UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

Julie Brill
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))) Docket No. C-430 6
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COMPLAINT

The Federal Trade Commission, having reason to believe that Mark Dreher, Ph.D.,

POM Wonderful LLC ("POM Wonderful") from approximately August 2005 to May 2009. Individually or in concert with others, he participated in the policies, acts, or practices of the corporation, including the acts or practices alleged in this complaint. His principal office outribution of pro-

Juice (hereinafter "POM Juice"), and POMx Pills and POMx Liquid (hereinafter "POMx"). POM Juice and POMx are "foods" and/or "drugs" within the meaning of Sections 12 and 15 of the Federal Trade Commission Act.

- 3. 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.
- 4. Respondent participated in the dissemination of or caused to be

time increased to 54 months. Testing on patient blood serum showed a 12% decrease in cancer cell proliferation and a 17% increase in cancer cell death (apoptosis).

— <u>POMx Pills and Liquid Prostate Newsletter</u> (Fall 2007-Feb. 2008) [**Exh. B**]

- 5. As early as May 2007, Respondent knew that a large, double-blind, placebo-controlled study, funded by POM Wonderful and led by Dr. Michael Davidson ("the Davidson Study"), showed no significant difference after 18 months between consumption of pomegranate juice and a control beverage in reducing carotid arterial wall thickness. The Davidson study was published in October 2009. Respondent participated in touting POM Wonderful's cardiovascular research and benefits despite the negative results of the Davidson study.
- 6. Through the means described in Paragraph 4, Respondent has represented, including in some instances through statements as an expert endorser, expressly or by implication, that clinical studies, research, and/or trials prove that:
 - A. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart; and
 - B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart.
- 7. In truth and in fact, clinical studies, research, and/or trials do not prove that:
 - A. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart; and
 - B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart.

Among other things, the Davidson Study showed no significant difference between consumption of pomegranate juice and a control beverage in carotid intima-media thickness progression rates after 18 months; two smaller studies funded by POM Wonderful or its agents showed no significant difference between consumption of pomegranate juice and a control beverage on measures of cardiovascular function; and multiple studies funded by POM Wonderful or its agents did not show that POM products reduce blood pressure.

- 8. Through the means described in Paragraph 4, Respondent has represented, including in some instances through statements as an expert endorser, expressly or by implication, that clinical studies, research, and/or trials prove that:
 - A. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and
 - B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT.
- 9. In truth and in fact, clinical studies, research, and/or trials do not prove that:
 - A. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging PSADT; and
 - B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT.

Among other things, at the time the claims were made, the evidence relied on by Respondent consisted of results from an unblinded, uncontrolled study; and the study report stated that it is "controversial whether modulation of PSA levels represents an equally valid clinical end point," and that "further research is needed to . . . determine whether improvements in such biomarkers (including PSADT) are likely to serve as surrogates for clinical benefit."

- 10. Therefore, the representations made in Paragraphs 6 and 8, were, and are, false or misleading.
- 11. Through the means described in Paragraph 4, Respondent has represented, including in some instances through statements as an expert endorser, expressly or by implication, that:
 - A. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart; and
 - B. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats heart disease, including by (1) decreasing arterial plaque, and (2) improving blood flow to the heart.
 - C. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, prevents or reduces the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); and

- D. Drinking eight ounces of POM Juice, or taking one POMx Pill or one teaspoon of POMx Liquid, daily, treats prostate cancer, including by prolonging PSADT.
- 12. Through the means described in Paragraph 4, Respondent has represented, including in some instances through statements as an expert endorsering pressly