

1. 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. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the Respondent and this proceeding is in the public interest.

ORDER

DEFINITIONS

For the 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 6.0000 of the Commission's Rules of Practice and Procedure.

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

- 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 on November 4, 2030, 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.

By the Commission.

Donald S. Clark
Secretary

ISSUED: November 4, 2010