

Complaint

IN THE MATTER OF

MARK DREHER, PH.D.CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5(A) AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket No. C-4306; File No. 082 3122
Filed November 4, 2010 — Decision, November 4, 2010

The consent order settles allegations that that Mark Dreher, Ph.D., as Vice President of Science & Regulatory Affairs of POM Wonderful LLC, disseminated or caused to be disseminated false or misleading advertisements and promotional materials for POM Juice and POMx products. Specifically, the complaint alleges that Mr. Dreher represented that clinical studies, research and/or trials prove that drinking eight ounces of POM Juice, taking one POMx Pill, or taking one teaspoon of POMx Liquid, daily, treats, prevents, or reduces the risk of heart disease or prostate cancer. The consent order prohibits Mr. Dreher from representing that any POM product is effective in the diagnosis, cure, mitigation, treatment, or prevention of any disease, unless the FDA specifically approves such a claim. The consent order further prohibits Mr. Dreher from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research; or from misrepresenting the health benefits, performance, or efficacy of POM's products. The consent order also requires Mr. Dreher to keep copies of relevant advertisements and materials substantiating advertising claims and to notify the Commission of any changes in employment for the next 20 years.

Participants

For the *Commission*: *Tawana E. Davis, Janet M. Evans, Mary L. Johnson, Elizabeth Nach, Elise Whang, and Andrew Wone.*

For the *Respondent*: *William M. Hannay and Ron Safer, Schiff Harden LLP.*

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:

Complaint

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

Picture
of
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

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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]

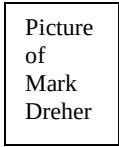
b. * * *

**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.

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* * *

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

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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.

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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.

Complaint

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,

Complaint

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.

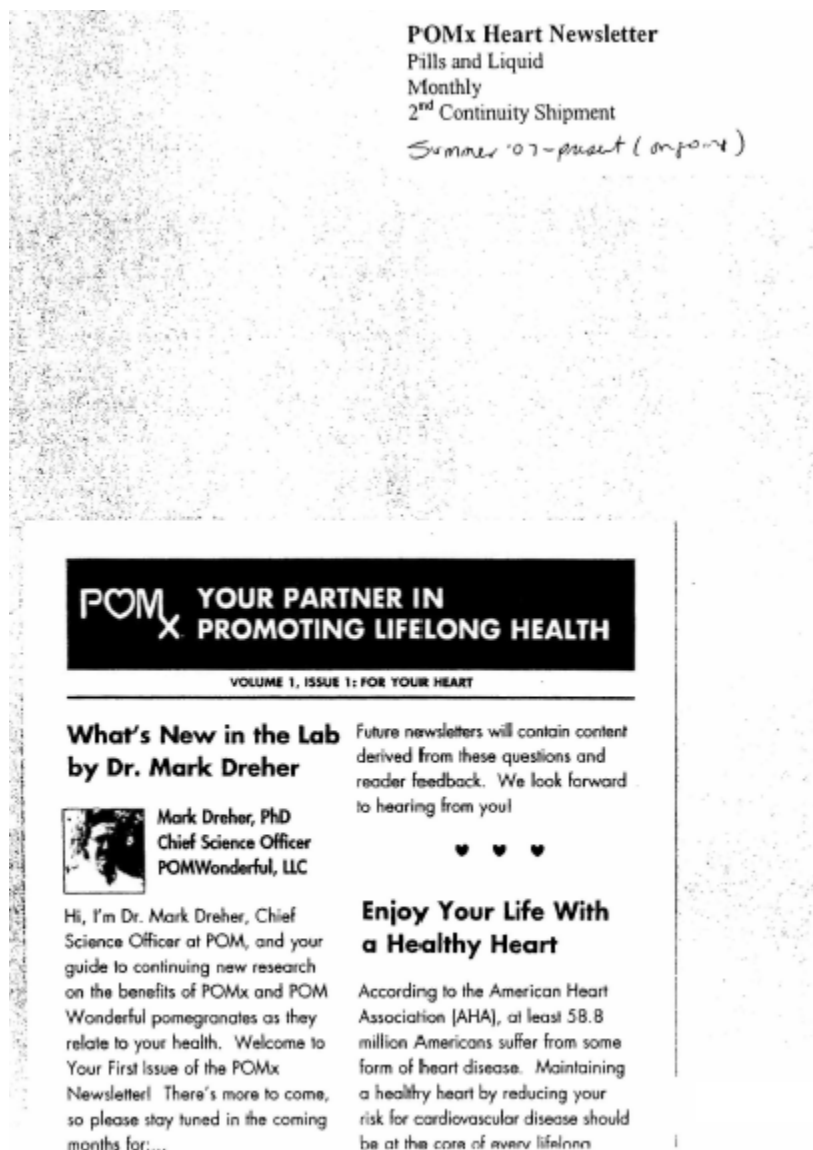
13. In truth and in fact, Respondent did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 11, at the time the representations were made. Therefore, the representation set forth in Paragraph 12 was, and is, false or misleading.

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 fourth day of November, 2010, has issued this complaint against Respondent.

By the Commission.

Complaint

EXHIBIT A

Complaint

EXHIBIT A


**YOUR PARTNER IN
PROMOTING LIFELONG HEALTH**

VOLUME 1, ISSUE 1: FOR YOUR HEART

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


 Mark Dreher, PhD
 Chief Science Officer
 POM Wonderful, LLC

Hi, I'm Dr. Mark Dreher, Chief Science Officer at POM, and your guide to continuing new research on the benefits of POMs and POM Wonderful pomegranates as they relate to your health. Welcome to Your First Issue of the POMs Newsletter! There's more to come, so please stay tuned in the coming months for...

- POM Wonderful's latest research
- Health tips
- Pomegranate facts
- New product information

There's a strong pipeline of research supporting initial findings that POM Wonderful 100% Pomegranate Juice and its counterpart, POMs, are successfully fulfilling their promise for promoting heart health. We are committed to continually testing our products, not only prior to market

Did You Know?

POLYPHENOLS

Polyphenols are antioxidants that naturally occur in pomegranates. These antioxidants neutralize free radicals, helping to prevent the cell and tissue damage that can lead to disease. The heart health benefits associated with California grown, Wonderful variety pomegranates are due to their very high levels of polyphenols.

release but at every step in their evolution. Various patient studies across a wide variety of health concerns are in the works, and we look forward to sharing the results of this research with you.

At POM Wonderful, we aim to be your partner in the promotion of good health that lasts a lifetime. It is our commitment to you and our mission as a company. If you have any questions and/or concerns please send them directly to me at chiefscienceoffice@pomwonderful.com

Future newsletters will contain content derived from these questions and reader feedback. We look forward to hearing from you!

• • •

Enjoy Your Life With a Healthy Heart

According to the American Heart Association (AHA), at least 58.8 million Americans suffer from some form of heart disease. Maintaining a healthy heart by reducing your risk for cardiovascular disease should be at the core of every lifelong wellness plan. A nutrient-rich diet and active lifestyle are the best weapons you have for combating heart disease and enhancing your vitality at any age.

The AHA recommends eating plenty of fruits and vegetables loaded with the vitamins, minerals and fiber your body requires, without the extra calories it doesn't need. But even though you may be eating enough of the right foods, your body still may not be getting all the nutrients it needs to keep you heart truly healthy.

ANTIOXIDANTS: YOUR ALLY IN FIGHTING HEART DISEASE

In order to keep your body in tip-top shape and your heart beating to the rhythm of all you wish to do in life, you need help in the prevention of cell and tissue damage that can lead to disease.

Science tells us that antioxidants neutralize the free radicals that can aggressively destroy healthy cells in your body. But not all antioxidants are equal – some are better at neutralizing free radicals than others. And because your body may not always produce enough of the antioxidants required to neutralize all the free radicals that can lead to cell damage, we have developed POMs to harness and deliver the most potent antioxidants around.

THE FREE RADICAL FIGHTER

Pomegranates contain polyphenols – powerful antioxidants that are important as part of a balanced diet. Published research has shown that the unique polyphenol antioxidants

(please turn to back)

Complaint

EXHIBIT A

VOLUME 1, ISSUE 1: FOR YOUR HEART

Healthy Heart (from Ford)
in POMx and POM Wonderful 100%
Pomegranate juice are superior
fighters in the battle against free
radicals. Each dose of POMx
contains the same amount of
antioxidant polyphenols found in
8oz of POM Wonderful 100%.

**The antioxidants in
POMx are supported by
\$20 million in initial
scientific research**

Pomegranate Juice, and POMx is
the most concentrated source of
pomegranate polyphenol
antioxidants available.

POM Wonderful is committed to
understanding the effects of POM
Wonderful Pomegranate Juice on
cardiovascular health. To date,
our scientists have found that
pomegranate juice may help
counteract factors leading to arterial
plaque build up, as well as inhibit
a number of factors associated with
heart disease.

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),

In his 2004 POMx study,
Dr. Michael Avram,
one of the world's
pre-eminent cardiovascular
researchers from the
Technion Institute in Israel,
remarked that "POMx is as
potent an antioxidant as
pomegranate juice and
just like pomegranate juice,
POMx may promote
cardiovascular health."

those patients who consumed
8oz 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 8oz of POM
Wonderful 100% Pomegranate

Juice daily for three months
experienced 17% improved blood
flow. Those who drank a placebo
experienced an 18% decline.

**PROMOTES HEALTHY
BLOOD VESSELS**

An in vitro study at the University
of California, Los Angeles (UCLA)
showed that pomegranate juice
uniquely possesses enough
antioxidant activity to protect
nitric oxide (an important bio-
chemical that helps maintain
healthy blood vessels for proper
blood flow) against oxidative
destruction thereby enhancing its
biological activity. In other
words, pomegranate juice by
protecting nitric oxide promotes
healthy blood flow.

THE POWER OF POWER

The antioxidants in POMx are
supported by \$20 million in initial
scientific research from leading
universities and so far we've
uncovered encouraging results.

**POMx supplements
your diet
without adding calories,
allowing you to
more easily maintain
a healthy weight
while still getting the
necessary antioxidants**

Due to this promising information,
our studies on POMx and heart
health continue. It is our mission to
deliver the latest information on our
research to you in this newsletter as
soon as studies are completed. At
POM Wonderful we are committed
to learning all we can about the
health benefits of this miraculous
fruit and sharing them with you.

♥ ♥ ♥

NEXT ISSUE: PROSTATE HEALTH

One out of every six men will get
prostate cancer, but only one out of
34 will die from the disease. In our
newsletter next month, we will
discuss preventative measures all
men need to know to manage their
prostate health.

1.888.POMWILL
WWW.POMWILLS.COM

**POM
WONDERFUL**

Complaint

EXHIBIT B**POMx Prostate Newsletter**

Pills and Liquid

Monthly

3rd Continuity Shipment*Fall '07 - present (ongoing)*

VOLUME 1, ISSUE 2: PROSTATE HEALTH

**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.

**Prostate cancer
is the second
leading cause of**

fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or

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

Mark Dreher, PhD
Chief Science Officer
POMWonderful, LLC

Research studies like the ones discussed in this newsletter and

Complaint

EXHIBIT B

POM X YOUR PARTNER IN PROMOTING LIFELONG HEALTH

VOLUME 1, ISSUE 3: PROSTATE HEALTH

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.

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

Since the early 1990's, prostate cancer incidence and deaths have been declining, but the American Cancer Society estimates that there will still be about 218,890 new cases of prostate cancer and 27,050 deaths in the United States in 2007.

According to the American Cancer Society, some of the risk factors for prostate cancer include:

Age – Growing older raises a man's risk of prostate cancer. About two of every three prostate cancers are found in men over the age of 65.

Family History – Men with close family members (father or brother) who have had prostate cancer are more likely to get it themselves, especially if their relatives were young when they got the disease.

Diet – One risk factor that can be changed is diet. The National Cancer Institute's research suggest that obesity and weight gain is linked to increased prostate cancer mortality.

Men who eat a lot of red meat or high-fat dairy products seem to have a greater chance of getting prostate cancer. These men also tend to eat fewer

fruits and vegetables. Doctors are not sure which of these factors causes the risk to go up but the best advice is to consume daily the equivalent of five or
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What's New in the Lab by Dr. Mark Dreher



Mark Dreher, PhD
Chief Science Officer
POM Wonderful, LLC

Research studies like the ones discussed in this newsletter and conducted by UCLA (my alma mater) serve to validate the many reasons I am proud to be affiliated with POM Wonderful and POMx.

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.

Working at POM Wonderful gives me the unique opportunity to really make a difference in the world. That's what gets me up every morning! I get to work with renowned scientists, including a Nobel Laureate, at leading

Studies funded by POM represent the vast majority of medical research ever conducted on pomegranates.

universities around the world. In fact, studies funded by POM represent the vast majority of human medical research ever conducted on pomegranates. No other company that I know of is as dedicated as POM in pursuing the truth and keeping our customers informed.

At POM Wonderful, we aim to be your partner in the promotion of good health that lasts a lifetime. It is our commitment to you, our mission as a company.

Complaint

EXHIBIT B

VOLUME 1, ISSUE 3: PROSTATE HEALTH

Prostate Cancer (from fruit)
more servings of vegetables
and fruits rich in antioxidants
and to eat less red meat and
high-fat foods.

**EARLY DETECTION SEEN AS KEY TO
INCREASING SURVIVAL RATES***

The prostate-specific antigen (PSA)
test and rectal exam can be used to
detect the presence of prostate
cancer when no symptoms are
present. They may help catch the
disease at an early stage when
treatment is more effective.

During a PSA test, a small amount
of blood is drawn and the level
of PSA (a protein produced by the
prostate) is measured to determine
the level of risk. When prostate
cancer is found and treated, the PSA
test may also measure the potential
risk for the cancer to return.

*Please talk to your doctor for more
specific prostate cancer information.

**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
of POM Wonderful 100%
Pomegranate Juice to drink daily. A

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

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 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).

In another study, in vitro laboratory
testing at UCLA showed that POMx
significantly decreased human
prostate cancer cell growth and
increased cancer cell death.

Based on the promising results of
these preliminary studies, two
additional studies are underway to
more fully investigate the potential of
POMx to extend PSA doubling time.

According to Dr. David Heber,
Director of UCLA's
Center for Human Nutrition,
"The most abundant
and most active ingredients
in pomegranate juice
are also found in POMx.
Basic studies in our
laboratory so far indicate
that POMx and pomegranate
juice may have
the same effects."

**SEND US YOUR
QUESTIONS AND COMMENTS**
We encourage you
to participate in our commitment
to a lifetime of good health
by sending your questions
and/or concerns to
chiefscienceofficer@pomwonderful.com
Future newsletters will contain
content derived from these
questions and reader feedback.
We look forward to
hearing from you!

♥ ♥ ♥

**NEXT ISSUE: POMEGRANATE
SUPPLEMENT COMPARISONS**

How does POMx compare with
other pomegranate supplements for
antioxidant potency?

♥ ♥ ♥

1.888.POMWELL
WWW.POMWELL.COM

**POM
WONDERFUL**

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Exhibit B, Page 3

Decision and Order

DECISION AND ORDER

The Federal Trade Commission having initiated an investigation of certain acts and practices of the Respondent named in the caption hereof, and the Respondent having been furnished thereafter with a copy of a draft of complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge the Respondent with violation of the Federal Trade Commission Act; and

The Respondent and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the Respondent of all the jurisdictional facts set forth in the aforesaid draft complaint, a statement that the signing of the agreement is for settlement purposes only and does not constitute an admission by the Respondent that the law has been violated as alleged in such complaint, or that any of the facts as alleged in such complaint, other than jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the Respondent has violated the Act, and that complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of thirty (30) days for the receipt and consideration of public comments, and having duly considered the comments received from interested persons, now in further conformity with the procedure described in Commission Rule 2.34, 16 C.F.R. § 2.34, the Commission hereby issues its complaint, makes the following jurisdictional findings, and issues the following Order:

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.

Decision and Order

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 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
3. “Covered Product” shall mean any food, drug, or dietary supplement for human use or consumption, including, but not limited to, the POM Products.
4. “Food” and “drug” shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
5. “Endorsement” shall mean as defined in 16 C.F.R. § 255.0.
6. “Employment” shall mean any affiliation with any business, non-profit, or government entity, including the performance of services as an officer, owner, manager, supervisor, employee, consultant, or independent contractor; and “Employer” shall mean any and all individuals or entities for whom Respondent performs services as an employee, consultant, or independent contractor.
7. “POM Product” shall mean 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

Decision and Order

and assigns, containing POM Wonderful pomegranate or its components, including, but not limited to, POM Wonderful 100% Pomegranate Juice and pomegranate juice blends, POMx Pills, POMx Liquid, POMx Tea, POMx Iced Coffee, POMx Bars, and POMx Shots.

8. The term “including” in this Order shall mean “without limitation.”
9. The terms “and” and “or” in this Order shall be construed conjunctively or disjunctively as necessary, to make the applicable phrase or sentence inclusive rather than exclusive.

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;

Decision and Order

- 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

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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;

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- 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
- D. All acknowledgments of receipt of this Order, obtained pursuant to Part VI.

VI.

IT IS FURTHER ORDERED that Respondent shall, for a period of seven (7) years after the date of issuance of this Order, deliver a copy of this Order to all current and future principals, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this Order, and shall secure from each such person a signed and dated statement acknowledging receipt of the Order. Respondent shall deliver this Order to such current personnel within thirty (30) days after the effective date of this Order, and to such future personnel within thirty (30) days after the person assumes such position or responsibilities.

VII.

IT IS FURTHER ORDERED that Respondent shall, for a period of five (5) years after the date of issuance of this Order, notify the Commission of the discontinuance of his current business or employment, or of his affiliation with any new business or employment. The notice shall include Respondent's new business address and telephone number and a description of the nature of the business or employment and his duties and responsibilities. Unless otherwise directed by a representative of the Commission, all notices required by this Part shall be sent by overnight courier to the Associate Director for Enforcement,

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Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. Mark Dreher. *Provided, however*, that, in lieu of overnight courier, notices may be sent by first-class mail, but only if electronic versions of such notices are contemporaneously sent to the Commission at DEbrief@ftc.gov.

VIII.

IT IS FURTHER ORDERED that Respondent shall within sixty (60) days after the effective date of this Order, file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of his compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, he shall submit additional true and accurate written reports.

IX.

IT IS FURTHER ORDERED that Respondent must reasonably and in good faith cooperate with the Commission in connection with its litigation in the matter of POM Wonderful LLC et al. (File No. 082-3122) and any subsequent investigations or litigation related to or associated with the transactions or occurrences that are the subject of the Commission's administrative complaint in that matter. Respondent acknowledges, understands, and agrees that such cooperation shall include, but not be limited to, the following:

- A. Appearing for interviews as may reasonably be requested by the Commission;
- 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

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- 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.

Analysis to Aid Public Comment

**ANALYSIS OF 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

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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,

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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

Analysis to Aid Public Comment

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.

Opinion of the Commission

IN THE MATTER OF

POLYPORE INTERNATIONAL, INC.OPINION AND FINAL ORDER OF THE COMMISSION AND
CONCURRING OPINION OF COMMISSIONER ROSCH*Docket No. D-9327; File No. 081 0131**Complaint, September 9, 2008 — Initial Decision, February 22, 2010 —
Opinion and Order, November 5, 2010*

The Commission issued an administrative complaint, 149 F.T.C. 486, challenging Polypore International, Inc.'s ("Polypore") acquisition of rival battery separator manufacturer Microporous Products L.P. ("Microporous") in February 2008. In his Initial Decision, 149 F.T.C. 501, Chief Administrative Law Judge J. Michael Chappell ("ALJ") held that Polypore's acquisition of Microporous was anticompetitive and that a joint marketing agreement between Polypore and a rival battery separator manufacturer violated antitrust laws. At the same time, the Court dismissed a separate allegation that Polypore engaged in exclusionary conduct. Polypore appealed the Initial Decision. On appeal, the Commission unanimously affirmed in part and reversed in part the Initial Decision. The Commission held that the acquisition harmed competition in three of the four relevant markets; in the fourth relevant market, the Commission reversed the ALJ and ruled in favor of Polypore. The Commission further ordered Polypore to divest Microporous to a Commission-approved buyer within six months.

Participants

For the *Commission*: Stephen Antonio, Morris Bloom, Kyle Chadwick, Joel Christie, Steven Dahm, Eric D. Edmondson, Benjamin Gris, Catharine Moscatelli, J. Robert Robertson, and Christian H. Woolley.

For the *Respondent*: Steven G. Bradbury, Paul T. Denis, and Irene Ayzenberg-Lyman, Dechert LLP; and Deborah D. Edney, John F. Graybeal, William L. Rikard, Jr., Adam Shearer, and Eric D. Welsh, Parker Poe Adams & Bernstein LLP.