

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

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In the Matter of)	FILE NO. 082 3122
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MARK DREHER, PH.D.,)	AGREEMENT CONTAINING
individually.)	CONSENT ORDER
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_____)	

The Federal Trade Commission (“Commission”) has conducted an investigation of certain acts and practices of Mark Dreher, Ph.D., individually (“proposed respondent”). Proposed respondent, having been represented by counsel, is willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Mark Dreher, Ph.D., individually, and counsel for the Federal Trade Commission that:

1. Proposed respondent Mark Dreher, Ph.D., was the Vice President of Science & Regulatory Affairs of POM Wonderful LLC from approximately August 2005 to May 2009. His current principal office or place of business is located in Wimberley, Texas.
2. Proposed respondent admits all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondent waives:
 - a. Any further procedural steps;
 - b. The requirement that the Commission’s decision contain a statement of findings of fact and conclusions of law; and
 - c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.
4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission,

it, together with the draft complaint, will be placed on the public record for a period of thirty (30) days and information about it will be publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondent, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondent that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.
6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondent, (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time frame provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondent's address by any means specified in Section 4.4(a) of the Commission's Rules shall constitute service. Proposed respondent waives any right he may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.
7. Proposed respondent has read the draft complaint and consent order. Proposed respondent understands that he may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

ORDER

DEFINITIONS

For purposes of this Order, the following definitions shall apply:

1. Unless otherwise specified, "respondent" shall mean Mark Dreher, Ph.D., individually.
2. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. "Covered Product" shall mean any food, drug, or dietary supplement for human use or consumption, including, but not limited to, the POM Products.
4. "Food" and "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.

5. “Endorsement” shall mean as defined in 16 C.F.R. § 255.0.
6. “Employment” shall mean any affiliation with any business, non-profit, or government entity, including the performance of services as an officer, owner, manager, supervisor, employee, consultant, or independent contractor; and “Employer” shall mean any and all individuals or entities for whom respondent performs services as an employee, consultant, or independent contractor.
7. “POM Product” shall mean any food, drug, or dietary supplement labeled, advertised, promoted, offered for sale, sold, or distributed by POM Wonderful LLC, Roll International Corporation, and their successors and assigns, containing POM Wonderful pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.
8. The term “including” in this Order shall mean “without limitation.”
9. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

I.

IT IS ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any POM Product, in or affecting commerce, shall not make any representation in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, including, but not limited to, any representation that the product will treat, prevent, or reduce the risk of heart disease, including by decreasing arterial plaque, lowering blood pressure, or improving blood flow to the heart; or treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time (“PSADT”); unless, at the time it is made, the representation is non-misleading and:

- A. the product is subject to a final over-the-counter (“OTC”) drug monograph promulgated by the Food and Drug Administration (“FDA”) for such use, and conforms to the conditions of such use;
- B. the product remains covered by a tentative final OTC drug monograph for such use and adopts the conditions of such use;
- C. the product is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use; or

- D. the representation is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990.

II.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not misrepresent, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, trademark, or trade name, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

III.

IT IS FURTHER ORDERED that respondent, directly or through any corporation, partnership, subsidiary, division, trade name, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Covered Product, in or affecting commerce, shall not make any representation, other than representations under Part I of this Order, in any manner, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, about the health benefits, performance, or efficacy of any Covered Product, unless the representation is non-misleading, and, at the time of making such representation, respondent relies upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted in the relevant scientific fields, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. *Provided that*, for any representation made by respondent as an expert endorser, respondent must possess and rely upon competent and reliable scientific evidence, and an actual exercise of his represented expertise in evaluating medical research at least as extensive as an expert in that field would normally conduct in order to support the conclusions presented in the representation. For purposes of this Part, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, and that are generally accepted in the profession to yield accurate and reliable results.

IV.

IT IS FURTHER ORDERED that:

- A. Nothing in Parts II and III of 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
- B. Nothing in Parts II and III of this Order shall prohibit respondent from making any representation for any drug that is permitted in the labeling for such drug

under any tentative final or final monograph promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

V.

IT IS FURTHER ORDERED that respondent shall, for five (5) years after the last date of dissemination of any representation covered by this Order, maintain and upon request make available to the Commission for inspection and copying:

- A. All advertisements, labeling, packaging, and promotional materials containing the representation;
- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in his possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the representation, including complaints and other communications with consumers or with governmental or consumer protection organizations; and
- D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

VI.

IT IS FURTHER ORDERED that respondent shall, for a period of seven (7) years after the date of issuance of this Order, deliver a copy of this Order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. Respondent shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that respondent shall, for a period of five (5) years after the date of issuance of this Order, notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. Mark Dreher*. Provided, however, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

IT IS FURTHER ORDERED that respondent shall within sixty (60) days after the effective date of this Order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of his compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, he shall submit additional true and accurate written reports.

IX.

IT IS FURTHER ORDERED that respondent must reasonably and in good faith cooperate with the Commission in connection with its litigation in the matter of *POM Wonderful LLC et al.* (File No. 082-3122) and any subsequent investigations or litigation related to or associated with the transactions or occurrences that are the subject of the Commission's administrative complaint in that matter. Respondent acknowledges, understands, and agrees that such cooperation shall include, but not be limited to, the following:

- A. Appearing for interviews as may reasonably be requested by the Commission;
- B. Responding to all reasonable inquiries of the Commission;
- C. Providing all documents, records, and other tangible evidence reasonably requested by the Commission;
- D. Providing truthful declarations, affidavits, certifications, and written testimony reasonably requested by the Commission; and
- E. Appearing and providing oral testimony at any trial, deposition, or other proceeding. Respondent agrees to accept service by overnight delivery of any subpoena to appear and provide testimony.

The foregoing cooperation shall be upon reasonable written notice by the Commission. Respondent's failure to cooperate as required herein constitutes a material breach of the settlement between the parties and a violation of this Order.

X.

This Order will terminate twenty (20) years from the date of its issuance, or twenty (20) years from the most recent date that the United States or the Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

- A. Any Part in this Order that terminates in less than twenty (20) years; and
- B. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

Provided, further, that if such complaint is dismissed or a federal court rules that respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this Part as though the complaint had never been filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

Signed this 14th day of September, 2010.

By: _____
MARK DREHER, PH.D.

Date: _____

By: _____
WILLIAM M. HANNAY
Schiff Harden LLP
Counsel for respondent

Date: _____

JANET EVANS
Counsel for the Federal Trade Commission

Date: _____

APPROVED:

MARY K. ENGLE
Associate Director
Division of Advertising Practices

Date: _____

DAVID C. VLADECK
Director
Bureau of Consumer Protection

Date: _____