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In the Matter of Mark Dreher, Ph.D.

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 Mark Dreher, Ph.D. ("respondent"). The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement or make final the agreement's proposed order.

This matter involves the advertising and promotion of POM Wonderful 100% Pomegranate Juice ("POM Juice") and POMx Pills and POMx Liquid ("POMx"). According to the FTC complaint, respondent represented, in advertisements and promotional materials, including as an expert endorser, that clinical studies, research, and/or trials prove that drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease (including by decreasing arterial plaque, or improving blood flow to the heart) and prostate cancer (including by prolonging prostate-specific antigen doubling time ("PSADT")). The complaint alleges that these claims are false or misleading. The FTC complaint further charges that respondent represented, including as an expert endorser, that POM Juice and POMx treat, prevent, or reduce the risk of heart disease and prostate cancer, and that respondent possessed and relied on a reasonable basis, including an actual exercise of his represented expertise in evaluating medical research at least as extensive as an expert in the field would normally conduct in order to support the conclusions presented in the endorsements, that substantiated the representations, at the time the representations were made. The complaint alleges that respondent did not possess and rely upon a reasonable basis that substantiated the conclusions presented in the endorsement. Accordingly, the complaint alleges that respondent violated Sections 5(a) and 12 of the FTC Act.

The proposed consent order contains provisions designed to prevent respondent from engaging in similar acts or practices in the future. Part I of the consent order prohibits respondent from representing that any POM Product (defined as "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") is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease including, that such a 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 prostate cancer (including by prolonging PSADT), unless, at the time the claim was made, the representation is non-misleading and: (a) the product is subject to a final over-the-counter ("OTC") drug monograph promulgated by the Food and Drug Administration ("FDA") for such use, and conforms to the conditions of such use; (b) the product remains covered by a tentative final OTC drug monograph for such use and adopts the

conditions of such use; (c) the product is the subject of a new drug application for such use approved by FDA, and conforms to the conditions of such use; or (d) the representation is specifically permitted in labeling for such product by regulations promulgated by the FDA pursuant to the Nutrition Labeling and Education Act of 1990 ("NLEA").

Under this provision, therefore, respondent cannot make a claim that a POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of a disease, unless the FDA specifically approved such a claim. The Commission has not concluded that the only way a food or supplement advertiser can adequately substantiate disease treatment, prevention, or risk-reduction claims is through FDA authorization. However, the consent order provision requiring FDA pre-approval before respondent makes these types of claims for POM Products in the future will facilitate compliance with the order and is reasonably related to the violations alleged.

Respondent may decide to make an advertising claim characterizing limited scientific evidence supporting the relationship between POM Products and a disease. However, if the net impression is that a POM Product is effective in the diagnosis, cure, mitigation, treatment, or prevention of a disease, and not merely that there is limited scientific evidence supporting the claim, the advertisement would be covered under Part I. Staff's experience and research show that it is very difficult to adequately qualify a disease treatment, prevention, or risk-reduction claim in advertising to indicate that the science supporting the claimed effect is limited. In other words, reasonable consumers may interpret an advertisement to mean that the product will treat, prevent, or reduce the risk of a disease, even if respondent includes language indicating that the science supporting the effect is limited in some way. However, if respondent possesses reliable empirical testing demonstrating that the net impression of an advertisement making a qualified claim for a POM Product does not convey that it is effective in the diagnosis, cure, mitigation, treatment, or prevention of a disease, then that claim would be covered under the relevant subsequent parts of the order.

Although Part I requires FDA approval before respondent can make claims that a POM Product treats, prevents, or reduces the risk of a disease, the Commission does not intend Part I to limit respondent to using the precise language specified by the FDA. To the contrary, if the FDA has approved a claim that a POM Product treats, prevents, or reduces the risk of a disease, respondent may use a variety of words and images to communicate that claim in advertising. Likewise, regardless of the particular words or images used, if the net impression of an advertisement is that a POM Product treats, prevents, or reduces the risk of a disease, then for the advertisement to comply with the order, the FDA must have specifically authorized such a claim, based upon its review of the available scientific evidence.

Part II of the consent order prohibits respondent, in connection with the advertising or marketing of any Covered Product (defined as "any food, drug, or dietary supplement for human use or consumption, including, but not limited to, the POM Products"), from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or

research.

Part III of the consent order prohibits respondent from making representations, other than representations covered under Part I, about the health benefits, performance, or efficacy of any Covered Product (as defined above), unless the representation is non-misleading, and, at the time of making such representation, respondent possesses and 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. In addition, it provides 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 Part III, competent and reliable scientific evidence means tests, analyses, research, or studies that have been conducted and evaluated in an objective manner by qualified persons, that are generally accepted in the profession to yield accurate and reliable results.

Part IV of the consent order provides that nothing in Parts II and III of the 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 FDA pursuant to the NLEA.

Parts V through IX of the consent order require respondent to keep copies of relevant advertisements and materials substantiating claims made in the advertisements; to provide copies of the order to current and future principals, officers, managers, and personnel; to notify the Commission of changes in his business or employment; to file compliance reports with the Commission; and to cooperate with the Commission in connection with litigation related to its complaint against POM Wonderful LLC, FTC File No. 082-3122. Part X provides that the order will terminate after twenty (20) years, with certain exceptions.

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