

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

COMMISSIONERS: **Jon Leibowitz, Chairman**
 William E. Kovacic
 J. Thomas Rosch
 Edith Ramirez
 Julie Brill

_____)
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In the Matter of))
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MARK DREHER, PH.D.,))
) **Docket No.**
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))
individually.))
_____)

COMPLAINT

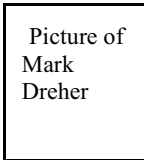
The Federal Trade Commission, having reason to believe that Mark Dreher, Ph.D., individually, has violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Mark Dreher, Ph.D., was the Vice President of Science & Regulatory Affairs of 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 or place of business from 2005 to 2009 was that of the corporation, and his current principal office or place of business is in Wimberley, Texas.
2. Respondent participated in the manufacturing, advertising, labeling, offering for sale, sale, and distribution of products to the public, including POM Wonderful 100% Pomegranate 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 disseminated advertising and promotional materials for POM Juice and POMx. Examples of those advertising and promotional materials are attached as Exhibits A and B. These materials contain the

following representations or statements, including statements made as an expert endorser, among others:

A. * * *

What's New in the Lab by Dr. Mark Dreher



Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMx and POM Wonderful pomegranates as they relate to your health.

* * *

NEW RESEARCH OFFERS FURTHER PROOF OF THE HEART-HEALTHY BENEFITS OF POM WONDERFUL JUICE

30% DECREASE IN ARTERIAL PLAQUE

After one year of a pilot study conducted at the Technion Institute in Israel involving 19 patients with atherosclerosis (clogged arteries) . . . those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily saw a 30% decrease in arterial plaque.

17% IMPROVED BLOOD FLOW

A recent study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily for three months experienced 17% improved blood flow. Those who drank a placebo experienced an 18% decline.

* * *

— POMx Pills and Liquid Heart Newsletter (Sept. 2007-Feb. 2008) [Exh. A]

B. * * *

**Prostate Cancer Affects
1 Out of Every 6 Men**

Prostate cancer is the second leading cause of cancer related death in men in the United States according to the National Cancer Institute.

Prostate cancer incidence rates rose dramatically in the late 1980's with improved detection and diagnosis through widespread use of prostate-specific antigen (PSA) testing.

* * *

What's New in the Lab by Dr. Mark Dreher

Picture of
Mark
Dreher

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

* * *

POM Wonderful 100% Pomegranate Juice and POMx are backed by a \$25 million dollar investment in world-class scientific research. This includes ten clinical studies published in top peer-reviewed medical journals that document the pomegranate's antioxidant health benefits such as heart and prostate health.

* * *

In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates.

* * *

NEW POMEGRANATE RESEARCH OFFERS HOPE TO PROSTATE CANCER PATIENTS

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. 46 men who had been treated for prostate cancer with surgery or radiation were given 8oz [sic] of POM Wonderful 100% Pomegranate Juice to drink daily.

Patients with prostate cancer showed a prolongation of PSA doubling time, coupled with corresponding lab effects on reduced prostate cancer as well as reduced oxidated stress.

A majority of the patients experienced a significantly extended PSA doubling time. Doubling time is an indicator of prostate cancer progression – extended doubling time may indicate slower disease progression.

Before the study, the mean doubling time was 15 months. After drinking

8oz [sic] of pomegranate juice daily for two years, the mean PSA doubling 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).

— POMx Pills and Liquid Prostate Newsletter (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 endorser, expressly or by implication, that he possessed and relied upon 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 endorsement, that substantiated the representations set forth in Paragraph 11, at the time the representations were made.
13. In truth and in fact, respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 11, at the time the representations were made. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.
14. Respondent's practices, as alleged in this complaint, constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

THEREFORE, the Federal Trade Commission, this ___ day of _____, 2010, has issued this complaint against respondent.

By the Commission.

Donald S. Clark
Secretary