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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

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 monogr

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 Nutritional Labeling and Education Act of 1990 ("NLEA").

Under this provision, therefore, respondent cannot ma

research.

Part II 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 reg