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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and ROLL GLOBAL, as successor in interest to Roll International companies, and	)	**Docket No. 9344**
	)	**PUBLIC**
	)	
	)	
STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies	)	
	)	
	)	

RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART A. RESNICK, AND LYNDA RAE RESNICK'S BRIEF ON APPEAL FROM THE ALJ'S INITIAL DECISION

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STATEMENT OF THE CASE

A. SUMMARY OF ARGUMENT

The POM Wonderful products at issue here consist of 100% pomegranate juice and PomX pills, which are 100% extracted from pomegranates. As the Administrative Law Judge found, these natural food products are perfectly safe and affirmatively promote good health. Prominent scientists have conducted a host of studies exploring the beneficial health effects of pomegranates. These studies, seventy of which have been published in leading peer-review journals, indicate that the POM products at issue in this litigation ("POM Products") promote better heart and prostate health and also improve erectile function. Leading experts in the field testified that these studies were methodologically sound and provided substantial competent and reliable evidence to support the beneficial health effects of POM's products.

As the ALJ further found, there is nothing explicitly false or misleading in POM's challenged advertisements touting the health benefits of their 100% pure pomegranate products, including those which describe accurately the studies showing these products as promoting heart, prostate, and erectile health. Nor, as the ALJ noted, has POM marketed its products as substitutes for medical treatments. POM Wonderful is sold as a food item in the juice section of grocery stores and the challenged advertisements say just that.

These facts should end this case. The FTC has an important history of protecting consumers against entities selling snake oil, misrepresenting ingredients, or making generalized claims that their products are "proven" to cure various medical ailments without credible scientific backing. But POM fits none of these categories. It sells a food that has been thought to promote health for thousands of years. And it has marketed its products not by declaring that they are proven to cure heart disease or prostate cancer or impotence, but rather by tailoring its ad campaigns to what tens of millions of dollars' worth of scientific studies conducted by highly-

respected scientists at some of the world's most prominent public health research institutions have actually shown.

The FTC has no legal basis to sanction an advertiser under these circumstances, and it is bad policy to do so. As the ALJ found, POM Products deliver health benefits to consumers. It makes no sense to prohibit or chill an advertiser from telling them so. Yet that is what Complaint Counsel seeks; and, notwithstanding the ALJ's rejection of many aspects of Complaint Counsel's approach, that is what the ALJ's initial decision, if affirmed, would do.

In bringing this case, Complaint Counsel sought to impose on healthy food products the same scientific standards that apply at the FDA to drug treatments and, in particular, to require double-blind, randomized, placebo-controlled clinical trials ("RCTs") as support for any and all health-related claims. The ALJ wisely rejected this approach, recognizing that establishing such a novel and onerous testing requirement is not called for by the FTCA, would contravene best practices, and raise grave First Amendment concerns. (ALJ Initial Decision [hereinafter "ALJID"] 238-43.)[1] As the ALJ correctly held instead, when an advertiser is marketing a natural food without offering it as a substitute for conventional medical treatment, the level of substantiation for health claims must be "flexible" – factoring in the validity of the underlying science, the costs of additional scientific research and the nature of the health claims being made. (*Id.* at 243-44.) *See In re Pfizer*, 81 F.T.C. 23 (1972) (requiring "reasonable" substantiation).

Importantly, the ALJ found most of POM's challenged ads to be unobjectionable. (ALJID 86-87.) The ALJ also rejected Complaint Counsel's hyper-aggressive attempt to sanction Respondents for interviews in news magazines and on TV talk shows. (*Id.* at 206-10.) Nor would the ALJ countenance Complaint Counsel's effort to cast POM as having flouted the

[1] Although not mentioned by the ALJ, establishing a novel legal standard through adjudication rather than rulemaking would also violate the Administrative Procedure Act.

law or intentionally misled consumers because POM did not simply bow to Complaint Counsel's view of the law. (*Id.* at 216-18.) To the contrary, the ALJ recognized that POM was fully within its rights to resist Complaint Counsel's untested interpretation of the law, much of which the ALJ rejected.

But the ALJ's opinion, to the extent it holds that a subset of POM's ads violate sections 5 and 12 of the FTC Act, also contains fatal errors of law and fact. As elaborated below, the ALJ somehow managed: 1) to deem explicit truths to be implicit falsehoods in contravention of FTC precedent on the interpretation of advertisements and with disregard for POM's First Amendment rights; 2) to transmogrify ads making no explicit claims regarding the prevention, treatment or reduction of the risk of disease into ads purportedly containing implicit claims of prevention, treatment, or risk reduction; 3) to impose a clinical trial standard of substantiation at odds with all the expert testimony; 4) to override the substantiation offered by highly-qualified experts that matched the health claims actually being made in the challenged ads; 5) and to find that the ads were material to consumer choice despite evidence to the contrary, and to impose an order of a breadth and duration that is both unsupported and, again, chilling of POM's free speech rights.

In its long history, the FTC has never sanctioned an advertiser under comparable circumstances – that is, where the advertiser is promoting a healthy food product not as medicine but for what it is (a healthy food) and had made health claims specifically tailored to the actual results of reputable scientific research. There is a good reason for this void. As the USDA recognizes when it gives nutritional advice, we want consumers to choose foods that are good for them. Sanctioning food producers when they tout health benefits violates their First Amendment

rights and inhibits more informed consumer choice. That makes no sense and, accordingly, the Commission should dismiss this Complaint.[2]

B. STATEMENT OF FACTS RELEVANT TO THE ISSUES FOR REVIEW

1. Respondents' $35 Million Research Program Has Produced Powerful Evidence that POM Juice and POMx Enhance Heart and Prostate Health and Improve Erectile Function.

In the 1990s, long before they started selling POM Juice, Respondents Lynda and Stewart Resnick began to explore the potential health benefits of pomegranates, which had been the subject of folklore for thousands of years. (Respondents' Findings of Fact [hereinafter "RFF"] 254, 256.) In 1998, the Resnicks collaborated with Dr. Michael Aviram, world-renowned for his groundbreaking work exploring the antioxidant properties of red wine, to assist them in learning about the potential health benefits of pomegranate juice. (RFF 257) What Dr. Aviram saw in his initial research was remarkable and he told Mr. Resnick that the antioxidant properties in the pomegranate were the most powerful he had ever researched. (RFF 258-259)

Dr. Aviram's initial research spawned a massive scientific undertaking by the Resnicks, who have invested more than $35 million in pomegranate-related research. (RFF 268, 269, 278, 375.) The Resnicks have recruited renowned scientists to conduct more than a hundred studies at forty-four of the world's most prestigious research institutions. (RFF 268, 269, 278, 375, 522.) Seventy of these studies, including 17 studies done on humans, have been published in highly-respected peer review journals. (RFF 268, 269, 393, 522.) The Resnicks also established at POM a science review program run by distinguished scientists, as well as an outside science and health advisory board, whose members have included doctors and scientists from world-leading

[2] These Respondents assert that the Commission should dismiss the Complaint as to Matthew Tupper because, in addition to the reasons set forth herein and as discussed more fully in his separate brief, there is no basis for imposing individual liability as to him.

institutions such as the Dana-Farber Cancer Institute at the Harvard Medical School and the Cedars-Sinai Medical Center. (RFF 341, 344.)

As reflected in the extensive record, POM's health research program yielded a series of scientific studies suggesting that POM Juice, mainly because of its high concentration of bioavailable antioxidants, promotes heart and prostate health and improves erectile function by inhibiting oxidative damage to cell tissue, preserving helpful concentrations of nitric oxide in the body, and by acting as an anti-inflammatory in arteries.

2. Peer-reviewed Scientific Studies Conducted By Leading Scientists Credibly And Reliably Show Positive Effects Of POM Products On Cardiovascular Health.

Respondents have sponsored at least 15 published studies evaluating the effects of pomegranate juice or its derivatives on cardiovascular health *in vitro* and in animals. (RFF 1064.) Around 2000, Dr. Aviram began the earliest studies. (RFF 1065; 1077.) He and his colleagues observed several beneficial effects of pomegranate juice and its extracts at the cellular and animal stage. These included: (1) reduction in oxidation of LDL cholesterol; (2) lessening the "uptake" of oxidized LDL by macrophage foam cells; (3) decrease in size of atherosclerotic lesions and foam cells; and (4) diminishing of platelet aggregation. (RFF 1077.)

Other *in vitro* and animal studies examined the impact of pomegranate juice on nitric oxide concentration in the body and its effects cardiovascular health. (RFF 1087.) Dr. Louis Ignarro, recipient of the Nobel Prize for his discoveries concerning nitric oxide, oversaw a number of studies finding that pomegranate juice and/or POMx: (1) increased and preserved levels of nitric oxide in cell cultures; (2) decreased LDL oxidation, the size of atherosclerotic plaques, and foam cell formation; and (3) reversed effects of shear stress. (RFF 1088.)

In addition to 15 published studies at the cellular and animal level, Respondents have sponsored approximately 10 published studies analyzing the effects of pomegranate juice or its

extracts on cardiovascular health in humans. (RFF 1089.) Among these studies is one conducted by Dr. Dean Ornish, a world-renowned medical doctor and clinical professor of medicine at the University of California at San Francisco. Dr. Ornish examined the effects of POM Juice on a patient's myocardial perfusion (blood flow). (RFF 136, 143, 1127-1138.) His study found that, after three months, patients drinking POM Juice experienced a 35 percent comparative benefit in blood flow. (RFF 1131.) In another study by Dr. Michael Davidson, the Medical Director of Radiant Research who has been involved in over 700 clinical studies, a subgroup of patients at high risk for cardiovascular disease experienced a statistically significant reduction in carotid intima-media thickness ("CIMT") after 18 months. (RFF 1094-95, 1139-1146.) CIMT is used to detect the presence of atherosclerotic disease and may be predictive of cardiovascular disease. Given the subgroup at risk, Dr. Davidson's finding alone could benefit tens of millions of people in the United States. (RFF 1470.) Furthermore, a clinical study conducted by Dr. Aviram found that patients who consumed 8 ounces of pomegranate juice a day for a year showed a decrease in CIMT of up to 30%. (RFF 1111-1126.) Dr. Davidson testified that his findings were consistent with and supported the findings of Dr. Aviram. (RFF 1560-69.)

3. Peer-reviewed Scientific Studies By Leading Scientists Credibly and Reliably Show That POM Products Promote Prostate Health, Including By Lengthening the Key Marker Of PSA Doubling Time.

PSA doubling time ("PSADT"), a measure of the time it takes the levels of prostate specific antigen ("PSA") – a protein made by prostate cells – to double in a man's blood, is an important indicator for recurrence of prostate cancer following radical prostatectomy or radiation therapy. (RFF 1746.) Generally, the shorter the doubling time the greater the risk of cancer recurrence. (RFF 1745.) As reflected in multiple peer-reviewed articles in leading journals, PSADT accurately reflects prostate cancer cell behavior and there is now widespread acceptance

of PSADT as a valid surrogate and "powerful" predictor of recurrence of prostate cancer and death. (RFF 1841-46, 1850, 1889-1893; deKernion Expert Report and Reference Articles appended to thereto; RFF 1719, 1739, 1743-1744, 1869-1903).

Clinical studies have shown a direct link between drinking POM Juice and the lengthening of PSADT. Among them is a 2006 study conducted by Dr. Allan Pantuck of UCLA Medical School, entitled "*Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen Following Surgery or Radiation for Prostate Cancer*," which was published in the prestigious *Journal of Clinical Cancer Research* (RFF 1661, 1673) This study involved men who had undergone radical prostatectomy or radiotherapy. It found that drinking 8 ounces of POM juice daily materially lengthened PSADT in nearly 50% of men after 18 months. In fact, PSADT almost tripled. The study also found that when POM Juice was tested *in vitro* on prostate cell assays, it was found to decrease prostate cancer cell proliferation by 12% (i.e., slow its growth) and stimulate prostate cancer cell apoptosis (cell death) by 17%. Additionally, serum nitric oxide – a molecule found to inhibit inflammation correlated to cancer risk – increased by 23% in men who consumed POM. (RFF 1661-1664, 1670, 1965.)

In 2008, Dr. Pantuck presented a follow-up report to his 2006 study to the American Society of Clinical Oncology. (RFF 1676.) The 2008 report demonstrated that those subjects who continued with the pomegranate juice regimen maintained the lengthening of their PSADT as compared to those who did not continue that regimen. (RFF 1681.) The prestigious *Journal of Urology* published this study in 2009. (RFF 1887.)

Another major study, a randomized Phase II trial by Carducci, et al. (Johns Hopkins School of Medicine) in 2011, entitled "*A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy*" and published in the highly

respected Journal of Clinical Oncology, confirmed clinical findings of the first Pantuck, et al. study. In the Carducci study, 104 men, who had previously been treated for prostate cancer, were randomized into a double-blind clinical trial and were given either 1 or 3 doses of POMx Pills (equivalent to 8 ounces of pomegranate juice) for 18 months. This study showed a near doubling of PSADT from taking POMx Pills independent of dose. (RFF 923; 1695-1700.)

The dramatic results of the Pantuck and Carducci clinical studies were consistent with, and thus reinforced by, pre-clinical laboratory and animal studies that showed a robust effect of POM Juice on prostate cancer in *in vitro* and in *in vivo* mouse models. In this pre-clinical research, POM Juice was found to inhibit cancer cell growth, promote prostate cell death, and inhibit the inflammatory process that is correlated with the growth of cancer. (RFF 1639-1658, 1661, 1676, 1699.)

For example, a study by Seeram, Heber et al., entitled "*Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland*," and published in 2007, showed that pomegranate extract significantly inhibited the growth of the human prostate cancer in the mouse as compared to the control. Similarly, it was found that the hydrolyzed derivatives of ellagitannins – the most abundant polyphenol anti-oxidant present in pomegranate juice – significantly inhibited the growth of human prostate cancer cells *in vitro*. (RFF 1641, 1869.)

In the same vein is a study by Rettig MB, Heber et al., entitled "*Pomegranate Extract Inhibits Androgen-Independent Prostate Cancer Growth Through a Nuclear Factor-κB-Dependent Mechanism*," and published in Molecular Cancer Therapy in 2008. (RFF 1650-1653, 1870.) This study evaluated POMx Pills and POM Juice and found that their consumption in immunodeficient mice with human prostate cancer grafts led to cancer cell growth reduction and

decreased PSA levels. Based on these results, the researchers concluded that pomegranate juice could have potential as a dietary agent to prevent the emergence of androgen-independence, thus potentially prolonging life expectancy of prostate cancer patients. (RFF 1628-1629, 1650-1653, 1870.)

Similarly, in another study by Sartippour MR et al., entitled "*Ellagitannin-rich Pomegranate Extract Inhibits Angiogenesis in Prostate Cancer in vitro and in vivo*," and published in the International Journal of Oncology in 2008, it was found that POMx significantly inhibited angiogenesis (blood vessel growth) both *in vitro* on human prostate cancer tissue and in immunodeficient mice grafted with human prostate cancer tissue. (RFF 1654-1658, 1871.) Angiogenesis is a critical element of cancer growth as sufficient blood flow is necessary to support the fast growing cancer cells. (*Id.*) Prostate cancer cell growth in turn is directly linked to PSADT. (RFF 1743-1755, 1869-1903.) Given this linkage, the researchers concluded, "[t]hese findings strongly suggest the potential of pomegranate ellagitannins for prevention of the multi-focal development of prostate cancer as well as to prolong survival in the growing population of prostate cancer survivors of primary therapy." (RFF 1654-1658, 1871.)

4. Peer-reviewed Scientific Studies By Leading Scientists Show That POM Products Improve Erectile Health And Function.

The studies linking pomegranates to erectile health also are compelling. Among those studies is one conducted by Dr. Ignarro evaluating pomegranate juice's capacity to protect nitric oxide, which is an important indicator of erectile health, against oxidative destruction. (RFF 1965.) Based on this *in vitro* research, Dr. Ignarro concluded that pomegranate juice possesses potent antioxidant activity that results in marked protection of nitric oxide against oxidative destruction, and thereby resulting in augmentation of the beneficial biological actions of nitric

oxide. (RFF 1966-1967). Dr. Ignarro later concluded that "pomegranate juice was 20 times better than any other fruit juice at increasing nitric oxide." (RFF 2091.)

Other studies show similar results. Using an animal model, for example, Dr. Kazem Azadzoi and colleagues found that, due to its high antioxidant capacity, long-term pomegranate juice intake increased intracavernosal blood flow in the penis, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. (RFF 1945-1953.)

In addition to these *in vitro* and *in vivo* studies, multiple other significant scientific studies demonstrate not only the antioxidative powers of pomegranates in enhancing and preserving nitric oxide, but also support the general proposition that antioxidants positively influence erectile health. (RFF 1988-1991.)

Building on this strong basic scientific foundation, Dr. H. Padma-Nathan performed a RCT of pomegranate juice versus placebo in men with erectile dysfunction – the first and only clinical trial of its kind. (RFF 1971-1975, 1978.) This study, which had all the same scientific rigors of any drug study, was published in the distinguished International Journal of Impotence Research in 2007. (Hereinafter referred to as the "*Forest/Padma-Nathan RCT Study*"). (RFF 1974, 1975, 1977.) The study engaged 53 completed subjects with mild-to-moderate erectile dysfunction who underwent two four-week treatment periods separated by a two-week washout. (RFF 1976.) Using a global assessment questionnaire ("GAQ"), Dr. Padma-Nathan found that participants rated pomegranate juice 50% more effective than placebo at improving erections. (RFF 1979-1982; 1985.) The GAQ results achieved a probability value ("p-value") of 0.058, meaning that the positive results of the study were 94.2% likely to be the result of something other than "chance." (RFF 1983-1984.)

5. Respondents' Five Distinguished Expert Witnesses Unequivocally Affirmed The Competence and Reliability of The Scientific Evidence

Regarding The Beneficial Effects Of POM's Products On Heart and Prostate Health And Erectile Function.

At trial, Respondents' five highly-credentialed expert witnesses attested to the credibility, reliability, and probative value of the scientific studies showing that POM Juice and POMx are beneficial to heart and prostate health and erectile function.

Dr. David Heber, a practicing physician, Professor of Medicine and Public Health at UCLA and the Director of the UCLA Center for Human Nutrition, reviewed Respondents' substantive bodies of science in the areas of cardiovascular, prostate, and erectile health. (RFF 119-121.) He concluded that Respondents' science showed that POM's products were likely to cause a significant improvement in cardiovascular health and help to reduce the risk of cardiovascular disease. (RFF 131.) Dr. Heber also concluded that it is likely that POM's products lengthen PSA doubling time for men who have prostate cancer and that those men may experience a deferred recurrence of the disease or death from prostate cancer. (RFF 132). Moreover, Dr. Heber opined that POM's products are likely to reduce the risk of prostate problems for men who have not yet been diagnosed with prostate cancer. (RFF 133.) Additionally, Dr. Heber opined that animal studies showed that pomegranate juice markedly improved proper erectile function and would probably do so in humans due to the effect of pomegranate juice on nitric oxide in the body. (RFF 134.) Additionally, Dr. Heber confirmed that the *Forest/Padma-Nathan RCT Study* showed that consumption of POM Juice significantly improved erectile function among men with erectile dysfunction. (RFF 135.) Dr. Heber also testified that POM's products are entirely safe for human consumption, a fact corroborated by another of Respondents' experts, Dr. Denis Miller, and that Complaint Counsel's experts effectively conceded. (RFF 109-110, 129-130, 708-717; 1038-1039; 2120.)

With respect to heart health specifically, Dr. Ornish validated POM's use of basic science to support POM's cardiovascular health claims and affirmed pomegranate juice's beneficial impact on reducing the risk of cardiovascular disease. (RFF 143.) Both Dr. Ornish and Dr. Heber testified that, based on the full range of Respondents' cardiovascular studies, POM's Products are likely to help prevent or reduce the risk of heart disease by decreasing arterial plaque, lowering blood pressure, and/or improving blood flow to the heart. (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX 0355 Ornish Dep., at 42; PX0192-0045; PX0353 (Heber Dep. at 76-80.)

Respondents offered Dr. Jean deKernion as an expert in the area of prostate health. (RFF 165-174.) Dr. deKernion is the Chairman of the Department of Urology and Senior Associate Dean for Clinical Affairs at the UCLA School of Medicine and served as the Dean of Urology at the UCLA School of Medicine for twenty-six years. (RFF 165-166.) He opined that there is a high degree of probability that the POM Products inhibit the clinical development of prostate cancer cells even in men who have not been diagnosed with prostate cancer. (RFF 173.) Dr. deKernion also concluded there was a high degree of probability that the POM Products provide a special benefit to men with PSA after radical prostatectomy and that they lengthened PSA doubling time and, thus, may defer death from prostate cancer. (RFF 174.) Dr. deKernion confirmed the positive findings of the PSA doubling-time studies of Dr. Pantuck and further opined that that PSA doubling-time is a valid and effective endpoint for recurrence and death from prostate cancer after a radical prostatectomy. (RFF 172.)

With respect to POM's benefits for erectile function, Dr. Arthur Burnett, a Professor of Urology at the Johns Hopkins University School of Medicine/Johns Hopkins Hospital, who has treated more than 10,000 patients for erectile dysfunction and is world-renowned for his

groundbreaking work on nitric oxide, validated POM's science that establishes that pomegranate juice is beneficial to erectile health. (RFF 144-147, 151.) Dr. Burnett stated unequivocally that Respondents' basic scientific and clinical evidence supports the conclusion that pomegranate juice's high antioxidant content improves erectile health and function by increasing the level and preservation of nitric oxide. (RFF 152, 153, 2068, 2081, 2089, 2093, 2100-2106.) In particular, Dr. Burnett testified that the basic scientific studies alone "provide a powerful support for pomegranate juice . . . as antioxidants; that they work with very potent effects on the nitric oxide regulatory mechanism," and that "there's good basic science support that pomegranate juice is a very effective agent factor . . . in vascular function." (RFF 2100-2106.) Dr. Burnett also testified that the *Forest/Padma-Nathan RCT Study* demonstrates pomegranate juice is "a potential treatment for ED." (RFF 1987.)

Dr. Burnett's testimony was reinforced by Dr. Irwin Goldstein, an expert in sexual medicine and on the impact of pomegranate juice, antioxidants, and nitric oxide on erectile function and dysfunction. (RFF 155-164.) Dr. Goldstein is a board certified urologist and sexual medicine physician who has been involved in sexual medicine clinical practice, clinical research, and basic research since 1980. (RFF 155, 156, 2030-2032.) Dr. Goldstein affirmed that competent and reliable scientific evidence suggests that pomegranate juice produces a benefit to erectile function. (RFF 162, 2110-2112, 2097-2099.)

6. POM Markets Its Products As Healthy Food And Creates Ads Tracking The Scientific Research.

Beginning in 2003, as the positive scientific results rolled in, POM began marketing the health benefits of its products using advertising slogans, eye-catching graphics, and accurate descriptions of the supporting science, including an emphasis on the high content of free radical-attacking antioxidants. (CX0016.) With the exception of a few isolated ads from before 2006,

POM's approach has been to describe what research was done, where it was done, and to summarize the results of the specific studies referenced in its advertisements. (Tupper, Tr. 2984-85.) In some cases, POM's advertisements would also direct consumers to its website to read the full scientific study. (Tupper, Tr. 2985-86.) Respondents strictly avoided stating that its products were "clinically proven" to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer, and erectile dysfunction or that they "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer and erectile dysfunction. (RFF 2467-2468.) Instead, the advertisements used qualified language to describe the scientific studies, such as "promising," "encouraging" or "hopeful," and they also were careful, when appropriate, to characterize the studies referenced in the ads as "preliminary" or "initial."[3] At all times, Respondents marketed POM Juice as a healthy food product sold in the juice section of grocery stores and not as a substitute for medical treatment. (RFF 495-499; 524-550).[4]

7. The ALJ Rejects The Core Of Complaint Counsel's Case, But Finds A Subset Of Ads "Impliedly" Misleading and Imposes A Sweeping Injunction.

The ALJ agreed that Respondents' products were safe and that Respondents never marketed the products as a substitute for medical treatment. (ALJID 246.) Given these facts, the ALJ recognized that legal precedent favored a policy of greater rather than lesser information

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[3] For example, the "Drink to Prostate Health" ad stated: "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." (CX0260 and CX 1426 Ex. B.)

[4] Respondents are by no means alone in touting the health benefits of pomegranate juice. The University of Texas MD Anderson Cancer Center, Memorial Sloan-Kettering Cancer Center, Johns Hopkins Hospital and the Mayo Clinic all publicize the role pomegranate juice may play in fighting heart disease or prostate cancer or erectile dysfunction – often citing Respondent-sponsored scientific research to support those statements. (RFF 1802-1820.)

disclosure, as well as rejection of Complaint Counsel's basic framing of the case, which was to treat the products as medicinal drugs subject to FDA standards of clinical proof, including the requirement for RCTs. (*Id.* at 238-42.) The ALJ also found that none of the ads made express claims that the POM Products prevent, treat or reduce the risk of disease and had been proven to have those effects. Moreover, the ALJ found that most of the ads were not false or misleading. (ALJID Findings of Fact [hereinafter "ALJIDFF"] 585-588.)

In an ironic twist, however, the ALJ found that, in those instances where Respondents' ads got specific – that is, when they accurately summarized the findings of scientific studies and directed consumers to the full study results – those ads were (despite expert testimony and extrinsic evidence to the contrary) making "implied" claims to prevent, treat, or cure disease and, thus, subject to a heightened substantiation requirement. (ALJIDFF 580-583.) Further, even though the ALJ found that there was scientific evidence showing that Respondents' products enhance heart and prostate health and improve erectile function, and even though the ALJ found affirmatively that the products do enhance prostate health and erectile function, and even though the ALJ did not identify a single false statement in any of the ads, and even though he rejected the underlying premise of Complaint Counsel's expert witnesses that POM's products should be subject to the hyper-exacting standards of the FDA, the ALJ nonetheless resolved the "conflicting" scientific evidence in favor of Complaint Counsel and found a subset of Respondents' ads to be insufficiently substantiated and, thus, misleading. (ALJIDFF 961; ALJID 289.) Moreover, despite the paucity of objectionable ads out of an original pool of more than 600, and even though Respondents have never before been cross-wise with the FTC, the ALJ imposed a sweeping 20 year injunction, which covers not only the POM Products but also other Roll Global products, such as Fiji Water and Paramount pistachios, on the ground that

Respondents have "explored" testing to see whether those products, like POM juice, might actually deliver health benefits to consumers. (ALJID 311.)

C. STATEMENT OF QUESTIONS TO BE URGED

1. Did the ALJ err in finding that certain of Respondents' advertisements violate Sections 5 and 12 of the FTC Act?

2. Did the ALJ err in his imposition of relief against Respondents?

ARGUMENT

I. THE IMPOSITION OF LIABILITY ON RESPONDENTS WOULD VIOLATE THE FIRST AMENDMENT AND CONTRAVENE FTC LAW GOVERNING THE INTERPRETATION OF ADVERTISEMENTS.

The ALJ's decision barely mentions it, but commercial advertising is firmly protected by the First Amendment. *See Va. State Bd. of Pharmacy v. Va. Citizens Council*, 425 U.S. 748 (1976). This guarantee rests on the principle that the free flow of commercial information serves societal interests by expanding consumer knowledge regarding the choices of goods and services available in the marketplace. *Id.* at 770; *see also Edenfeld v. Fane*, 507 U.S. 761, 767 (1993). ("The commercial marketplace, like other spheres of our social and cultural life, provides a forum where ideas and information flourish . . . . [T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented."). The constitutional command that the channels of commercial information generally should remain free from government interference has "great relevance" with respect to "the fields of medicine and public health," *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011), which, are of course, the fields of the POM advertisements at issue in this case.

The ALJ elided any real discussion of the First Amendment because he believed that certain of Respondents' advertisements were false and misleading and thus not constitutionally protected. This was an error of many dimensions.

First, the ALJ failed to ground his ruling in a long line of Supreme Court caselaw defining what it means for commercial speech to be false or misleading. Under those precedents, because the POM advertisements state accurate and verifiable information, the ALJ could not properly deem them misleading. Second, the ALJ's interpretation of the advertisements as making implied prevention, treatment, and reduction of the risk claims rests on leaps of reasoning that find no support in FTC precedent or elemental logic. Third, the ALJ's s ruling

that Respondents lacked competent and reliable substantiation for those implied claims is untenable not just in light of the dozens of studies conducted by some of the world's most prominent researchers, published in leading peer-reviewed journals, and verified for their reliability at trial by an equally-renowned set of experts, but also in light of the fact that the ALJ himself rejected the "RCTs are necessary" theory on which the objections of Complaint Counsel's experts to Respondents' studies rested. Fourth, the ALJ's resolution of a genuine and vigorous scientific dispute between the parties here in favor of Complaint Counsel's experts cannot render Respondents' advertisements false and misleading and hence unprotected by the First Amendment. *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), which the ALJ largely ignored, says just that. It holds that a lack of significant scientific agreement about the adequacy of health claims made in commercial speech by makers of dietary supplements does not allow the government to declare that expression false or misleading and ban it outright. *Id.* at 655. If the First Amendment bars the government from closing down discussion of the scientific debate about dietary supplements, which are subject to regulation because of consumer safety concerns, *id.* at 652-55, it certainly precludes the government from closing down discussion of the scientific debate about the health benefits of POM's products, which are nutritious and pose no such concerns. In short, were it to sustain the ALJ's liability ruling, the Commission would run head on to the significant constraints that the First Amendment imposes on its FTCA enforcement authority.[5]

[5]The Supreme Court has zealously guarded the First Amendment right to commercial expression. Over the past twenty years, only twice has the Court upheld commercial speech restrictions. *Edge Broad. Co. v. United States*, 509 U.S. 418 (1993); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618 (1995). In all of its other cases (and there are ten), from *Edenfeld* in 1993 to *Sorrell* in 2011, the Supreme Court has struck down every single commercial speech restriction that has come before it. *See Edenfeld, supra*, (1993); *Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91 (1990); *City of Cincinnati v. Discovery Network, Inc.* 507 U.S. 410

A. The Health Benefit Claims In Respondents' Advertisements Are Protected By The First Amendment.

Under Supreme Court precedent that the ALJ disregarded, the First Amendment does not protect advertisements that are "actually or inherently misleading," and therefore such advertisements can be banned outright. By contrast, an advertisement that is only "potentially misleading" is constitutionally protected, cannot be banned outright, and any restrictions on it must satisfy searching constitutional review under the *Central Hudson* test that governs challenges to regulation of commercial speech.[6] *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136, 144-46 (1994); *Peel v. Att'y Disciplinary Comm'n*, 496 U.S. 91, 109-11 (1990); (plurality opinion); *Shapero v. Ky. Bar Ass'n*, 486 U.S. 466, 479 (1988); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 644 (1985); *In re R.M.J.*, 455 U.S. 191, 203 (1982). The Supreme Court established these principles in cases involving advertising for attorney and accounting services, but lower courts have applied them to advertisements for other goods and services, including in *Pearson* to advertisements touting the health and medical benefits of dietary supplements.

1. Respondents' Advertisements Are Not Actually Misleading Because There Is No Evidence In The Record That Anyone Was Misled.

The Supreme Court has long held that an advertisement can be adjudged actually misleading only if there is evidence that consumers in fact have been misled. *R.M.J.*, 455 U.S. at 202; *see id.* at 203 (advertising is actually misleading if "experience has proved that in fact" has been "subject to abuse"); *Peel*, 496 U.S. at 105-06 (plurality opinion) (advertisement is actually

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(1993); *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, Bd. of Accountancy*, 512 U.S. 136 (1994); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001); *Thompson v. W. States Med. Ctr.*, 535 U.S. 357 (2002); and *Sorrell*, *supra* (2011).

[6] *Central Hudson Gas & Elec. v. Public Services Com'n.*, 447 U.S. 557, 566 (1980).

misleading if there is empirical evidence that it deceived consumers). Here, as the ALJ himself found, there is no credible evidence that anyone was actually deceived by POM's advertisements. The only consumer survey evidence in the record showed that "none of the survey respondents [construed] the 'main idea of the billboard advertisements was prevention, risk reduction, or treatment of any specific disease.'" (ALJIDFF 572.) Instead, that evidence showed overwhelmingly that "[t]he most common main idea communicated [to the consumers surveyed] (at least 90%) was that POM Juice had general health benefits," a proposition that the ALJ accepted.

2. Respondents' Advertisements Are Not Inherently Misleading On Their Face Because They Accurately State Verifiable Information About The Health Benefits Of The POM Products.

The Supreme Court has acknowledged that an advertisement can be adjudged inherently misleading on its face in the absence of consumer survey evidence, but it also has made clear that an advertisement cannot be inherently misleading on its face when it states objectively accurate and verifiable facts. *R.M.J.*, 455 U.S. at 205 (truthful statements regarding the jurisdictions in which lawyer was admitted to practice and the nature of his practice areas were not inherently "misleading on [their] face"); *Zauderer*, 471 U.S. at 645 (lawyer statements regarding Dalkon Shield litigation were "easily verifiable and completely accurate," and thus not inherently misleading); *Peel*, 496 U.S. at 100 (plurality opinion) (statements on attorney's letterhead regarding certifications he had received and the jurisdictions in which he was licensed to practice were "true and verifiable" and not inherently misleading); *Ibanez*, 512 U.S. at 144 ("As long as" attorney continued to hold the certification referenced in advertisement, "we cannot imagine how consumers can be misled by her truthful representation to that effect").

An advertisement that states accurate and verifiable facts may, in some instances, be potentially misleading. But in in that event, the advertisement remains constitutionally protected

and it may not be banned; rather, it may only be regulated consistent with the strong First Amendment limits on government restrictions of commercial speech. *See, e.g., R.M.J.*, 455 U.S. at 205; *Pearson*, 164 F.3d at 655-56.

Here, all of the advertisements for which the ALJ found Respondents liable state that antioxidants promote health by fighting free radicals that have harmful effects in the human body and that the POM Products are high in antioxidants and thus promote health. Those facts are absolutely accurate and verifiable, as the ALJ agreed. (*E.g.*, ALJID 254-255). Also accurate and verifiable in the advertisements for which the ALJ found Respondents liable are all of the statements related to the scientific studies of the health benefits of POM Products. The ALJ did not find otherwise. Additionally, it is accurate and verifiable, as some of the advertisements state, that the studies were conducted by world-renowned researchers; that the studies were supported by multi-millions of dollars of funding; and that the results of the studies were published in peer-reviewed journals. The ALJ did not dispute any of that either. The statements about the disease-specific findings of the studies are accurate and verifiable as well. To take but a few examples, it is accurate and verifiable that a study conducted by Dr. Aviram and published in 2002 found that pomegranate juice is 8 times better than green tea at preventing formation of LDL, and that another clinical pilot study conducted by Aviram and published in 2004 found that an 8 ounce glass of POM juice consumed daily reduces plaque that clogs the arteries by up to 30%. (CX031; CX0034; ALJFF 791-792.) It also is accurate and verifiable that a study by Dr. Pantuck of UCLA found that after drinking eight ounces of POM juice daily for at least two years, 46 men who were the subjects of the study experienced significantly slower PSA doubling times. (CX0314; CX0372; CX0379; CX0380; ALJFF 1044-1045.) And it is accurate and verifiable that a pilot study published in the International Journal of Impotence Research found

that POM Juice had beneficial effects on erectile dysfunction. (CX0128; ALJFF 1206, 1250, 1251, 1252.) None of the statements in the advertisements about the specific findings of any of the other studies is any different. Accordingly, the advertisements' accurate and verifiable statements regarding what the studies actually say cannot be inherently misleading, and there is no constitutional basis for a cease and desist order banning those advertisements.

B. The ALJ Improperly Construed Some Of Respondents' Advertisements To Make Implied Claims.

In its Complaint and throughout most of the trial, Complaint Counsel refused to identify which of the more than 600 advertisements of Respondents it was actually targeting as false or misleading, and even misled Respondents by telling them it was excluding ads published after December 2008. (PX0296 at 0010; Mazis, Tr. 2753-54). This game of hide and seek naturally prejudiced Respondents. It also confused the ALJ, who found liability for ads in the time period ostensibly excluded by Complaint Counsel. Procedural irregularities aside, the ALJ's approach to add interpretation cannot stand. While the ALJ correctly found that no advertisements made express claims that POM Products would prevent, treat or reduce the risk of disease or that such effects have been clinically proven (ALJIDFF 586),[7] he erred in straining to find that such efficacy and establishment claims were implied in some of the advertisements.

1. "Efficacy" Claims

As a threshold matter, the ALJ erred in failing to distinguish between purported implied claims of "prevention," "treatment," and "reduction of the risk," which are three very distinct concepts, each calling for different scientific inquiries and potentially different levels of substantiation. By interpreting some of Respondents' ads as implying an undifferentiated claim of "prevent, treatment, or reduction of risk," the ALJ hopelessly confused his analysis and

[7] Thus, the advertisements were not literally false under FTC precedents. *See FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 40 n.2 (D.C. Cir. 1985).

created internal inconsistencies in his ruling. For example, the ALJ found that the POM Products do, in fact, improve prostate and erectile health, (ALJFF 1012, 1137-1142, 1142, 1181-1184, 1250-1252, 1305, 1310, 1312), which is really just another way of saying that the POM Products reduce the risk prostate disease and erectile problems. Had the ALJ not lumped together "prevention," "treatment," and "reduction of the risk," he should, at least, have found the ads to be sufficiently substantiated to the extent that their implied claims extended only to "reduction of risk" in a general and common-sense manner.

In any event, the ALJ's entire chain of interpretive reasoning is legally, logically and linguistically unsound. To take one illustration, the ALJ found that advertisements such as CX0016 contained language to the effect that POM Products are high in antioxidants, that antioxidants fight free radicals, and that free radicals have been shown to cause adverse effects associated with heart disease. (ALJID 43-44.) In the ALJ's view, these statements constituted a "clear and direct connection" between the actual claims, that the product is high in antioxidants and that antioxidants fight free radicals (which are all true), and an implied claim that the product prevents or treats heart disease. (ALJFF 294-295)

Such a connection, however, is neither direct nor clear. The ALJ's sequential reasoning is inconsistent with accepted principles of advertising interpretation and violates several basic rules of logic. A finding that reasonable consumers would draw a connection between a claim that a product is high in antioxidants, on the one hand, and a claim that the product prevents or treats heart disease, on the other, requires significant leaps in logic. Such a connection cannot be made on a "facial" analysis and would, at a minimum, require extrinsic evidence. There was no such extrinsic evidence in this case.

Under settled law, the Commission may find that an advertisement makes an "implied" claim if that claim is clearly and conspicuously contained in an ad even though the claim is not express. The Commission ordinarily considers the totality of the elements present in an ad to make this determination. This does not mean, however, that the Commission can (or does) inject something to an ad that is not present, particularly in a "facial" analysis without aid of extrinsic evidence. *See, e.g., In re Thompson Med. Co.* 104 F.T.C. 648, 788-89 (1984), *petition for review denied sub nom. Thompson Med. Co v. FTC*, 791 F.2d 189 (D.C. Cir. 1986). Indeed, the Commission "does not have license to go on a fishing expedition to pin liability on advertisers for barely imaginable claims." *Kraft, Inc. v. FTC*, 970 F.2d 311, 319-20 (7th Cir. 1992). Similarly, the more attenuated and speculative a chain of reasoning would be required for consumers to reach a "misleading" conclusion, the less likely such a conclusion can be fairly implied without extrinsic evidence. *See Thompson Med.*, 104 F.T.C. 648; *Cf. United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1181 (8th Cir. 1998) ("[t]he greater the degree to which a message relies upon the viewer or consumer to integrate its components and draw the apparent conclusion . . . the less likely it is that a finding of literal falsity will be supported.").

Here, each of the elements of the ALJ's proffered syllogism are true and not facially misleading – independently or in combination. POM is high in antioxidants, antioxidants do fight free radicals, and free radicals do have harmful effects in the body. Each of these statements is, however, highly conditional and indefinite. To leap to a further conclusion based on a statement regarding the antioxidant properties of POM that POM treats, prevents or the reduces the risk specific diseases, even if such diseases were referenced in the ad, requires that one assume that no other factors are relevant to the onset of such diseases and that each step suggests an absolute and comprehensive effect on the following steps, for example that if free

radicals are eliminated from the body the body will not encounter disease. Not only are such suggestions not present in the ads, but specific language in the ads is contrary to and negates such conclusions (e.g. "helps fight").

The ALJ's approach also violates straightforward principles of logic. It incorrectly assumes that each step in the analytical framework is a necessary and sufficient result of the prior step and makes causal assumptions without evidence. In the category of *non sequiturs*, this argument could be said to commit a pure fallacy or the "fallacy of composition," in which conclusions about a whole are improperly drawn from a part of the whole, reflecting inadequate or missing elements in the chain of deduction. *See* S. F. Barker, *The Elements of Logic* 192-95 (2d. ed. 1974). Consider the following illustration: if John drives a car to work every day, and cars emit carbon dioxide, and carbon dioxide causes acid rain, and acid rain causes damage to forests in Canada, does it follow that John is damaging forests in Canada? The link is far too attenuated for any reasonable consumer to condemn John for damaging forests in Canada based on a statement in an advertisement that cars emit carbon dioxide and that carbon dioxide causes acid rain. To come closer to this case, perhaps at most it could be said that if John stops driving his gasoline-powered car he would be making a contribution, however small, to a cleaner environment that might down the road (if combined with many other factors) lessen acid rain damage to forests in Canada. An equally absurd syllogism is the following: beef contains protein, protein is essential to life, therefore beef is essential to life. That last step does not logically follow from the first two. But that is precisely the sort of jump that the ALJ made.

Because the ALJ could not have validly concluded from a facial analysis alone that Respondents' advertisements making these antioxidant claims (which were true) also made specific disease treatment or prevention claims, such a conclusion would require extrinsic

evidence that consumers did in fact draw such a conclusion. *See Thompson Med.*, 104 F.T.C. 648. Complaint counsel offered none. There is therefore no basis for drawing such a conclusion.

What, then, do the statements in POM's advertisements mean? The plain reading of these messages is that the high antioxidant content of POM juice is likely a good thing, because it can help promote healthy functioning of various natural processes in the body.

The ALJ's unprecedented and improper form of implied claim analysis would cause much mischief in the marketplace if adopted by the Commission. Many advertisements, and particularly advertisements on nutrition themes, focus on a particular factor or element that could have implications for health on a broader scale. The U.S. government itself, of course, is constantly making such claims. If an advertiser must imagine and be responsible for all consequent effects that such a factor or element might cause, no matter how speculative, there will be considerably less advertising in areas of significant public benefit. This case is Exhibit A. POM Juice is healthy. But fewer will drink it if the ALJ's ruling is sustained.

2. "Establishment" Claims

As with the efficacy claims, the ALJ properly found that no advertisements made express "establishment" claims. He nevertheless determined that such claims could be implied in some of the ads, and that such a determination could be made by a "facial" look at the advertisements without reference to any extrinsic evidence. (ALID 212.) The fundamental problem with that determination is that the approach the ALJ employed to find that some of the ads did *not* make establishment claims was equally applicable to the remainder of the ads. In other words, under the ALJ's own stated mode of analysis, none of the ads make establishment claims.

In particular, the ALJ found no establishment claim implied when reference to a study was in smaller print than other text, was combined with qualifying language, or if the references

to studies were "vague, non-specific, substantially qualified, and/or otherwise non-definitive." (ALJID 222.) This was correct. However, the ALJ found establishment claims in other ads, even though he acknowledged that the actual descriptions of scientific studies and principles in those ads were also carefully qualified by language stating "that the degree of clinical proof is not fully conclusive." (ALJIDFF 312, 333; *see also* ALJIDFF 342.)

All of Respondents' ads accurately and precisely described the specific findings of the referenced studies. For example, ads referring to studies that showed an increase of PSADT used those terms to describe the studies. (ALJIDFF 311, 314.) References to studies that showed pomegranate juice reduced plaque in arteries discussed the studies in precise terms of atherosclerosis. (ALJIDFF 295, 301.) The ALJ's leap to a conclusion that such advertisements claimed clinical proof of disease treatment or prevention suffers from the same flaw as his similar conclusion as to efficacy claims: the true "overall, common-sense net impression" of these advertisements is that studies have found that the product has certain specific effects that may be of general health benefit, but those effects are attenuated from an ultimate conclusion about disease treatment or prevention. Extrinsic evidence would have been necessary to establish that consumers would make that additional leap to an unstated conclusion.

C. The ALJ's Substantiation Ruling Is Legally and Factually Incorrect.

1. The ALJ Adopted An Unsupported Standard Of Substantiation.

The Bureau recently has been adamant that the substantiation necessary for health-benefit claims of food products must include RCTs.[8] Complaint Counsel hewed to this bright line position in its briefs, and Complaint Counsel's experts did the same in their reports and direct

[8] *See* Randal Shaheen & Amy Ralph Mudge, *Has the FTC Changed The Game on Advertising Substantiation*, 25 Antitrust 65 (2010).

testimony. (Complaint Counsel Brief 32; Complaint Counsel Reply Brief 18.) The ALJ, however, correctly rejected this dogmatic approach.

First, as the ALJ recognized (ALJID 238-241), RCTs simply are not required by the FTC Act to support health-benefit claims generally. *FTC v. QT, Inc.*, 512 F.3d 858, 861 ("Nothing in the Federal Trade Commission Act . . . requires placebo-controlled, double-blind studies."); *see also Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1319-20 (2011) (courts have recognized that "medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials").

Second, as the ALJ found, the expert testimony did not establish that RCTs were required to support the health-benefit claims in this case. (ALJID 242-43.) That testimony showed "that RCTs are not required to convey information about a food or nutrient supplement where, as here, the safety of the product is known; the product creates no material risk of harm; and the product is not being advocated as an alternative to following medical advice." (*Id.* at 243.) The testimony to the contrary by Complaint Counsel's experts was properly discredited. Among other things, it came out at trial that several of those experts actually employed non RCT-based standards in their own research, including research on the health benefits associated with food, and to support public statements selling products. (Stampfer, Tr. 801-02, 805, 810, 814; Melman, Tr. 1148, 1153-55, 1158; Eastham, Tr. 1329-32).

Respondents' experts testified that the totality of the research that has been done – everything from basic science analysis and *in vitro* studies, and from animal studies to human clinical trials – can constitute competent and reliable scientific evidence for the health-benefit claims of foods. None of Respondents' experts testified that a health-benefit claim that is not

supported by a clinical study automatically lacks substantiation. (ALJID 242; Heber, Tr. 1948-49, 2166, 2182; Miller, Tr. 2194; PX0206-0007, 15; Ornish, Tr. 2327-31.)

Neither side thus advocated a clinical studies standard. Complaint Counsel advocated its RCTs are necessary standard, and Respondents advocated their flexible, all-science-should be considered approach. Yet, from out of nowhere, ALJ ruled that clinical studies are necessary to substantiate Respondents' health-benefit claims. (ALJID 273, 285.) A review of the evidence that the ALJ cited for this proposition underscores that it has no moorings in the record.

For example, in stating that clinical studies are necessary to substantiate cardiovascular health claims, the ALJ cited only to the testimony of Dr. Heber, one of POM's experts. (ALJIDFF 711.) But Dr. Heber did not so testify. To the contrary, Dr. Heber made clear not only that clinical trials had significant drawbacks for the study of nutrient substances, but that "the totality of evidence from cellular mechanism studies, studies in animals, as well as studies in humans, some of which may not be clinical RCTs," should be considered. (Heber, Tr. 1949, 2058, 2085-89, 2182.)

In making a similar finding that clinical trials are required for prostate cancer claims, the ALJ cited only to the expert reports of two of Complaint Counsel's experts, Eastham and Stampfer. (ALJID 273 (citing ALJFF 966).) But the ALJ's reliance on those experts is directly at odds with the ALJ's rejection and discrediting of their testimony that RCTs are necessary. There was no basis for the ALJ's rehabilitation of them as justification for the clinical study requirement that he adopted.

The ALJ fared no better with the evidence he cited for the proposition that clinical studies are required to substantiate erectile dysfunction health claims. There, the ALJ relied on the testimony of one of Respondents' experts, Dr. Burnett. (ALJIDFF 1148.) But Dr. Burnett did

not testify that clinical studies are necessary to substantiate erectile dysfunction health claims. Rather, he testified that basic science alone may support such claims, and that Respondents' basic science does just that. (Respondents' Reply Findings of Fact [hereinafter "RRFF"] 764, 1083; *see also* RFF 573; 839; Burnett Tr. 2262-63.)

Complaint Counsel's experts criticized Respondents' clinical studies, and faulted POM for relying on non-clinical studies. But those objections are insufficient to establish the "clinical studies are a must" standard that the ALJ adopted.

The ALJ compounded his error of requiring clinical studies by holding Respondents to an impossibly high and legally untenable standard of dispositive proof through the clinical studies that the POM Products have the health benefits that the ALJ believed that Respondents were claiming.

This flaw is highlighted the ALJ's finding that that "no clinical studies, research, and/or trials *show definitively* that the POM Products treat, prevent, or reduce the risk of prostate cancer." (ALJID 282.) (emphasis added) The testimony of Respondents' expert Dr. deKerninon that the ALJ cited to support this finding states that "no clinical study, research, or trial provides 100% proof" that the POM Products prevent or reduce the risk of prostate cancer, and that the POM Products are not "absolutely preventative." (ALJID FF 1138) But Dr. deKernion was not suggesting there that anything short of "100%" and "absolutes" is unreliable. All that is required is competent and reliable evidence, as both sides acknowledged in their briefing to the ALJ. (ALJID 238.) Yet, the ALJ apparently was requiring much more than that.

That the ALJ imposed this uber-standard of proof is also evident in his finding that Respondents lacked substantiation for their heart health benefit claims. There, ALJ stated "no clinical studies, research, and/or trials *prove* the[] effects" that he said POM was claiming.

(ALJIDFF 962 (emphasis added)). That finding, too, suggests ALJ required definitive proof, not merely competent and reliable evidence.

The ALJ's findings with respect to erectile dysfunction do not, on their face, reflect a 100% guarantee standard. (ALJID FF 1310-1314.) But it is apparent that the "absolute proof" standard tainted his findings there too because, as set forth below, it is clear from the record that Respondents had more than adequate substantiation for the erectile dysfunction claims that the ALJ believed Respondents were making.

2. The ALJ's Ruling That Respondents' Substantiation Was Incompetent And Unreliable And Thus Misleading Defies The Evidence And Flouts The First Amendment.

It is undisputed that the studies on which Respondents relied were conducted by top-flight researchers at top-flight institutions, and that many of the studies were published in prominent, peer-reviewed journals. It is also undisputed that the experts who testified for Respondents at trial and attested to the validity of the studies are themselves world-renowned in their fields. The notion, then, that Respondents' studies are not competent and reliable makes no sense. Would prominent, peer-reviewed journals publish study after study that is not competent and unreliable? Of course not. In short, Respondents obviously had competent and reliable evidence supporting the claims that they made. But even if Respondents made the "treat," "prevent," and "reduce the risk" claims that the ALJ said that they made, the science supports those claims too.

With respect to the heart disease claims, Dr. Ornish and Dr. Heber both testified in no uncertain terms that the POM Products are likely to help prevent or reduce the risk of heart disease in numerous ways. (RFF 1209-1210; PX-0025-0005; Ornish Tr. 2354-55, 2374-75; PX 0344 (Ornish Dep. at 42); PX 0192-0045; PX0353 (Heber Dep. at 76-80.)) The testimony of Dr. Sacks, one of Complaint Counsel's experts, supports what Dr. Ornish and Dr. Heber said.

According to Dr. Sacks, healthy foods (and everyone agrees that the POM Products are healthy) can help treat or prevent heart disease. (RFF 1260; PX 0361 (Sacks Dep. at 25).) To hold, as the ALJ did, that this evidence is not competent and reliable gives a new and bizarre meaning to competent and reliable.

The ALJ's conclusion that there is no competent and reliable evidence to support the prostate health claims that he said Respondents made also does not stand up to scrutiny. The peer-reviewed evidence on which Respondents relied shows that the POM Products may help treat prostate cancer by extending PSA doubling time with men with rising PSA following primary therapy for prostate cancer. Dr. deKernion testified in each of POM's clinical studies, when the subjects were given POM Juice, the studies showed that it slowed the growth of their prostate tumors as expressed by the longer time it took for those tumor cells to double. (RFF 1763, deKernion Tr., 3059-3061.) The evidence on prevention and treatment of prostate cancer is also more than sufficient to meet the competent and reliable standard. The *in vitro* and animal studies, as well as the Pantuck and Carducci studies, show with a high degree or probability that the POM Products inhibit the development of prostate cancer cells in men who have not been diagnosed. (RFF 1577-1578, 1611.) Dr. deKernion, Dr. Heber, and Dr. Miller all attested to the validity and strength of these findings. (RFF 1778, 1779, 1780, 1781, 1783.)

Likewise, with respect to the erectile dysfunction claims, there is ample competent and reliable evidence in the record that supports claims that the ALJ thought that Respondents made. Both Dr. Goldstein and Dr. Burnett testified in detail as to the "treatment" effects of the POM Products. As to "prevention," Dr. Burnett testified that if prevention means "something that potentially has a risk modification benefit that may help preserve erectile function...pomegranate juice has that potential [preventative] role." (Burnett Tr., 2301; 2272-73.) Dr. Goldstein's

testimony was in the same vein. He said unequivocally that "substantial scientific data" shows that pomegranate juice "can counter the inflammatory endothelial [related erectile dysfunction] problems." (RRFF 1088; PX 0352; Goldstein Dep. at 44, 57.) Dr. Goldstein also testified firmly that the evidence shows that pomegranate juice reduces the risk of endothelial related erectile dysfunction. (RRFF 1088; PX 0352.)

Complaint Counsel's experts viewed Respondents' studies and the testimony of Respondents' experts through the prism of their "RCTs are necessary" perspective that the ALJ properly rejected. Thus, their opinions questioning the validity of Respondents' studies should have been given no weight. The ALJ treated their opinions as dispositive, however, in ruling that Respondents lacked reliable and competent substantiation. The ALJ cited no authority for the proposition that witnesses who have been thoroughly discredited can nevertheless tip the evidentiary balance in favor of the party on whose behalf they testified and against the party whose witnesses' credibility was unsullied.

Even if Complaint Counsel's experts are credited, the First Amendment still precludes the imposition of liability on Respondents. This is not a case in which the deck of scientific evidence was stacked against Respondents. To the contrary, even the ALJ recognized that the studies on which Respondents relied were weighty. Complaint Counsel had no countervailing studies of its own that it offered. It simply presented the testimony of its own experts, who adopted a different view of POM's studies and a different view than POM"s experts who testified that the studies were valid. The ALJ wrongly resolved the competing views in favor of Complaint Counsel. But even if the ALJ struck the evidentiary balance correctly, that disposition cannot render Respondents' expression about the studies false and misleading and beyond the ambit of the First Amendment. *Pearson* forecloses that result. As the D.C. Circuit

held there, a genuine disagreement about the meaning of scientific evidence generally cannot extinguish the First Amendment rights of the party against whom the dispute was resolved. 164 F.3d at 655.[9]

It is conceivable that consumers may not fully comprehend the nuances of the scientific disagreement between Respondents' experts and Complaint Counsel's experts. But the First Amendment strips the government of power to suppress commercial speech on the basis of the paternalistic assumption the consumers are unsophisticated and will be easily deceived by commercial messages. The Supreme Court has long adopted a different assumption: "that people will perceive their own best interests if only they are well enough informed. . . ." *Virginia Pharmacy*, 425 U.S. at 770. The Court repeatedly has applied its consumer-knows-best assumption in cases in which it struck down bans on advertisements for attorney and accounting services, which had been justified on the premise that the complexities of law and finance are too difficult for consumers to grasp. *See Bates v. State Bar of Ariz.*, 433 U.S. 350, 374-75 (1977) ("[T]he argument assumes that the public is not sophisticated enough to realize the limitations of advertising, and that the public is better kept in ignorance than trusted with correct but incomplete information. We suspect the argument rests on an underestimation of the public. In any event, we view as dubious any justification that is based on the benefits of public ignorance."); *Zauderer*, 471 U.S. at 644-45 (rejecting "the premise that it is intrinsically difficult to distinguish advertisements containing legal advice that is false or deceptive from those that are truthful and helpful, much more so than is the case with other goods or services"); *Peel*, 496 U.S.

[9] The outcome might be different in a case in which there is scientific disagreement about the potential harmful side effects of a drug. If the substantiation in such a case tips slightly against the drug maker or is even in equipoise, then public safety considerations may allow the government to block the drug maker's expression about the purported benefits of its product. That is not the case, however, because the POM Products are not a drug, but a perfectly safe food that is not advertised as a substitute for traditional medicine.

at 105 (plurality opinion) ("We reject the paternalistic assumption that the recipients of petitioner's letterhead are no more discriminating than the audience for children's television"); *see also Ibanez*, 512 U.S. at 147.

The D.C. Circuit in *Pearson* extended this anti-paternalism principle to commercial speech regarding scientific studies on the health properties of dietary supplements. The D.C. Circuit rebuffed the idea that such claims "are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment at the point of sale." 164 F.3d at 655. That idea, the D.C. Circuit said, conceives of consumers as if they are "asked to buy something while hypnotized, and therefore they are bound to be misled." *Id.* The D.C. Circuit called this jaundiced view of consumer behavior "almost frivolous" and rejected it out of hand. *Id.*[10]

The D.C. Circuit acknowledged in *Pearson* that health claims that lack significant scientific agreement may be "potentially misleading." 164 F.3d at 655. The D.C. Circuit noted, however, that under Supreme Court precedent, potentially misleading commercial speech is protected by the First Amendment; thus, the government cannot ban it, but only may regulate it. *Id.* at 655-56 (citing cases). The D.C. Circuit held in *Pearson* that the FDA had not demonstrated that the asserted potentially misleading effects of the health claims at issue there could not be cured short of a draconian ban, through the far narrower remedy of disclaimers

[10] While the Supreme Court has said that a presumption of consumer ignorance should not be countenanced under the First Amendment, it has acknowledged that "[t]he determination whether an advertisement [for legal services] is misleading requires consideration of the legal sophistication of its audience." *Bates*, 433 U.S. at 384 n.37. To the extent that evidence of audience sophistication is relevant here, it undercuts the ALJ's ruling that the POM advertisements are inherently misleading. As the ALJ himself found, that evidence shows the audience for the advertisements is educated, affluent, health-conscious individuals who would not likely believe that POM's products prevent, treat, and reduce the risk of heart disease, prostate cancer, or erectile dysfunction. (ALJID 219-20.)

about the health claims that themselves must satisfy the rigors of the *Central Hudson* test. *Id.* at 656-57. Here too, even if it can be shown that references in Respondents' advertisements to the studies about the health properties of POM Products are potentially misleading, then the FTC may not prohibit the advertisements altogether. At most, all the FTC can do is to require Respondents to issue limited disclaimers that are carefully tailored under the *Central Hudson* test to address the concern that consumers may be potentially misled.

II. THE ALJ'S MATERIALITY FINDINGS ARE NOT SUPPORTED BY THE PREPONDERANCE OF THE EVIDENCE.

In finding that the allegedly misleading ads were material to prospective consumers, the ALJ misapplied the burden of proof and ultimately relied on evidence insufficient to support his ruling. Although the ALJ did not articulate the appropriate burden-shifting analysis, he relieved Complaint Counsel of its legal burden – in the absence of a presumption or, as here, once any presumption was rebutted – to come forward with affirmative evidence to support a materiality finding. Complaint Counsel produced no such evidence, and in that absence, the ALJ made up his own evidentiary basis for his finding. This was legal error, which the ALJ then compounded by improperly discounting Respondents' substantial evidence of non-materiality.

By far the most probative evidence on the issue of materiality is the Reibstein Survey, which showed that 1% or fewer of POM Juice buyers bought or would buy again because they believe the juice prevents or cures any specific disease. (RFF 2631-32, 2636-37, 2646-57.) The ALJ disregarded the Reibstein Survey's findings because, in his view, they "did not expose consumers to the challenged ads or to the challenged claims" and failed to probe what the survey respondents meant when they indicated that they bought POM juice as a "healthy" choice. (ALJFF 1371.) This was error. The Reibstein Survey was methodologically sound in measuring materiality and did, in fact, appropriately probe the respondents' answers. (RFF 2665-67; RRFF

655, 657-59; Reibstein, Tr. 2492, 2546, 2553-54, 2585-86.) Indeed, the survey's methodology was recommended by Complaint Counsel's own survey expert, Professor Mazis, as one way of proving that an advertisement was not material to consumers. (RFF 2665-71, 2703, 2713, 2717.)

The testimony of another one of Complaint Counsel's experts, Professor Stewart, further confirmed the results of the Reibstein Survey. Professor Stewart acknowledged that it takes "three good exposures" to an advertisement before that ad can have an effect on the consumer, and that it takes "many exposures" to constitute three "good" exposures. (RFF 2696.) Professor Mazis (again, one of Complaint Counsel's experts), concurred with Professor Stewart on this point. (RFF 2697.) The record contains not a shred of evidence that any of the Challenged Advertisements had more than a single run, much less bringing about "many" exposures of the advertisement to any consumer. (RFF 2698-2701). Accordingly, based on the opinions of Complaint Counsel's own experts, the weight of the evidence on materiality conclusively demonstrates that that the ads could not have affected consumer behavior. Even Professor Mazis agreed and conceded that there was no evidence in this case to say that "it's probable that any POM Juice or POMx advertisement was likely to affect anyone's belief about POM." (RFF 2689, 2719-2720.)

Complaint Counsel failed to counter Respondents' strong evidence that consumers did not in fact purchase POM Products to prevent or treat disease and were not sufficiently exposed to the ads to have a material impact. And while the ALJ improperly scrounged the record to make up this deficit, the evidence on which rested his materiality is not probative. First, the ALJ improperly relied on Respondents' creative briefs as evidence that Respondents designed their ads to appeal to consumers interested in heart, prostate and erectile health. To begin with, those briefs should be afforded little probative value because the uncontroverted evidence is that they

were typically prepared by junior POM marketing employees and reflected the opinions of only these employees, not those of senior executives. (L. Resnick, Dep. 102-03, 109); Tupper, Tr. 923-24; Perdigao, Tr. 623-24, 2790-91; Leow, Tr. 459-60). No less important, although the creative briefs may show an intent to communicate generalized benefits, they do not suggest an effort to sell POM Products as preventing, treating, or reducing the risk of disease – which is the alleged false or misleading conduct that must be material to support any sanction. Accordingly, the creative briefs provide no evidence of materiality whatsoever.

Nor is there any reliable evidence that Respondents made "disease treatment" claims in order to generate sales or that they "were aware" of such an effect. ALJID 290-293. When directly asked about this issue, Respondents' witnesses denied such facts and explained why they were unlikely to be true. *See* Tr. 369:17-370:1; Posell Dep. 231-236.

In any event, such evidence should be insufficient as a matter of law. Once the presumption of materiality is rebutted, the Commission looks to more direct evidence, such as consumer surveys, not just "intent" evidence, to satisfy the burden of establishing materiality. *See In re Novartis*, 127 F.T.C. 580, 689-90 (1999), *petition for review denied sub nom Novartis Corp. v. FTC*, 223 F.3d 783 (D.C Cir. 2000).

Similar flaws permeate the OTX A&U and Zoomerang studies, which the ALJ found probative. The record is replete with evidence that these two surveys fail to address materiality and are so methodologically flawed that they cannot possibly support a finding of materiality. (RFF 2722-25, 2279, 2232-33, 2238, 2743-44; RRFF 648-50).

Finally, the ALJ erroneously concluded that Professor Reibstein testified that the claims in question would motivate consumers to purchase POM Juice. (ALJID 295.) As the record reflects, Professor Reibstein never testified that the supposedly improper implied claims were

material to consumer purchase decisions. (RRFF 338). He merely stated that "it was indeed possible" for such claims to be important if they are made in Complaint Counsel's strongest formulation, but noted that "that's different than saying that they [consumers] would believe it." (PX0356 (Reibstein Dep. 117-19)). A mere possibility, unsubstantiated by any actual evidence, cannot support a finding of materiality.

III. EVEN IF RESPONDENTS VIOLATED THE FTCA, THERE IS NO BASIS FOR A CEASE AND DESIST ORDER OF ANY KIND, AND NO BASIS FOR AN ORDER COVERING PRODUCTS NOT AT ISSUE HERE.

A. An Injunction Is Unwarranted Because Respondents Have Stopped The Conduct For Which The ALJ Would Impose Liability And That Conduct Is Unlikely To Recur.

"Past wrongs are not enough for the grant of an injunction; an injunction will issue only if the wrongs are ongoing or likely to recur." *FTC v. Evans Prods Co.*, 775 F.2d 1084, 1087 (9th Cir. 1985) (internal quotation marks omitted). This standard cannot be met here. The ALJ found actionable only a small sample of the more than 600 ads originally challenged by Complaint Counsel and many of the actionable ads are extremely dated "outliers" that predated a shift in ad policy and reviewing processes begun in 2006. Respondents stopped running these outlier ads long ago. They also have implemented corrective measures to ensure that the actionable ads are not repeated. (RFF 2254-2263.) Accordingly, injunctive relief is not warranted. *See, e.g., Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 149 (2d Cir. 1964) ("Cessation of the offending activity, with the likelihood that the petitioner will not again resume it or a related activity, has been one factor which courts have considered in limiting broad Commission orders.)

The ALJ implicitly recognized that the old outlier ads were too remote to justify an injunction, but imposed one nonetheless because, in his view, "even if the exact same advertisements have not been repeated, this does not mean that Respondents' violations will not be repeated, particularly in light of the fact that numerous advertisements disseminated after

2006 were found to have made implied disease claims, without adequate substantiation." (ALJID 298.) To support this view, however, the ALJ could cite to only a handful of advertisements. Those advertisements do not provide a basis for injunctive relief. First, as the record shows overwhelmingly, Respondents have long ceased running the "outlier" ads and implemented corrective measures to ensure a change in approach to avoid repetition. Thus, even assuming these ads to be actionable, they are moribund. (RFF 2254-2263). Second, even assuming that the post-2006 ads cited by the ALJ as supporting an injunction are indeed actionable, only the September 2009 *Time Magazine* wrap, the June/July 2010 print advertisement in *Advocate* and *Playboy*, and certain 2009/2010 website captures were published between the time the Commission began its investigation in early 2009 to when it filed its complaint. These extremely few and quite minor alleged transgressions, on their own, are not enough to support injunctive relief.

The ALJ's reliance on *In re Fedders Corp.*, 85 F.T.C. 38 (Jan. 14, 1975) is misplaced. In that case, a company was found to have promulgated 173 separate false advertisements and to have stopped the conduct only after an investigation commenced. Here, Respondents have made at worst only a handful of unsupported statements as determined by the ALJ and voluntarily ended the substantial majority of their challenged advertising before the commencement of the investigation.

B. A Cease And Desist Order Covering Respondents' Other Products Is Unwarranted.

The ALJ's rationale for imposing a sweeping, 20-year, multiproduct order against entities with no history of FTCA violations, and in particular his findings with respect to transferability, seriousness, and deliberateness, are wrong as a matter of fact and law.

1. Transferability.

The ALJ's justification for imposing an injunction covering not only POM Products but all Roll Global "food, drug, or dietary supplement products" boils down to the idea that all such products are similarly situated and, as required by precedent, the alleged offending marketing practices are "fully transferable." (ALJID 311-12.) This does not bear scrutiny. Transferability analysis is supposed to focus on whether the violative practice could be easily transferred to other products. *Telebrands Corp. v. FTC*, 457 F.3d 354, 358 (4th Cir. 2006). Here, the answer to that question is clear. The tens of millions of dollars Respondents spent on scientific research specifically related to pomegranate juice, and their advertising publicizing this research, are not "transferable" to completely different products sold by other Roll Global companies, such as tangerines or pistachios or bottled water. Roll Global has been selling these other products for many years without ever embarking on such a combined research and marketing program. And the record contains no evidence that the Roll Global companies would likely start similar actions with respect to their many other commodity food and drink products that would be covered by the proposed order.

A finding of transferability is inappropriate when the product being advertised is one of many different products, when those other products are differently positioned with respect to the violative practice, and when the same practice could not reasonably be applied to those other products. *Am. Home Prods. v. FTC*, 695 F.2d 681, 711 (3d Cir. 1982) (court modified FTC's order where evidence did not support an inclination or tendency to misrepresent non-comparative claims where comparative claims were found to be in violation of the FTCA). This case fits that description to a tee. The criteria for transferability cannot be manufactured by the ALJ's vague observation that Roll Global has considered whether some of its other products might have

potential health benefits. Does the government really want to chill food producers from exploring whether their products are healthy? Yet that is what the ALJ's reasoning would do.

2. Seriousness.

The ALJ rests his finding of "seriousness" mainly on the notion that Respondents' ads implicate serious diseases, as was true in *Daniel Chapter One* and *Stouffer*. (ALJID 312.) But a comparison with those cases shows precisely why a finding of seriousness is not warranted here. In *Daniel Chapter One*, the challenged product was both dangerous and an untested drug that respondents suggested should be consumed as a substitute for traditional cancer treatments. *Daniel Chapter I,* FTC Docket No. 9329 (2009). This combination threatened very serious consumer harm – that consumers, at respondents' urging, would forego beneficial medical treatments and/or imbibe a food product that would cause a dangerous drug interaction. Here, the exact opposite is the case. As the ALJ himself found, POM's Products are safe – indeed they are healthy – and they have never been marketed as substitutes for medical treatment.

The ALJ's reliance on *Stouffer* is similarly misplaced. In *Stouffer*, the respondents represented that its food product was low in sodium when it actually was not. *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 747 (1994). The Commission observed that the seriousness of the low sodium claim there stemmed "from the overall health ramifications of any sodium claim" and further explained that there was "medical evidence supporting a link between sodium consumption and high blood pressure." *Id.* at 812. Thus, in *Stouffer,* the low sodium claim was serious because of the negative health ramifications from consuming that product. Again, however, the ALJ found the opposite here: *i.e.*, that the science shows that it is absolutely safe to consume POM's products and consumption of the juice has a positive impact on both prostate,

erectile, and cardiovascular health. (ALJIDFF 77-81, 85-88, 699, 754, 1011, 1012, 1138-1142, 1144, 1250, 1252, 1310, 1312).[11]

3. Deliberateness

The ALJ's approach to the deliberateness inquiry is also rife with legal and factual error. The ALJ found Respondents' conduct to meet the deliberateness standard because it did not involve an "isolated instance." (ALJID 312, internal quotation marks omitted.) But this dramatically understates the deliberateness test. The primary inquiry is whether there was a blatant disregard of the law. *Standard Oil Co. v. FTC*, 577 F.2d 653, 662 (9th Cir. 1978). Under that standard, the record must show that Respondents continuously and knowingly disseminated claims despite having substantial information that the statements were false. *See In re Brake Guards Prods, Inc.*, 125 F.T.C. 138, 213 (1998) (deliberateness found where record showed "respondents' continuous, knowing dissemination of claims designed to sell their product regardless of whether they had sufficient information to support the truth of these claims, and despite substantial information that they were false.")

Complaint Counsel did not come close to meeting this standard. There is no evidence that Respondents had any knowledge that the science was so flawed or unreliable that it could not support the advertising claims. To the contrary, the evidence shows that Respondents were informed over and over again by leading scientists about the dramatic positive health effects of their products and the research supporting such a view. (RFF 326-27, 329, 333-34, 335-36, 340-

[11] The ALJ made a passing reference to *Litton Industries*, but it is inapposite. In *Litton*, the Commission did not conclude, as the ALJ suggests, that the claims were serious on account of survey results to support claims of product superiority. *In re Litton Indus., Inc.*, 97 F.T.C. 1, 80(1981). Rather, the Commission found that the seriousness of the violation hinged upon the fact that *Litton* made claims about the challenged product "despite clear indication that t lacked a reasonable basis to make them." *Id.*

45.). In contrast to the respondents in *Daniel Chapter One*, a case heavily relied on by the ALJ, the Respondents here conducted real and serious research conducted by leading scholars and published in distinguished prominent peer-review journals. *See Daubert v. Merrell Dow Pharms, Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995) ("That the research is accepted for publication in a reputable scientific journal after being subjected to the usual rigors of peer review is a significant indication that it is taken seriously by other scientists . . . . "). Indeed, unlike the typical food company, Respondents accumulated an unprecedented amount of reliable and peer-reviewed scientific evidence at a great expense, conducted and vetted by outstanding and world-renowned scientists and doctors, and, over time, established a robust internal vetting process. (RFF 326-27, 329, 333-34, 335-36, 340-45.)[12] Even when the research yielded positive results, Mr. Resnick, on multiple occasions, double-checked the conclusions by employing the use of blinded independent reviewers. (RFF 436-39, 443.) In short, the overwhelming weight of the evidence reflects that Respondents genuinely believe that their scientific support was rigorous, reliable, and fully capable of supporting their marketing claims. (RFF 502-550.)

A comparison with the deliberateness cases cited by the ALJ is instructive. In *Sears*, the Ninth Circuit justified a finding of deliberateness not, as the ALJ erroneously stated, on the cost of and extensiveness of the advertising campaign, but rather on Sears' "blatant and utter disregard for the law" because Sears knew that its central claim in its advertising was false at all times. *Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 394 (9th Cir. 1982) (internal quotation marks omitted).

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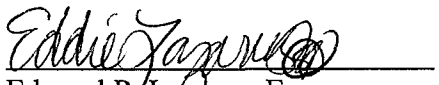
[12]Among the specific errors in his deliberateness analysis, the ALJ failed to account for the internal procedures that Respondents used to evaluate their advertisements. *Standard Oil*, 577 F.2d at 663 (modifying order because Commission failed to consider procedures petitioners used to evaluate the advertisements before they were aired).

Similarly, in *Thompson Medical*, the Commission found that the respondents there acted deliberately because they had "good reason to know" that their advertisements conveyed a misleading message. *Thompson Medical*, 104 F.T.C.at 99. They also had, prior to litigation, conducted copy tests on the challenged advertisements that directly indicated that consumers misinterpreted the advertisements. *Id.* No such evidence exists here. Even accepting the ALJ's finding that a small subset the ads were misleading, at worst, the evidence shows Respondents inadvertently miscalculated the weight of the scientific evidence supporting their ads and does not reflect that Respondents blatantly disregarded any law or intended to mislead consumers.

CONCLUSION

For the foregoing reasons, the Commission should reject the ALJ's Initial Decision and issue an order dismissing the administrative complaint and stating that the Commission will take no action against Respondents related to the matters set forth in the complaint.

Respectfully,



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CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of **RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART RESNICK, AND LYNDA RESNICK'S BRIEF ON APPEAL FROM THE ALJ'S INITIAL DECISION**, and that on this 18th day of June, 2012, I caused the foregoing to be served by hand delivery and e-mail on the following:

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Washington, DC 20580

The Honorable D. Michael Chappell
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Federal Trade Commission
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I hereby certify that this is a true and correct copy of the foregoing and that on this 18th day of June, 2012, I caused the foregoing to be served by e-mail on the following:

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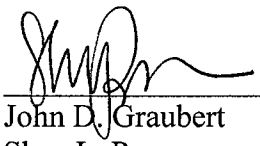

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UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

In the Matter of	)	
	)	
POM WONDERFUL LLC and ROLL GLOBAL, as successor in interest to Roll International companies, and	)	**Docket No. 9344**
	)	**PUBLIC**
	)	
	)	
STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER, individually and as officers of the companies	)	
	)	
	)	

[PROPOSED] ORDER

Having considered the record below, the briefing before the Commission, and the allegations made by Complaint Counsel in this case, it is hereby ordered that the Complaint is dismissed as to all Respondents.

SO ORDERED _____.

DATED: _____.