creates a “high probability” that the suppliers will cease doing business with WSN and that WSN will be unable to find alternative suppliers – failing which it will cease business operations. Petition at 10. This claim is too speculative and unsupported to serve as the basis for relief.⁵

V. CONCLUSION AND ORDER

For all the foregoing reasons, **IT IS ORDERED THAT** the Petition to Quash filed by Petitioner be, and it hereby is, **DENIED**. Pursuant to Rule 2.7(e), the new date for Petitioner to comply with the CID is November 5, 2007.

By direction of the Commission.

⁴ If information regarding this proprietary process is in fact confidential, then such information should be designated confidential when submitted. Commission staff are bound to comply with set procedures regarding materials so designated. *See generally*, 16 C.F.R. §§ 4.9-4.11. Petitioner provides no evidence that the confidentiality protections provided by 15 U.S.C. § 57b-2 are inadequate to protect this information.

⁵ *See Federal Trade Comm. v. Standard American, Inc.*, 306 F.2d 231, 235 (3rd Cir. 1962) (finding petitioner had not provided sufficient evidence that compliance would lead to the “virtual destruction” of a business).

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