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# UNITED STATES OF AMERICA FEDERAL TRADE COMMISSION

COMMISSIONERS: Jon Leibowitz, Chairman

William E. Kovacic J. Thomas Rosch Edith Ramirez Julie Brill

In the Matter of

POM WONDERFUL LLC and ROLL INTERNATIONAL CORP., companies, and

STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies. Docket No. 9344

# **COMPLAINT**

The Federal Trade Commission, having reason to believe that POM Wonderful LLC and Roll International Corporation, companies, and Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of the companies ("respondents"), have 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 POM Wonderful LLC ("POM Wonderful") is a Delaware limited liability company with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. POM Wonderful is wholly owned by the Stewart and Lynda Resnick Revocable Trust, dated December 27, 1988, as amended ("1988 Resnick Trust"). Stewart A. Resnick and Lynda Rae Resnick are the sole trustees and the sole beneficiaries of the 1988 Resnick Trust and have the power to revoke or amend the 1988 Resnick Trust at any time. POM Wonderful is a member-managed company, and the 1988 Resnick Trust is the sole member.
- 2. Respondent Roll International Corporation ("Roll") is a Delaware corporation with its principal office or place of business at 11444 West Olympic Boulevard, Los Angeles, California 90064. Roll is wholly owned by the 1988 Resnick Trust and is a sister company

to POM Wonderful. Roll provides shared services such as legal, consulting, and human resources services to POM Wonderful. Through an in-house advertising agency known as "Fire Station Agency" or "the agency" ("Fire Station"), Roll works with POM Wonderful employees to create content for, and determine placement of, the print, outdoor, direct mail, and online ads for the POM Wonderful products. Fire Station also monitors the effectiveness of the POM Wonderful ad campaigns.

- 3. Respondent Stewart A. Resnick is the Chairman of POM Wonderful. He also is the Chairman and President of Roll, and a Director of Roll. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of the companies, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of the companies.
- 4. Respondent Lynda Rae Resnick is a co-Director of Roll with respondent Stewart Resnick. She, along with Stewart Resnick, also has authority over POM Wonderful and Roll in her capacity as a trustee and beneficiary of the 1988 Resnick Trust. Individually or in concert with others, she formulates, directs, or controls the policies, acts, or practices of the companies, including the acts or practices alleged in this complaint. Her principal office or place of business is the same as that of the companies.
- 5. Respondent Matthew Tupper is the President and Chief Operating Officer of POM Wonderful. Individually or in concert with others, he formulates, directs, or controls the policies, acts, or practices of POM Wonderful, including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of the companies.
- 6. Respondents have manufactured, advertised, labeled, offered for sale, sold, and distributed 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.
- 7. POM Wonderful and Roll have operated as a common enterprise while engaging in the deceptive acts and practices alleged below, and individual respondents Stewart A. Resnick and Lynda Rae Resnick have formulated, directed, controlled or had authority to control, or participated in the acts and practices of POM Wonderful and Roll. Because these companies have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below.
- 8. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

#### **POM JUICE MARKETING**

9. Respondents have disseminated or have caused to be disseminated advertising and promotional materials for POM Juice, including product labeling, print advertising, websites, blogs, banner and flash ads on third-party sites, and video ads. Examples of those ads are attached as Exhibits A through H. These materials contain the following representations or statements, among others:

#### A. SUPER HEALTH POWERS!

[Chart comparing antioxidant power of POM Juice and other beverages] \*For more information, visit pomwonderful.com/compare © 2009 POM Wonderful LLC.

#### 100% PURE POMEGRANATE JUICE.

It's 100% pure! It's heroically healthy! It's The Antioxidant Superpower, POM Wonderful 100% authentic pomegranate juice. Backed by \$25 million in medical research. Proven to fight for cardiovascular, prostate and erectile health. Committed to keeping you healthy for a good, long time!

— POM Juice hang tag, Giant Food, Westbard Shopping Center, Bethesda MD (Sept. 2009) [Exh. A]

# B. Drink to prostate health.

[image of POM Juice bottle]

Sometimes, good medicine can taste great. Case in point: POM Wonderful. A recently published preliminary medical study followed 46 men previously treated for prostate cancer, either with surgery or radiation. After drinking 8 ounces of POM Wonderful 100% Pomegranate Juice daily for at least two years, these men experienced significantly longer PSA doubling times. Want to learn more about the results of this study? Visit pomwonderful.com/prostate. **Trust in POM**.

Pomwonderful.com

— print ad, Prevention magazine (Dec. 2008) [Exh. B]

### C. I'm off to save PROSTATES!

[image of POM Juice bottle blasting off]

Man by man, gland by gland, The Antioxidant Superpower® is 100% committed to defending healthy prostates. Powered by pure pomegranate juice . . . backed by \$25 million in vigilant medical research\* . . . there's no telling just how far it will go to improve prostate health in the future.

\* Prostate study details at http://www.pomwonderful.com/health benefits.html

\* \* \*

— print ad, <u>Men's Fitness</u> magazine (Feb. 2009) [Exh. C]; see also Exh. D (print ad, <u>Fitness</u> magazine, Feb. 2009); Exh. E-4 (POM Wonderful website flash ad, Apr. 30, 2009); Exh. G ("Amaze your urologist" internet banner ad, Feb. 14, 2009); Exh. H (internet banner ad, Feb. 17, 2009)

# D. The truth about our pomegranates.

\* \* \*



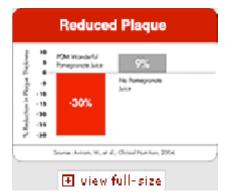
# Backed by science.

POM is the only pomegranate juice backed by \$25 million in medical research. To date, numerous published clinical studies have documented the benefits of drinking pomegranate juice, benefits that include improved heart and prostate health and better erectile function. All of these studies featured patients who drank POM Wonderful 100% Pomegranate Juice, not any other brands. . . . Read more.

\* \* \*

— pomegranatetruth.com (Apr. 28, 2009) [Exh. E-1]

# E. Real Studies. Real Results.



#### Arterial Plaque.

This pilot research study involved 19 elderly individuals who had <u>atherosclerosis</u>, or hardening of the arteries, where <u>plaque</u> was already built-up to a dangerous level. Ten of the patients drinking just 8 oz. of POM Wonderful 100% Pomegranate Juice a day for one year had **up to a 30%** decrease in the thickness of the lining of their <u>carotid artery</u>, while the control group made up of nine patients that didn't drink POM Wonderful, actually had an increase of 9%. In addition, those who drank the pomegranate juice also had a 21% decrease in their <u>systolic blood pressure</u>. [footnote omitted]



#### ACE and Systolic Blood Pressure.

With hypertension, or high blood pressure, the heart works harder. Arteries are under pressure and the chances of a stroke or heart attack are greater. [footnote omitted] ACE (or angiotensin converting enzyme) is an enzyme that the body produces which may lead to high blood pressure resulting in atherosclerosis. [footnote omitted] In a preliminary research study, ten elderly patients with hypertension drank 8 oz. of POM Wonderful 100% Pomegranate Juice a day for just two weeks. After those two weeks, in those patients drinking POM Wonderful ACE activity was significantly decreased by 36%, and, they also saw their systolic blood pressure drop by 5%. [footnote omitted]

— pomwonderful.com "Real Studies" page (Apr. 29, 2009) **[Exh. E-2]** 

F. [video clip opening with image of three adults wearing white lab coats, seated at a table – scientist seated in the center holds a red pomegranate]

[Narrator:] Pomegranate contains powerful antioxidants needed to prevent cancer and diseases.

[male scientist seated on left tries unsuccessfully to open the pomegranate, while female scientist seated on right effortlessly places a straw into a bottle of POM Juice and slowly drinks]

[Narrator:] POM Juice makes it a little easier.

\* \* \*

— www.pomwonderful.com, "Video Gallery" page (Apr. 30, 2009) **[Exh. E-3]** 

G. \*\*\*

[Interviewer:] Should I take vitamins?

[Lynda Resnick:] I don't know your family history. How's your father?

[Interviewer:] He's in good health. Had a bout of prostate

cancer, but that's—

[Lynda Resnick:] You have to be on pomegranate juice. You

have a 50 percent chance of getting it. Listen to me. It is the one thing that will keep your PSA normal. You have to drink pomegranate juice. There is nothing else we know of that will keep your PSA in check. Ask any urologist—your father should be on it. Your father should be on it. I'm sorry to do this to you, but I have to tell you. We just did a study at UCLA, on 43 men ... It arrested their PSA.

How old are you, 28?

[Interviewer:] **Twenty-six.** 

[Lynda Resnick:] Get a base line now. [Pause, wink] It's also 40 percent as

effective as Viagra. Not that you need it. But—couldn't hoit

[sic]!

— Interview with Lynda Resnick, posted on Pom Wonderful Blog page,

http://blog.pomwonderful.com/pom\_wonderful/2009/03/striking-out-on-your-own.html (Mar. 20, 2009) [Exh. F]

# H. Backed by Science

Only POM Wonderful products are backed by \$32 million in medical research. Actually, we are the only pomegranate juice backed by any medical research at all.

There has been a lot of talk lately about the role of pomegranates in promoting heart health, prostate health and proper erectile function. . . .

So what are the medical results on POM Wonderful 100% Pomegranate Juice?

#### Cardiovascular

A 2005 study published in the American Journal of Cardiology showed improved blood flow to the heart in patients drinking 8oz [sic] daily of POM Wonderful 100% Pomegranate Juice for 3 months.

Researchers studied a total of 45 patients with coronary heart disease who had reduced blood flow to the heart.

Patients drinking POM Wonderful 100% Pomegranate Juice experienced a 17% improvement in blood flow, compared to an 18% worsening in patients drinking a placebo.

#### **Prostate**

A preliminary UCLA medical study, published by The American Association for Cancer Research, found hopeful results for prostate health.

The study tested 45 men with recurrent prostate cancer who drank 8 oz of POM Wonderful 100% Pomegranate Juice daily for two years. **Post-prostate surgery PSA average doubling time increased from 15 to 54 months.** PSA is a protein marker for prostate cancer, and a slower PSA doubling time indicates slower disease progression.

#### **Erectile Function**

A pilot study released in the International Journal of Impotence Research in 2007 examined 61 male subjects with mild to moderate erectile dysfunction. Compared to participants taking a placebo, those men drinking 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily for four weeks were 50% more likely to experience improved erections.

\* \* \*

— www.pomwonderful.com, "POM Truth - Backed by Science" web page (Jan. 27, 2010) [Exh. E-5]; see also Exh. E-2 ("Health Benefits" web page, Apr. 29, 2009); Exh. E-1 ("Backed by Science" web page, Apr. 28, 2009)

I. \*\*\*

MS. RESNICK: . . . But, the Wonderfuls are the [pomegranates] ones that we grow because they're the sweetest and they have the health benefits.

\* \* \*

MS. STEWART: But, the medical benefits even outweigh the mythical benefits?

MS. RESNICK: Oh, they do, they do. I mean, it is the magic elixir of our age and of all ages, and we know that it helps circulation, it helps Alzheimer's, it helps all sorts of things in the body--

MS. STEWART: Antioxidants.

MS. RESNICK: Antioxidants. Polyphenol antioxidants off the chart.

MS. STEWART: Right.

MS. RESNICK: And if you know a man that you care about or you are a man, make him drink eight ounces of pomegranate juice a day because what it does for prostate cancer is amazing.

— Lynda Resnick interview (Nov. 20, 2008), available on YouTube at http://www.youtube.com/watch?v=t2vRPGH14u4 [Exh. E-6]

J. \*\*\*

MR. TUPPER: With pomegranate, the dose that's been shown to be effective is eight ounces a day. . . pomegranate is the one fruit that's actually been tested in human beings by dozens of researchers across the globe. There's actually been a study published recently on prostate cancer. Men suffering from advanced stages of prostate cancer drinking eight ounces a day saw the progression of the prostate cancer actually slow dramatically. In addition, there have been a number of studies published on cardiovascular disease in which sick patients again consuming eight ounces of pomegranate juice every day saw dramatic improvements in things like atherosclerosis, which is plaque in the arteries, the amount of blood flow delivered to the heart.

\* \* \*

MR. SULLIVAN: There's a lot of different pomegranate things. How many more products can you put out there, and how much of it is just hooey, . . . you know, pomegranate pills, et cetera?

MR. TUPPER: The products that we put into the market, though, all stem from the fundamental science of the pomegranate, and everything that we put into the market, whether it's juice, whether it's tea, whether it's the supplements that we sell, are all backed by an enormous investment in

science. We've actually funded more than \$25 million of scientific research worldwide since we started the business. And, therefore, every product that we sell is backed by that science. Every product that we sell contains those unique antioxidants. We don't do things for scents and flavors. We do them for the health benefits and for the science.

\* \* \*

— Matthew Tupper interview (June 17, 2008), available on YouTube at http://www.youtube.com/watch?v=Fy2MXbadUr4 [Exh. E-7]

### **POMx MARKETING**

10. Respondents have disseminated or have caused to be disseminated advertising and promotional materials for POMx, including labeling, websites, print advertising, and newsletters. Examples of those ads are attached as Exhibits E, and I through N. These materials contain the following representations or statements, among others:

A. \*\*\*

# The power of POM. Now in one little pill.

All of the antioxidant power of an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice is now available in the convenience of a single calorie-free pill. **Take one daily.** 

\* \* \*

#### Prostate health.

Prostate cancer is the most commonly diagnosed cancer among men in the United States and the second-leading cause of cancer death in men after lung cancer. [footnote omitted]

#### Time pill.

Stable levels of prostate-specific antigens (or PSA levels) are critical for men with prostate cancer. Patients with quick PSA doubling times are more likely to die from their cancer. [footnote omitted] According to a UCLA study of 46 men age 65 to 70 with advanced prostate cancer, drinking an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice every day slowed their PSA doubling time by nearly 350%. [footnote omitted]

83% of those who participated in the study showed a significant decrease in their cancer regrowth rate. [footnote omitted]

\* \* \*

To learn more, visit pompills.com/research.

"Basic studies indicate that POMx and POM Wonderful Pomegranate Juice may have the same effects on prostate health."

David Heber, MD, PhD, Professor of Medicine and Director, UCLA Center for Human Nutrition

\* \* \*

"POM Wonderful Pomegranate Juice has been proven to promote cardiovascular health, and we believe that POMx may have the same health benefits."

Dr. Michael Aviram, Lipid Research Laboratory, Technion Faculty of Medicine, Haifa, Israel

#### Heart health.

In two groundbreaking preliminary studies, patients who drank POM Wonderful 100% Pomegranate Juice experienced impressive cardiovascular results. A pilot study at the Rambam Medical Center in Israel included 19 patients with atherosclerosis (clogged arteries). After a year, arterial plaque decreased 30% for those patients who consumed 8 oz of POM Wonderful 100% Pomegranate Juice daily. [footnote omitted]

An additional study at the University of California, San Francisco 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 a 17% improvement in blood flow. Initial studies on POMx share similar promise for heart health, and our research continues. [image of heart]

\* \* \*

— POMx package insert (Monthly and Trial 1<sup>st</sup> Shipment, June 2007) **[Exh. I]** 

# B. **Take it daily. Feel it forever.**

One POMx Pill = the antioxidant power of an 8oz [sic] glass of POM Wonderful 100% Pomegranate Juice

\* \* \*

# **Science, Not Fiction**

- Made from the only pomegranates backed by \$25 million in medical research and the POM Wonderful brand
- Clinically tested

\* \* \*

Promotes prostate and heart health

— www.pompills.com, POMx Pills home page (Apr. 29, 2009) [Exh. E-8]; see also Exh. E-9 ("POMx Pills" web page, Jan. 27, 2010); Exh. E-8 ("POMx Liquid" web page, Apr. 29, 2009); Exh. E-9 ("POMx Liquid" web page, Jan. 27, 2010)

### C. Medical Benefits

# Research

The antioxidants in POMx are supported by \$32 million in initial scientific research from leading universities, and so far we've uncovered encouraging results. <u>Learn more</u>...

#### **Heart Health**

We have researched the effects of pomegranate juice on cardiovascular health for almost 10 years, and findings suggest 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. Initial pre-clinical tests have shown that POMx has equivalent cardiovascular benefits to POM Wonderful Juice, and additional studies are now going on. <u>Learn more</u>

### **Prostate Health**

A preliminary UCLA medical study on POM Wonderful 100% Pomegranate Juice showed hopeful results for men with prostate cancer who drank an 8oz [sic] glass of pomegranate juice daily. And every POMx capsule provides the antioxidant power

of an 8oz glass [sic] of POM Wonderful 100% Pomegranate Juice. Learn more

— www.pompills.com, Health Benefits web page, (Jan. 27, 2010) **[Exh. E-9]**; *see also* **Exh. E-8** ("Health Benefits" web page, Apr. 29, 2009)

#### D. The Heart of the Matter

# Amaze your cardiologist. Take POMx

POMx is made from the only pomegranates supported by \$32 million of initial scientific research from leading universities . . . .

\* \* \*

# Promising results from studies on POM Wonderful Juice.

One pilot study on 19 patients with atherosclerosis (clogged arteries) at the Technion Institute in Israel demonstrated a reduction in arterial plaque growth. After one year, arterial plaque decreased 30% for those patients who consumed 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily, compared to a 9% worsening for patients who drank a placebo.

A recently published study at the University of California, San Francisco (UCSF) included 45 patients with impaired blood flow to the heart. Patients who consumed 8oz [sic] of POM Wonderful 100% Pomegranate Juice daily for 3 months experienced 17% improved blood flow; those who drank a placebo experienced an 18% decline.

#### POMx and heart health.

Initial research on POMx also shows promise for promoting heart health. In his 2006 POMx study, Dr. Michael Aviram, one of the world's preeminent cardiovascular researchers, remarked that "POMx is as potent an antioxidant as pomegranate juice and just like pomegranate juice, POMx may promote cardiovascular health."

— www.pompills.com, Heart Health page, (Jan. 27, 2010) [Exh. E-9]; see also Exh. E-8 (POMx "Heart Health" web page, Apr. 29, 2009)



# E. Pomegranates and Prostate Health

**Prostate Health** 

\* \* \*

# **Promising News**

A preliminary UCLA medical study involving POM Wonderful 100% Pomegranate Juice revealed promising news. Men who had been treated surgically or with radiation for prostate cancer were given 8oz [sic] of POM Wonderful 100% Pomegranate Juice. A majority of the 46 men participating in the study experienced a significantly extended PSA doubling time.

...[A] slower PSA <u>doubling time</u> may reflect slower progression of the disease.

Before the study of pomegranate juice, the average PSA doubling time for the participants was 15 months. After drinking 8oz [sic] of juice daily, the average PSA doubling time increased to 54 months. That's a 350% increase. <u>Learn more</u>.

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 have the same effect on prostate health."

— www.pompills.com, POMx Prostate Health web page (Apr. 29, 2009) [Exh. E-8]; see also Exh. E-9 (POMx "Prostate Health" web page, Jan. 27, 2010)

# F. HEALTHY. WEALTHY. AND WISE. (2 OUT OF 3 IN THIS ECONOMY AIN'T BAD.)

\* \* \*

#### \$32 million in medical research. A sound investment.

POMx is made from the only pomegranates backed by \$32 million in medical research at the world's leading universities. Not only has this research documented the unique and superior antioxidant power of pomegranates, it has revealed promising results for prostate and cardiovascular health.

#### Hope for the future. Yours.

Our POMx pills are made from the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted.

An initial UCLA study on our juice found hopeful results for prostate health, reporting "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in *Clinical Cancer Research*, '06 [footnotes omitted].

Two additional preliminary studies on our juice showed promising results for heart health. "Stress-induced ischemia (restricted blood flow to the heart) decreased in the pomegranate group," Dr. Dean Ornish reported in the *American Journal of Cardiology*, '05 [footnotes omitted].

"Pomegranate juice consumption resulted in significant reduction in IMT (thickness of arterial plaque) by up to 30% after one year," said Dr. Michael Aviram in *Clinical Nutrition*, '04 [footnote omitted].

— Washington Post, Parade Magazine (Sept. 27, 2009) [Exh. J]

# G. The antioxidant superpill.<sup>™</sup>

\* \* \*

Images of a POMx pill and a POM Juice bottle with an "=" sign between the two images POMx is made from the only pomegranates backed by \$32 million in medical research. These are the same pomegranates we use to make our POM Wonderful 100% Pomegranate Juice, on which each of the following medical studies was conducted. An initial UCLA MEDICAL STUDY on POM Wonderful 100% Pomegranate Juice found hopeful results for prostate health. The study reports "statistically significant prolongation of PSA doubling times," according to Dr. Allen J. Pantuck in Clinical Cancer Research, 2006. [footnotes omitted] Two additional preliminary studies on our juice found promising results for heart health. "Stress-induced ischemia decreased in the pomegranate group," Dr. Dean Ornish reported in the American Journal of Cardiology, 2005. [footnotes omitted] "Pomegranate juice consumption resulted in a significant IMT [footnote omitted] reduction by up to 30% after one year," said Dr. Michael Aviram, referring to reduced arterial plaque in Clinical Nutrition, 2004. [footnotes omitted]

— <u>Washington Post Sunday Circular Free Standing Insert</u> (Jan. 24, 2010) (emphasis in original) [Exh. K]; see also Exh. L (<u>New York Times Magazine</u>, Jan. 6, 2008)

H. \*\*\*

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

\* \* \*

# 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. M]

I. \*\*\*

# 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

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).

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

11. As early as May 2007, respondents 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. Respondents continue to tout POM Wonderful's cardiovascular research and benefits despite the negative results of the Davidson Study. *See, e.g., Exh. E-5* ("POM Truth" web page, Jan. 27, 2010); *Exh. E-9* (POMx "Health Benefits" and "Heart Health" web pages, Jan. 27, 2010); *Exh. K* (POMx newspaper circular, Jan. 24, 2010).

#### FALSE AND MISLEADING REPRESENTATIONS

12. Through the means described in Paragraphs 9 and 10, respondents have represented, 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, (2) lowering blood pressure, and/or (3) 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, (2) lowering blood pressure, and/or (3) improving blood flow to the heart.
- 13. 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, (2) lowering blood pressure, and/or (3) 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, (2) lowering blood pressure, and/or (3) 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 Wonderful products reduce blood pressure.

- 14. Through the means described in Paragraphs 9 and 10, respondents have represented, 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.
- 15. 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 respondents 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."

- 16. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that clinical studies, research, and/or trials prove that:
  - A. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
  - B. Drinking eight ounces of POM Juice daily treats erectile dysfunction.
- 17. In truth and in fact, clinical studies, research, and/or trials do not prove that:
  - A. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
  - B. Drinking eight ounces of POM Juice daily treats erectile dysfunction.

Among other things, a randomized, double-blinded placebo controlled study sponsored by respondents showed that drinking POM Juice provided no statistically significant results on erectile function.

18. Therefore, the representations made in paragraphs 12, 14, and 16 were, and are, false or misleading.

# UNSUBSTANTIATED REPRESENTATIONS

- 19. Through the means described in Paragraphs 9 and 10, respondents have represented, 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, (2) lowering blood pressure, and/or (3) improving blood flow to the heart;
  - 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, (2) lowering blood pressure, and/or (3) 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 PSADT;
- 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;
- E. Drinking eight ounces of POM Juice daily prevents or reduces the risk of erectile dysfunction; and
- F. Drinking eight ounces of POM Juice daily treats erectile dysfunction.
- 20. Through the means described in Paragraphs 9 and 10, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 19, at the time the representations were made.
- 21. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 19, at the time the representations were made. Therefore, the representation set forth in Paragraph 20 was, and is, false or misleading.
- 22. Respondents' 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.

#### NOTICE

Proceedings on the charges asserted against the respondents named in this complaint will be held before an Administrative Law Judge of the Federal Trade Commission, under Part 3 of the Commission's Rules of Practice, 16 C.F.R. Part 3 (2010). A copy of Part 3 of the Commission Rules is enclosed with this complaint, and the Rules are also accessible on the Commission Website at FTC Rules (16 CFR 0-999).

Notice is hereby given that the twenty-fourth day of May, 2011, at 10:00 a.m., is hereby fixed as the time, and the Federal Trade Commission offices, 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580, as the place when and where a hearing will be had before an Administrative Law Judge of the Federal Trade Commission, on the charges set forth in this complaint, at which time and place you will have the right under the Federal Trade Commission Act to appear and show cause why an order should not be entered requiring you to cease and desist from the violations of law charged in this complaint.

You are notified that the opportunity is afforded you to file with the Federal Trade Commission an answer to this complaint on or before the 14th day after service of it upon you. An answer in which the allegations of the complaint are contested shall contain a concise statement of the facts constituting each ground of defense; and specific admission, denial, or explanation of each fact alleged in the complaint or, if you are without knowledge thereof, a statement to that effect. Allegations of the complaint not thus answered shall be deemed to have been admitted.

If you elect not to contest the allegations of fact set forth in the complaint, the answer shall consist of a statement that you admit all of the material facts to be true. Such an answer shall constitute a waiver of hearings as to the facts alleged in the complaint and, together with the complaint, will provide a record basis on which the Commission shall issue a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding. In such answer, you may, however, reserve the right to submit proposed findings of fact and conclusions of law under § 3.46 of the Federal Trade Commission's Rules of Practice for Adjudicative Proceedings.

Failure to answer within the time above provided shall be deemed to constitute a waiver of your right to appear and contest the allegations of the complaint and to authorize the Commission, without further notice to you, to find the facts to be as alleged in the complaint and to enter a final decision containing appropriate findings and conclusions and a final order disposing of the proceeding.

The Administrative Law Judge will schedule an initial prehearing scheduling conference to be held not later than 10 days after the answer is filed by the last answering respondent in the complaint. Unless otherwise directed by the Administrative Law Judge, the scheduling conference and further proceedings will take place at the Federal Trade Commission, 600 Pennsylvania Avenue, N.W., Room 532-H, Washington, D.C. 20580. Rule 3.21(a) requires a meeting of the parties' counsel as early as practicable before the prehearing scheduling conference, but in any event no later than five days after the answer is filed by the last answering respondent. Rule 3.31(b) obligates counsel for each party, within five days of receiving a respondent's answer, to make certain initial disclosures without awaiting a formal discovery request.

The following is the form of order which the Commission has reason to believe should issue if the facts are found to be as alleged in the complaint. If, however, the Commission should conclude from record facts developed in any adjudicative proceedings in this matter that the proposed order provisions might be inadequate to fully protect the consuming public, the Commission may order such other relief as it finds necessary or appropriate.

Moreover, the Commission has reason to believe that, if the facts are found as alleged in the complaint, it may be necessary and appropriate for the Commission to seek relief to redress injury to consumers, or other persons, partnerships or corporations, in the form of restitution for past, present, and future consumers and such other types of relief as are set forth in Section 19(b) of the Federal Trade Commission Act. The Commission will determine whether to apply to a court for such relief

on the basis of the adjudicative proceedings in this matter and such other factors as are relevant to consider the necessity and appropriateness of such action.

#### **ORDER**

#### **DEFINITIONS**

For purposes of this Order, the following definitions shall apply:

- 1. Unless otherwise specified, "individual respondents" shall mean Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper, individually and as officers of Pom Wonderful LLC ("POM Wonderful") and Roll International Corporation ("Roll").
- 2. Unless otherwise specified, "respondents" shall mean POM Wonderful and Roll, their successors and assigns; the individual respondents; and each of the above's officers, agents, representatives, and employees.
- 3. "Commerce" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. § 44.
- 4. "Covered Product" shall mean any food, drug, or dietary supplement, including, but not limited to, the POM Products.
- 5. "Food" and "drug" shall mean as defined in Section 15 of the Federal Trade Commission Act, 15 U.S.C. § 55.
- 6. "Endorsement" shall mean as defined in 16 C.F.R. § 255.0.
- 7. "POM Product" shall mean any food, drug, or dietary supplement containing 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 respondents, 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; treat, prevent, or reduce the risk of prostate cancer, including by prolonging prostate-specific antigen doubling time ("PSADT"); or treat, prevent, or reduce the risk of erectile dysfunction; 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;
- 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 respondents, 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 respondents, 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, respondents rely 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. 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, that are generally accepted in the profession to yield accurate and reliable results.

IV.

#### **IT IS FURTHER ORDERED** that:

- A. Nothing in Parts II or III of the Order shall prohibit respondents 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 or III of the Order shall prohibit respondents from making any representation for any drug that is permitted in the labeling for such drug under any tentative final or final standard 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 POM Wonderful, Roll, and their successors and assigns, and individual respondents 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;
- B. All materials that were relied upon in disseminating the representation;
- C. All tests, reports, studies, surveys, demonstrations, or other evidence in their 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 POM Wonderful, Roll, and their successors and assigns, and individual respondents shall deliver a copy of this Order to all of their current and future principals, officers, directors, and managers, and to all of their current and future employees, agents, and representatives having managerial 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. POM Wonderful, Roll, and their successors and assigns, and individual respondents 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 POM Wonderful, Roll, and their successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporations or any business entity that POM Wonderful, Roll, and their successors and assigns, and individual respondents directly or indirectly control, or have an ownership interest in, that may affect compliance obligations arising under this Order, including but not limited to formation of a new business entity; a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor entity; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order; the proposed filing of a bankruptcy petition; or a change in the business or corporate name or address. Provided, however, that, with respect to any proposed change about which POM Wonderful, Roll, and their successors and assigns, and individual respondents learn less than thirty (30) days prior to the date such action is to take place, POM Wonderful, Roll, and their successors and assigns, and individual respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. 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, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line FTC v. POM Wonderful. Provided, however, that, in lieu of overnight courier, notices may be sent by firstclass 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 each individual respondent, for a period of ten (10) years after the date of issuance of this Order, shall 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, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580, with the subject line *FTC v. POM Wonderful.* 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.

IT IS FURTHER ORDERED that POM Wonderful, Roll, and their successors and assigns, and individual respondents within sixty (60) days after the effective date of this Order, shall each file with the Commission a true and accurate report, in writing, setting forth in detail the manner and form of their compliance with this Order. Within ten (10) days of receipt of written notice from a representative of the Commission, they shall submit additional true and accurate written reports.

X.

This Order will terminate twenty (20) years from the date of its issuance, 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; <u>provided</u>, <u>however</u>, 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;
- B. This Order's application to any proposed respondent that is not named as a defendant in such complaint; and
- C. This Order if such complaint is filed after the Order has terminated pursuant to this Part.

<u>Provided, further</u>, that if such complaint is dismissed or a federal court rules that respondents 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.

**IN WITNESS WHEREOF**, the Federal Trade Commission has caused this complaint to be signed by the Secretary and its official seal to be affixed hereto, at Washington, D.C., this twenty-fourth day of September, 2010.

By the Commission.

Donald S. Clark Secretary

SEAL: