ORIGINAL

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	)	
	)	

REPLY BRIEF OF RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART A. RESNICK, and LYNDA RAE RESNICK

Kristina M. Diaz, Esq.
Alicia Mew, Esq.
Johnny Traboulsi, Esq.
Brooke Hammond, Esq.
Roll Law Group P.C.
11444 West Olympic Blvd., 10th Floor
Los Angeles, CA, 90064
Tel: 310.966.8400
Fax: 310.966.8810
Email: kdiaz@roll.com

John Graubert, Esq.
Skye Perryman, Esq.
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.662.6000
Fax: 202.662.6291
Email: jgraubert@cov.com

Edward P. Lazarus, Esq.
5193 Watson Street, N.W.
Washington, DC 20016
Tel: 323.244-6831
Email: lazarus.eddie@gmail.com

Bertram Fields, Esq.
Greenberg Glusker Fields
Claman & Machtinger, LLP
1900 Avenue of the Stars, Suite 2100
Los Angeles, CA 90067
Tel: 310.553.3610
Fax: 310.553.0687
Email: bfields@greenbergglusker.com

Michael C. Small, Esq.
Akin Gump Strauss Hauer & Feld
2029 Century Park East, Suite 2400
Los Angeles, CA 90067
Tel: 310.229.1000
Fax: 310.229.1001
Email: msmall@akingump.com

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

I. INTRODUCTION

Complaint Counsel asks the Commission to treat this as a simple case. But it isn't. In the annals of reported FTC cases, no company has ever been found liable under similar circumstances. Certainly, Complaint Counsel has not cited any comparable precedent.

With respect to ad interpretation, there is no case in which this Commission, in order to find liability, has had to infer so much meaning from so little evidence. As the ALJ found, Respondents' ads do not make any of the "challenged claims" explicitly. Complaint Counsel failed to adduce a shred of extrinsic evidence -- no expert witness, no consumer survey -- to support its assertion that the ads implied the pharmaceutical-type disease claims Complaint Counsel has alleged. The only expert to testify on the meaning of the ads stated that they were not reasonably susceptible to the implied "net impression" inferred by Complaint Counsel, and also rejected Complaint Counsel's interpretation of specific components of individual ads.

With respect to substantiation, there is no case in which the Commission has found ads misleading due to a lack of substantiation where, as here, the ads limit their claims to generally accepted science (such as the fact that antioxidants fight deleterious free radicals) and accurate summaries of legitimate scientific studies evaluating the benefits of the advertised products. Generally, the reported cases finding lack of substantiation involve ads that explicitly or nearly explicitly claim that a product is "proven" to achieve a certain result and then either do not discuss supporting evidence or make bogus claims about the evidence. Here, the opposite is true. Respondents' ads do not explicitly claim that their products prevent, treat or reduce the risk of anything - instead, they consist of accurate statements about the beneficial effects of antioxidants and truthfully discuss relevant legitimate scientific studies.

Nor is there another case where the Commission has been asked to discount so much legitimate science (over 70 studies by leading scientists published in leading peer-reviewed

journals) and so many prominent experts. Multiple experts validated the science on which Respondents based their claims and confirmed the beneficial effects of Respondents' products. By contrast, Complaint Counsel relied on "experts" like Dr. Arthur Melman, who testified that water is a drug for FTCA purposes (because it is made up of oxygen and hydrogen), thought he was testifying as part of an FTC pre-approval process for marketing claims, and who denigrated Respondents' erectile health claims due to insufficient human trial evidence while touting as a "fountain of youth" his own competing and potentially dangerous erectile dysfunction gene therapy treatment without any human trial evidence at all.

With the facts and the law stacked against it, Complaint Counsel resorts to invective, accusing Respondents of "obscuring," "spinning," and "obfuscating" the evidence. Respondents ask only that the Commission, in considering the extreme position that Complaint Counsel advances, keep an open mind as to which party has actually more fairly characterized the evidence and the law.

Did Respondents' opening brief, as Complaint Counsel twice asserts, really "let the truth slip" and equate Respondents' "improve" your health claims with the kind of pharmaceutical-type "reduce the risk" of disease claims alleged in the Complaint? Actually, Respondents explicitly drew a distinction between Complaint Counsel's pharmaceutical-type use of the term "reduction of risk" and the very different "general and common sense" notion of "reduction of risk." Just read the cited passage on Page 23 of Respondents' opening brief.

Is it accurate to assert, as Complaint Counsel does, that Respondents' "Only Antioxidant Rated X" ad conveys a definitive ED treatment claim because the ad states "that the product may assist in the 'management of ED'"? (CCAB 6.) Actually, the ad accurately quotes a

"preliminary study" as saying that, due to the effect of POM's antioxidants, the product "has potential in the management of ED; further studies are warranted." Just read the ad.

Is it appropriate to argue, when interpreting Respondents' ads, that the term improving "erectile health" is really a "stand-in" for "treating erectile dysfunction " (CCAB 7) yet argue, when trying to undermine Respondents' expert testimony, that "erectile health is a separate and distinct concept from . . . treatment for the medical condition of erectile dysfunction"?

These are but a few illustrations of just how far Complaint Counsel is stretching to salvage a case that should be dismissed. Respondents' 100% pomegranate products are not drugs. Respondents don't sell them as drugs. As an impressive body of good science shows, the products are beneficial to heart and prostate health as well as erectile function. And they are perfectly safe. There is no reason in either policy or law for preventing Respondents from telling consumers about the healthy power of antioxidants (just like the U.S. Government does) or giving consumers access to promising test results regarding Respondents' antioxidant-rich products.

II. RESPONDENTS' ADVERTISEMENTS DID NOT MAKE PHARMACEUTICAL-TYPE DISEASE CLAIMS.

Respondents agree with Complaint Counsel that the Commission may find that an ad conveys an implied claim absent extrinsic evidence "assuming the net impression . . . is clear enough to find an implied claim." (CCAB 8.) But therein lies the rub. As Complaint Counsel concedes, the claim must be "conspicuous" and "clear from the face of the advertisement."

Complaint Counsel cannot meet this standard. Take the POMx ad that Complaint Counsel selectively chose as an allegedly egregious example of a challenged establishment claim. The ad's lengthy text is fairly summarized as follows: 1) "Emerging science suggests" that antioxidants are good for your health because they fight damaging free radicals; 2) POMx, is

a pomegranate extract chock full of the same free radical fighting antioxidants as 8 ounces of "POM Wonderful 100% Pomegranate Juice;" 3) $32 million worth of reputable research on the effects of POM Juice "has revealed promising results for erectile, prostate, and cardiovascular health"; 4) specifically, "preliminary studies" show "potential," "hopeful," "promising" results for improved erectile function, prolongation of PSA doubling times, and reduction of stress-induced ischemia.[1] These four statements are all true. As important, no reasonable person would read this ad -- which appeared in that renowned medical journal Playboy -- as conspicuously and clearly claiming on its face that POMx or POM Juice are "proven" to prevent or treat heart disease, prostate cancer, or ED. Nor would any reasonable person read this ad, which is adorned with images of ripe pomegranates, and decide to substitute POMx for medical treatment. The message of the ad, reflecting what the text actually says, is not remotely a pharmaceutical-type disease claim. As expert testimony confirmed, this is a common sense claim that antioxidant-rich fruits and vegetables, like pomegranates, blueberries or broccoli, are healthy for you (*i.e.*, may generally improve one's odds against disease) and that preliminary scientific studies are suggesting particular beneficial effects for Respondents' 100% pomegranate products. (RFF 183-85; Butters, Tr. 2018-22.)

The U.S. Government and leading medical institutions nationwide routinely make similar claims. This is an inconvenient fact that Complaint Counsel tries to distinguish on the ground that Respondents are "commercializing" their research results and the U.S. Government and leading medical institutions do not. (CCAB 10.) That does not fly. By Complaint Counsel's logic, it's okay for consumers to be told about promising scientific results for healthy foods from which they might benefit, just as long as it's not in the context of selling consumers those foods..

[1] Many of Respondents' challenged ads are similar in content, as reflected in the following CX-line of exhibits: 0180, 0279, 0280, 0328, 0331, 0337, 0342, 0348, 0350, 0353.

Complaint Counsel cannot change the "net impression" of the POMx-Playboy ad by selective quotation (such leaving out the key qualifier "further studies warranted") or by patently silly assertions that the ad's subheadings, such as "Always use protection" and "We're not just playing doctor," somehow "reinforce" the disease claim messaging. Actually, these subheadings undermine any serious medical message. They are amusing sexual double-entendres, as further exemplified by the subheading Complaint Counsel does not mention: "Is that POMx in your pocket." Nor does the subscript "x" add to the equation. Complaint Counsel, with no corroborating evidence, insists that this conveys a medical message based on the Rx symbol for prescriptions. Mx is patently not the same as Rx, however; there are other obvious meanings for the subscript "x" – such as "extract," which is what POMx is; and, in the context of this ad, the bold headline actually tells readers what the meaning of the "x" is: it means "rated X." Expert testimony confirmed all this. (Butters, Tr. 2945-47.)

Complaint Counsel seeks to prop up its interpretation of the ads through assertions about Respondents' intent. The record contains no evidence, however, showing that Respondents intended to make the claims alleged in the Complaint. To the contrary, the record contains abundant evidence that Respondents intended the more modest claims described above. (RRFF 628.) Yet again, Complaint Counsel invokes Lynda Resnick's personal views of the virtues of the POM Products, an alleged intent to target disease victims, and the Bovitz study (this time indirectly referenced through citations to Complaint Counsel's own proposed findings of fact). (CCAB 7.) But Ms. Resnick's personal views are not probative of what the ads actually say. Further, as the ALJ found, Complaint Counsel's assertions about patient targeting are not supported by the evidence (ALJID 218), and the Bovitz study, as the ALJ further found, is not

reliable evidence of much of anything, and certainly not that Respondents intended to convey the claims Complaint Counsel alleges they made. (*Id.* at 223.)

III. THE SUBSTANTIATION FOR RESPONDENTS' CLAIMS WAS CREDIBLE AND RELIABLE.

Complaint Counsel tried this case on a theory –rejected by the ALJ – that even a safe food product made from 100% pomegranates eaten for thousands of years without side effect should be held to a pharmaceutical-type level of substantiation for health benefit claims. Thus, Complaint Counsel insists on RCT studies that its experts conceded could cost hundreds of millions of dollars, only credits the results of human studies, and refuses to credit even those studies unless they show improvement in a very narrow set of FDA-designated "surrogate markers" that the FDA uses when approving drugs. At trial, several of Complaint Counsel's own experts backed away from this rigid approach. (RAB 34-35.) But Complaint Counsel reasserts it here -- and it infects Complaint Counsel's entire argument.

Contrary to what Complaint Counsel asserts, Respondents are not arguing that the adequacy of substantiation for a health claim for food products can always be determined on the basis of *in vitro* or animal tests alone (though they would be sufficient under some circumstances) or that inconclusive tests should be ignored. Backed by the testimony of numerous experts, Respondents are simply arguing; 1) it makes no sense to require an FDA-level of substantiation for health claims related to safe food products because that will deprive the public of potentially beneficial health information for no good reason; 2) substantiation should be based on a totality of the evidence, including *in vitro*, animal, and human testing; 3) Complaint Counsel persistently mischaracterizes the scientific evidence, including by incorrectly arguing that inconclusive testing undermines or contradicts positive test results; 4) the tests summarized in Respondents' ads reflect good science, even if they are not RCTs, and produced

meaningful positive results; and 5) as several experts attested, credible and reliable scientific evidence strongly suggests that Respondents' products improve heart and prostate health and erectile function.

More generally, Respondents urge the Commission to recognize the mistake of combining a hyper-aggressive reading of Respondents' ads with a hyper-aggressive approach to substantiation. This is a procrustean bed that the Commission should not substitute for the more flexible standard that the Commission has traditionally applied. Indeed, it would mark a sharp departure from longstanding practice, evidenced in the Commission's Enforcement Policy Statement on Food Advertising, recognizing that food health claims are fundamentally different from drug health claims and do not require the same level of qualification and disclosure. Under the Commission's traditional approach, Respondents' scientific evidence -- dozens of peer-reviewed published studies by eminent scientists as well as the testimony of leading experts -- more than adequately confirms that Respondents' ads are substantiated.

A. Cardiovascular Health Claims.

Complaint Counsel starts its critique of Respondents' scientific evidence regarding their cardiovascular health claims by completely ignoring 15 *in vitro* and animal studies showing exceptionally positive effects of pomegranate juice on the oxidation of LDL cholesterol and other chemical processes associated with cardiovascular disease. (RFF 1064-88.) *See* Appendix A (compendium of cardiovascular science). Complaint Counsel then compounds this error by unfairly maligning Respondents' human studies.

Complaint Counsel's basic tactic is to exaggerate problems with tests that yielded positive results and overstate the significance of tests that did not. True, Dr. Aviram's 2001 ACE/BP study and his 2004 CIMT/BP studies were relatively small in size. But their dramatic showings of improvement in blood pressure and arterial plaque, consistent with the *in vitro* and

animal studies, are still meaningful -- which is why a leading peer-reviewed journal published them. (RFF 1302.) Nor does the sample size undermine the findings of the Aviram studies. As Dr. Ornish explained, in smaller studies the effect of the treatment has to be even more powerful to achieve statistical significance, and the Aviram studies passed this bar. (RFF 1250.) Furthermore, as Dr. Davidson testified, many non-RCTs are accurate, reliable studies generally considered by other scientists and clinicians to be valid. (RFF 1287.)

Complaint Counsel next attacks the Ornish MP Study, which found that POM Juice caused a statistically significant 35% improvement in blood flow to the heart, on the pretense that the study didn't show improvement in other cardiac risk factors that it was not designed to measure and on the ground that blood flow, which is not one of the FDA's two surrogate markers for heart disease, does not correlate to heart health. This is nonsense. The fact that the study did not show improvement in cholesterol or blood pressure does not diminish the importance of the demonstrated improvement in blood flow, which, as Dr. Ornish testified, is the "bottom line" when it comes to heart disease. (ALJFF 771, 826; RFF 1346-1358.) Scientists and clinicians routinely consider biomarkers for heart disease other than the two officially recognized by the FDA. (RFF 1319.) That is certainly true of blood flow given that a lack of blood flow is what often causes the death of heart tissue. (RFF 1312.) Even Dr. Sacks, who was loath to concede anything, conceded that proper blood flow from the coronary artery and to the heart -- which is what the Ornish study measured -- is fundamental to lowering the risk of cardiovascular disease. (RFF 1327.)

Complaint Counsel further asserts that the Davidson CIMT study, which was an RCT, and an unpublished Ornish CIMT study undermine or contradict the positive results of other studies. This is wrong. To begin with, Complaint Counsel commits a methodological error in

arguing that a lack of a positive result in one set of tests negates other tests with positive results. As Complaint Counsel's own expert, Dr. Sacks, and courts have recognized, the lack of a statistically significant result is not proof of a negative. (RFF 1426); *see Pearson v. Shalala*, 130 F. Supp. 2d 105, 115 (D.D.C 2001).

Complaint Counsel also mischaracterizes the Davidson and Ornish studies. The Davidson study produced very positive cardiovascular results for patients at the 12-month mark. It also showed positive results for a large and important subset of patients at the 18-month mark -- a fact that Complaint Counsel skims over, but which demonstrated that POM Juice could significantly benefit tens of millions of people. (RFF 1470.)[2] Although these results were not replicated at 18 months for the entire patient group, Dr. Davidson and Dr. Ornish both testified that the most likely explanation for the drop-off was the fact that patients may have stopped following the protocol of drinking POM Juice. (RFF 1444-48.) In any event, the results of the Davidson study do not contradict the results of the Aviram studies because the respective studies are not comparable. Dr. Davidson excluded from his test group the very ill type of patients that Dr. Aviram had studied. (RFF 1564; Heber, Tr. 1819.) This, among other reasons, is why Dr. Davidson testified that his findings are consistent with results of the studies conducted by Dr. Aviram and others. (RFF 1569; CX1336 (Davidson, Dep. 227-229).)

Complaint Counsel's reliance on the Ornish CIMT study is also misplaced. As the record makes clear, the results of this study were quite promising but did not reach statistical significance because the study was "underpowered, meaning that it did not have enough participants (only 73 out of the originally planned 200). Dr. Ornish testified that the study

---

[2] Complaint Counsel objects that this finding was "post-hoc," but many important findings are made in retrospective reviews of studies. It does not negate their value. (RFF 1456-1479.)

almost certainly would have shown a statistically significant benefit from POM Juice had it included the full complement of patients originally contemplated. (RFF 1416-1424.)

As a last resort, Complaint Counsel suggests that Respondents' expert, Dr. Heber, did not in fact say that Respondents' products "were likely to cause a significant improvement in cardiovascular health." (CCAB 22.) This is unbecoming.[3] On the cited transcript page, Dr. Heber testified as follows:

> Q. . . . In your opinion, Doctor, is there competent and reliable evidence showing that POM and POMx are likely to lessen the risk of cardiovascular disease?
>
> A. Yes.

As Complaint Counsel also knows, Dr. Heber stated in his expert report: "In my expert opinion, there is credible scientific evidence that pomegranate juice and pomegranate extracts have significant health benefits for human cardiovascular systems, including: 1) decreases in arterial plaque; 2) lowering of blood pressure; and 3) improvement of cardiac blood flow, based on the biological mechanism of prolonging the half-life of nitric oxide in the vasculature." (RFF 1209; PX0192-0044-0045.) Dr. Heber was not alone. In Dr. Ornish's expert opinion, "clinical studies, research and trials provide significant evidence that pomegranate juice is likely to reduce blood pressure, improve blood flow, and reduce arterial plaque." (RFF 1207.) Complaint Counsel asks the Commission to disregard all of this expert testimony. The Commission should decline that invitation.

[3] Complaint Counsel seeks, implausibly, to denigrate Dr. Heber's credentials. As attested to at trial, Dr. Heber is an expert in the relationship between nutrition and various diseases as well as the biology and mechanisms of heart disease. (Heber, Tr. 2037.)

B. Prostate Health Claims.

Complaint Counsel's arguments with respect to Respondents' prostate related science are equally misguided. Once more, Complaint Counsel ignores the plethora of what an expert called "very convincing" *in vitro* and animal studies showing that Respondents' products have a robust effect on prostate cancer. (RFF 1777-1783.) *See* Appendix B (compendium of prostate science). Once more, Complaint Counsel's critique of Respondents' human trial evidence, which showed Respondents' products leading to substantial increases in PSA doubling times, is based on the fallacy that only RCT testing for FDA-approved surrogate markers should count. And, once more, this is nonsense.

Although not an FDA-approved surrogate marker, PSA doubling time is the best currently available marker for detecting prostate cancer and predicting eventual mortality. Literally dozens of articles say so. (RFF 1841-1851, 1869-1903.) Indeed, Dr. Eastham, Complaint Counsel's expert, wrote an article extolling PSA doubling time as "an important factor for evaluating men with newly diagnosed prostate cancer" and "a surrogate marker for prostate cancer death." (RFF 1838-40.) Another Complaint Counsel expert, Dr. Stampfer, agreed. (RFF 1835.)

Complaint Counsel's carping about a lack of placebo control group in the Pantuck Phase II study is similarly unconvincing. As reflected in voluminous expert testimony, there is no evidence that a lack of placebo affected the results and there is no reason it should have had an effect in a trial where patients do not subjectively report results. (deKernion, Tr. 3056-3061.) Neither the National Cancer Institute nor other regulatory agencies insists on placebo control groups for similar testing; the practice is not even standard. Remarkably, Complaint Counsel is insisting on a protocol that the FDA has not required even when approving cancer-fighting drugs. (RFF 753, 757-759, PX0206-0008.)

The Carducci Phase II study involving POMx, which showed meaningful slowing in the growth rate of cancer cells, was a randomized double-blind trial, and so Complaint Counsel can only gripe that it showed no statistical difference in result between patients receiving smaller and larger doses of POMx. (CCAB 19.) All that suggests, of course, is that the smaller dose did the trick, not that POMx did not work. (RFF 1763; *see also* RFF 1577, 1919-22.)

Finally, Complaint Counsel quibbles over whether various experts said the science provided "absolute" proof or used exactly the words of the challenged claims. Well, deKernion testified to a "high degree of probability" that POM Juice inhibits the development of prostate cancer in diagnosed patients and to "compelling" evidence that it may prevent or reduce the risk of the disease. (RFF 1783; deKernion, Tr. 3059-61; PX 00161.) Additionally, despite Complaint Counsel's denial (CCAB 20), Dr. Carducci affirmed that his study showed that POMx was a prostate cancer treatment. (CX 1340 (Carducci Dep. 87).) And Heber said Respondents' products may defer death in cancer patients and were likely to reduce the risk of prostate problems. (RFF 1779-80, 1783, 1914.) In sum, Respondents' many studies and the testimony of multiple experts more than suffices to substantiate Respondents' ads about the positive effect of POM Products on prostate health.

C. Erectile Health Claims.

Complaint Counsel's attack on the erectile function science follows the same misbegotten path: ignore "astonishing" (in the words of a Nobel winner) basic science demonstrating the beneficial effects of pomegranate juice on erectile function (RFF 433, 434; RRFF 764, 1083, 1084), and falsely denigrate the human clinical science. *See* Appendix C (compendium of erectile health science). The Forest/Padma-Nathan RCT study showed POM Juice to be 50% more effective than placebo at improving erections with a 94.2% likelihood that the result was not caused by chance. Complaint Counsel, like its discredited expert Dr. Melman, call that

insignificant because the arbitrary threshold for statistical significance is 95%. (CCAB 6, 21-25.) As experts testified, denying the value of the study on this basis is just as wrong as common sense suggests. (RFF 1982-87, 2098-2010, 2109, 2114, 2128, 2131.) Nor can the study be attacked for using a purported unvalidated "GAQ Questionnaire." As experts testified, the questionnaire is "widely used" and very "informative and . . . valuable to use in clinical studies." (RFF 1992-2002, 2169-71; RRFF 1056-1057, 1060-1061.)

D. Respondents' Internal Assessment Of Their Substantiation.

Complaint Counsel repeatedly cites Respondents' 2009 Medical Research Portfolio Review for the proposition the Respondents took a dim view of their own science. This canard was demolished by the record and rejected by the ALJ. (ALJID 313 n.24.) The Review reflects a candid, even hypercritical, self assessment of whether Respondents' science would meet the very high standard for FDA drug approval, not whether it met what ought to be -- and always has been -- a very different standard of substantiating the claims made in the challenged ads. (Tupper, Tr. 3008-3011, Dreher, Tr. 561-564). Once again, Complaint Counsel, which calls the Review its "most damning" evidence (CCAB 4), turns what should be a positive into a negative. What the review really shows is that Respondents, sincerely committed to the health benefits of their products, remain hopeful that, with some additional positive results, they may actually be in a position to seek a drug approval. The government should be in the business of encouraging this kind of further investment in science, not perversely turning the process into evidence of deception.

IV. THE FIRST AMENDMENT PROTECTS RESPONDENTS' EXPRESSION.

Complaint Counsel brushes aside Respondents' First Amendment arguments. It says that because Respondents' commercial expression is misleading, it receives no First Amendment protection whatsoever. (CCAB 29.) This conclusion leapfrogs an ample body of caselaw on

what it means for commercial speech to be so misleading that it is beyond the ambit of First Amendment protection. (RB 17-19.) To the extent Complaint Counsel engages with the precedents, it misapprehends them.

Under the case law, commercial speech is misleading and thus not protected by the First Amendment if it is either "actually misleading" or "inherently misleading." By contrast, speech that is merely "potentially misleading" is protected by the First Amendment; as such, it may not be proscribed altogether and can be restricted only consistent with the constitutional standards of *Central Hudson Gas & Electric Co. v. Public Services Commission*, 447 U.S. 557 (1980). (RB 19-21.)

Speech can be adjudged actually misleading only if there is evidence that consumers were misled. (RB 19.) As the ALJ found, there is no evidence that any consumers were actually misled by Respondents' advertisements. (ALJID 572.) That means that Respondents' expression is unprotected only if it is inherently misleading.

Commercial speech can be adjudged inherently misleading on its face in the absence of evidence that consumers were misled. (RB 20.)[4] According to Complaint Counsel, Respondents' advertisements are inherently misleading and unprotected by the First Amendment because Respondents' science does not substantiate the health claims that Complaint Counsel says Respondents made. (CCAB 30.) Complaint Counsel bases this argument on the testimony of its scientific experts, whom Complaint Counsel says are leaders in their fields. On the other side, are Respondents' experts, who have a different view of the science and who are world-

[4] In *Daniel Chapter One*, the Commission did not (and could not) "reject" (CCAB 29) the Supreme Court's holding that evidence of consumer deception is necessary to find that expression is actually (as opposed to inherently) misleading. Complaint Counsel is also wrong about *Peel v. Attorney Registration & Disciplinary Commission*, 496 U.S. 91 (1990). The Court's facial analysis of the advertisements there spoke to whether they were inherently misleading. *Id.* at 102-03, 105-06; *see id.* at 112 (Marshall, J., concurring).

renowned in their own right. Complaint Counsel denies it, but a resolution of this conflict in the scientific evidence in favor of Complaint Counsel's experts and an attendant suppression of Respondents' expression implicates the First Amendment. The question is whether the Commission can declare speech about the health benefits of a food product to be inherently misleading and therefore outside of constitutional protection based on a determination that the weight of the scientific evidence tips against the speaker. The answer is found in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), and it is a resounding No. *Pearson* involved an FDA ban on expression regarding the health benefits of certain dietary supplements. The FDA deemed the expression inherently misleading because of a lack of significant scientific agreement on whether the products actually had the asserted benefits. The D.C. Circuit held that the FDA's ban violated the First Amendment. It reasoned that the lack of significant scientific agreement over the health benefits of the products did not render expression about those benefits inherently misleading, and thus the FDA could not proscribe that expression outright. *Id.* at 655. If that is the constitutional command with respect to health claims about dietary supplements, which are subject to a special regulatory scheme due to concerns about their safety and quality (RAB 19), it certainly must be the constitutional command with respect to health claims about whole foods, like the POM Products, that are perfectly healthy, cause no side-effects, and are not marketed as a substitute for medical treatment.

Complaint Counsel nevertheless argues that the challenged advertisements are inherently misleading because consumers lack the sophistication necessary to referee for themselves the scientific disagreement between the experts on the health benefits of the POM Products. (CCAB 31.) That argument is also foreclosed by the First Amendment. A solid wall of Supreme Court authority holds that commercial speech may not be banned based on an assumption that

consumers will be unable to understand the speech, and *Pearson* extends that core constitutional principle to expression about the health benefits of dietary supplements. (RB 34-35.)

Complaint Counsel relegates *Pearson* to a footnote. It asserts that the Commission's decision in *Daniel Chapter One* proves that *Pearson* is irrelevant here because the speech in *Pearson* was constitutionally protected, whereas, by contrast and like Respondents' expression, the speech in *Daniel Chapter One* was not. (CCAB 32 n.36.) This begs the question of why the speech in *Pearson* was not inherently misleading and why the speech in *Daniel Chapter One* was.

Pearson acknowledges that health claims over which there is a lack of significant scientific agreement may be "potentially misleading" to consumers who cannot fully comprehend the intricacies of the scientific debate. 164 F.3d at 656. But as *Pearson* and the Supreme Court precedents on which it rests instruct, there is a world of constitutional difference between inherently misleading commercial speech and potentially misleading commercial speech: the former is unprotected but the later is. Complaint Counsel misapprehends this critical distinction. If Respondents' health claims are potentially misleading, the Commission may not ban the claims altogether. It may only restrict the claims, consistent with the *Central Hudson* standards. As *Pearson* explains, a constitutionally permissible *Central Hudson*-style restriction could take the form of a requirement that Respondents insert language into their advertisements that qualifies the nature of Respondents' scientific evidence. Such a restriction would pass constitutional muster if it is carefully tailored to counteract the prospect that consumers will be misled. (RAB 37.) Complaint Counsel fails to address in the slightest why disclaimers of that sort would not adequately address the problem of possible consumer deception.

V. THE ALJ's MATERIALITY RULING IS WRONG.

Under the Commission's rules governing proof of materiality, challenged claims are presumptively material if they "significantly involve health." *In re Novartis Corp.*, 127 F.T.C. 580, 686 (1999), *pet. for review denied sub nom.*, 223 F.3d 783 (D.C. Cir. 2000). On Complaint Counsel's theory, materiality should be presumed because Respondents made significant health claims thus shifting the burden to Respondents to rebut that presumption. *Novartis*, 127 F.T.C. at 686. Respondents met that burden by introducing into evidence a survey conducted by Dr. David Reibstein, a marketing professor at the University of Pennsylvania's Wharton School. The Reibstein Survey concluded that just 1% or fewer of POM Juice buyers purchased or would purchase that product again because of a belief that it prevents or cures a specific disease. (RFF 2631-32, 2636-37, 2646-57.) That miniscule number vitiates the notion that the claims Complaint Counsel says Respondents made were material to consumer decisionmaking. At minimum, the Reibstein Survey shifted the burden of proof on materiality back to Complaint Counsel. *Novartis*, 127 F.T.C. at 686. Complaint Counsel failed to satisfy that burden. It did not introduce a materiality survey of its own (RFF 2684), and its attacks on the Reibstein Survey misfire.

Complaint Counsel's opening salvo is that the Reibstein Survey "proves nothing about the impact of Respondents' ads [because it] was not based on consumers' review of the challenged ads or claims . . . ." (CCAB 36.) This is puzzling. After all, Complaint Counsel's own survey expert, Dr. Mazis, testified that "'the impact of advertising on beliefs about a product is not an appropriate measure of materiality.'" (CCAB 36 n. 38, quoting CX1297 (Mazis Report at 0009).) Furthermore, the OTX A&U and Zoomerang studies that Complaint Counsel touts as evidence of materiality (CCAB 35) were not based on consumer review of the challenged ads or

claims either (CX 0292_0025-26; CX 0370), and thus, under Complaint Counsel's reasoning, they too "prove[] nothing about the impact of Respondents' ads."[5]

If, contrary to Professor Mazis, Complaint Counsel takes the position that the impact of advertisements is an appropriate measure of materiality, then Respondents' advertisements could not have had any impact on consumer behavior. This conclusion flows from the testimony of another one of Complaint Counsel's experts, Professor Stewart. He testified that it takes "three good exposures" to an advertisement before the advertisement possibly can have an effect on a consumer. (RFF 2696.) Professor Stewart's testimony is critical because there is no evidence in the record that any of Respondents' challenged advertisements had more than a single run. (RFF 2698-2701.) Complaint Counsel offers no answer to this.

Complaint Counsel's attack on the Reibstein Survey's use of open-ended questions also fails. Here too, Complaint Counsel's argument is undone by its own expert, Dr. Mazis. For one, Dr. Mazis acknowledged that he authored an article that concluded that open-ended questions of the sort utilized in the Reibstein Survey are probative of materiality. (Mazis, Tr. 2754-2756.) Dr. Mazis further attested to the methodological soundness of open-ended survey questions when he acknowledged that such questions "make it significantly less likely that the respondents will be led into giving a particular answer" (Mazis, Tr. 2732.) To make matters worse for Complaint Counsel, Dr. Mazis testified that closed-end questions of the sort utilized in the OTX A&U and Zoomerang studies suffer from an inherent methodological flaw: they tend to skew the answers towards a particular direction. (Mazis, Tr. 2733.) Dr. Mazis stated that a valid open-ended survey can and should control for this problem, but he noted that the OTX A&U study did not do

[5] Complaint Counsel argues that the Reibstein Survey should be disregarded because it "did not address POMx." (CCAB 36.) That is also true, however, of the OTX A&U and Zoomerang studies. (CX 0370; CX 0292_0025-26.)

this. (Mazis, Tr. 2745.) *Compare Telebrands*, 140 F.T.C. 278, 319-23 (2005) (discussing controls imposed on open-ended survey questions designed by Professor Mazis).

With the methodology of the OTX A&U and Zoomerang studies called into substantial doubt, Complaint Counsel's materiality case ultimately rests on the proposition that Respondents intended for their health claims to affect consumer behavior. (CCAB 34.) This is insufficient. Evidence of intent to affect consumer behavior may give rise to an initial presumption of materiality, and if the presumption is rebutted, intent evidence remains part of the body of evidence from which materiality may be inferred. *Novartis*, 127 F.T.C. at 686-87. But Complaint Counsel cites no Commission precedent (and Respondents are aware of none) in which a materiality finding has been based wholly on evidence that an advertiser intended for its claims to affect consumer behavior when the relevant survey evidence conclusively proved that the claims actually did not affect consumer behavior.

VI. THERE IS NO BASIS FOR A CEASE AND DESIST ORDER AND, AT MINIMUM, NO BASIS FOR AN ORDER COVERING PRODUCTS NOT AT ISSUE.

Complaint Counsel maintains that a 20-year cease and desist order covering the POM Products as well as the entire range of Respondents' other products is necessary because "Respondents have not changed their attitude toward the violative nature of their advertising claims at all," and thus violations are likely to recur in the future. (CCAB 42.) This argument is belied by the evidence. The advertisements to which Complaint Counsel lodged its most serious objections (and which the evidence shows were outliers anyway) were halted by Respondents in 2006. And Respondents long ago instituted corrective measures to ensure that ads of that kind are never run again. (RB 39.) Complaint Counsel points to four post-2006 advertisements as proof that violations are likely to recur. (CCAB 41.) Complaint Counsel ignores, however, that these are the only challenged advertisements that Respondents ran between the time that the

Commission began its investigation and the time that the complaint against Respondents was filed, and that Respondents have stopped running these advertisements. (RB 40.) Complaint Counsel fails to demonstrate how this small set of advertisements justifies the imposition of a cease and desist order, let alone an order lasting two decades.

In any event, Complaint Counsel has not shown the need for a cease and desist order of any duration that extends to Respondents' products that are not at issue in this case. The three criteria the Commission applies in determining whether a multi-product remedial order is warranted -- past violations, the degree of transferability of the violations to other products, and the seriousness and deliberateness of the violations[6] -- are not met here.

The ALJ correctly found, and Complaint Counsel does not dispute, that "[t]here is no evidence of prior violations of the FTC Act by Respondents." (ALJID 313.)

Nor are the asserted violations transferable to Respondents' wide variety of other products, which run the gamut from water and wine to pistachios and citrus fruits. (RAB 41-42.) In arguing otherwise, Complaint Counsel says that Respondents made additional health claims about the POM Products that Complaint Counsel has not challenged. (CCAB 41.) This makes no sense. Even if true as to the POM Products, it hardly warrants a jump to the conclusion that Respondents are bound to make health claims about all of its other products. Complaint Counsel also states transferability exists because Respondents have deigned to "research[] the health benefits of their other food products . . . ." (*Id.*) There is no evidence, however, that this modest research is likely to lead to a broad health-based marketing program for Respondents' other food products. Moreover, that Complaint Counsel would condemn such research and invoke it as a basis for a multi-product remedial order is alarming. Adoption of Complaint

---

[6] *In re Thompson Med. Co.*, 104 F.T.C. 648, 832-33 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).

Counsel's "any kind of health research on foods raises red flags" theory of transferability could chill exploration into potentially useful scientific information. Equally misguided is Complaint Counsel's assertion that Respondents' other products are "in the same or similar line of business" as the POM Products. (*Id.*) The vast majority of the other products are patently different from the POM Products. That some of them (pistachios, citrus fruits, bottled water, and wine, for example) may be classified as foods or beverages does not render each and every one of them the "same or similar" for transferability doctrine purposes, and Complaint Counsel cites no authority that makes them so.[7]

Complaint Counsel bases its seriousness argument on its familiar broadsides against Respondents' advertisements and substantiation. (CCAB 39.) But even if the advertisements made disease claims and the substantiation for the claims was insufficient, this does not make the violation a serious one. The critical and undisputed facts for purposes of the seriousness analysis are that the advertisements were for healthy products that cause no side-effects; the advertisements did not market the products as a substitute for medical treatment; the advertisements accurately stated the results of the studies; and the studies were conducted by leading experts and many of them were published in top-flight peer-reviewed journals. On those facts, the notion that any violations were serious is untenable. *In re Schering Corp.*, 118 F.T.C. 1030 (1994), lends no support to Complaint Counsel's seriousness cause. That case involved a dietary supplement, not a healthy food product, and, unlike here, the advertisements made express claims that scientific studies had clinically proven the product's efficacy.

---

[7] Complaint Counsel's reliance on *FTC v. Accusearch Inc.*, 570 F.3d 1187 (10th Cir. 2009), is misplaced. The respondent in *Accusearch* had a limited line of business: it sold information, including telephone records, and that was it. Given the narrowness of that business, respondents' telephone record violations were transferable.

On deliberateness, Complaint Counsel steers clear of the ALJ, who found deliberateness on the ground that the alleged violations were not isolated. (ALJID 312.) That was wrong because the correct standard for deliberateness is a blatant disregard for the law. (RB 43.) Complaint Counsel contends that this standard is met because, among other things, Respondents failed to heed "concerns" about the substantiation for their advertisements expressed by Institutional Review Boards, Dr. Allen Pantuck, the FDA, Commission staff, and Respondents themselves in their 2009 internal assessment. Respondents have elsewhere shown that these supposed examples of their blatant disregard of the law are not that all. (*Supra* at 13 (internal assessment; RAB 8 n.3, 40-42 (Pantuck, IRB, FDA, and Commission staff). Nor are the remaining items on Complaint Counsel's laundry list:

- New York Attorney General Letter. In March 2005, the New York Attorney General sent a letter to POM requesting information about the substantiation for certain representations made in its advertisements. (CX1419_0002.) The letter did not take issue with those representations. (CX1419_0003.) POM responded to the letter. *Id.*; *see also* RRFF 662. And that is the end of this story: POM never heard from the New York Attorney General again. *Id.*
- NAD Actions. Any divergence from NAD standards could not possibly constitute a blatant disregard for the law because NAD does not enforce any laws. In any event, the evidence shows that Respondents' advertisements did not substantially diverge from those standards. In its 2005-06 actions to which Complaint Counsel refers, the NAD suggested only that Respondents insert language in the advertisements to qualify the science, a possible remedy that Complaint Counsel disregards. Subsequently, Respondents made changes to their

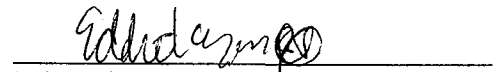
advertisements in line with NAD's recommendations. (CX0037_0007, 0010-0011; CX0055_0038-39, 0047; Tupper, Tr. 2983-84, 2985-87, 2996-97.)

- NBC Guidelines. Like the NAD standards, the NBC Guidelines are not "the law." In any event, and also like NAD, NBC proposed the addition of qualifying language of the sort that Complaint Counsel refuses to consider. (CX0193_0002-0003.) Furthermore, NBC did not construe Respondents' advertisements as stating that the health claims had been "clinically proven." (CX0193.)
- Respondents' Alleged Lack Of Responsibility. Complaint Counsel mischaracterizes Stewart Resnick's statement regarding consumer interpretation of the claims made in the POM "Decompress" ad. (CCAB 40.) The evidence shows that Mr. Resnick sincerely believes that none of Respondents' advertisements made the claims that Complaint Counsel alleges, but that Respondents' science is strong enough to support such claims anyway. (CX 1376, S. Resnick, Ocean Spray Dep. at 155.) The evidence further shows that Mr. and Mrs. Resnick take seriously their responsibilities as marketers of food products. That is why they invested millions of dollars to research the health benefits of the POM Products and established an advertising campaign that was tied to the results of that research. (RFF 448-454.)

VII. CONCLUSION

The Commission should 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 submitted,



Edward P. Lazarus, Esq.
5193 Watson Street, N.W.
Washington, D.C. 20016
Tel: 323.244-6831
Email:lazarus.eddie@gmail.com

Kristina M. Diaz, Esq.
Alicia Mew, Esq.
Johnny Traboulsi, Esq.
Brooke Hammond, Esq.
Roll Law Group P.C.
11444 West Olympic Blvd., 10th Floor
Los Angeles, CA, 90064
Tel: 310.966.8400
Fax: 310.966.8810
Email: kdiaz@roll.com

John Graubert, Esq.
Skye Perryman, Esq.
Covington & Burling LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004
Tel: 202.662.6000
Fax: 202.662.6291
Email: jgraubert@cov.com

Bertram Fields, Esq.
Greenberg Glusker Fields
Claman & Machtinger, LLP
1900 Avenue Of The Stars, Suite 2100
Los Angeles, Ca 90067
Tel: 310.553.3610
Fax: 310.553.0687
Email: Bfields@Greenbergglusker.Com

Michael C. Small, Esq.
Akin Gump Strauss Hauer & Feld
2029 Century Park East, Suite 2400
Los Angeles, Ca 90067
Tel: 310.229.1000
Fax: 310.229.1001
Email: msmall@akingump.com

GLOSSARY OF RECORD REFERENCES

RECORD REFERENCES

ALJID	Administrative Law Judge's Initial Decision
ALJFF	Administrative Law Judge's Findings of Fact in the Initial Decision
CCAB	Complaint Counsel's Answering Brief
CX	Complaint Counsel's Exhibits
PX	Respondents' Exhibits
RB	Respondent's Opening Brief on Appeal
RAB	Respondents' Answering Brief on Complaint Counsel's Appeal
RFF	Respondents' Findings of Fact
RRFF	Respondents' Reply to Complaint Counsel's Findings of Fact
Tr.	Trial Transcript Testimony

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2001	Kaplan, *et al.*, Pomegranate juice supplementation to atherosclerotic mice reduces macrophage lipid peroxidation, cellular cholesterol accumulation and development of atherosclerosis, 131 *J. Nutr.* 2082-89 (2001). (CX0543) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Apo E-deficient mice	Pomegranate juice supplementation to Apo E mice with advanced atherosclerosis reduced lesion size by 17% compared to placebo mice. This supplementation reduced macrophage oxidative stress.
2005	Fuhrman, *et al.*, Pomegranate juice inhibits oxidized LDL uptake and cholesterol biosynthesis in macrophages, 16 *J. Nutr. Biochemistry* 570-6 (2005). (PX0015) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	*In vitro*	Pre-incubation of macrophages with juice resulted in a significant reduction in ox-LDL degradation by 40%. Macrophage cholesterol biosynthesis was inhibited by 50% after cell incubation with juice.
2005	de Nigris, *et.al.*, Beneficial effects of pomegranate juice on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress, 102(13) *Proceedings of the National Academy of Sciences* 4896-4901 (2005). (PX0059) Researcher/Affiliation Drs. Napoli and Ignarro University of Naples and UCLA	POM Wonderful 100% pomegranate juice	*In vitro* and *in vivo*	Pomegranate juice significantly increased levels of nitric oxide in cell culture, as well as decreased the expression genes that are associated with stress and progression of atherosclerosis. These results were also seen in mice both when juice was used as a preventative and a therapeutic treatment. Furthermore, LDL oxidation, the size of the atherosclerotic plaques, and formation of foam cells were significantly decreased in mice.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2006	Rosenblat, *et al.*, Pomegranate byproduct administration to apolipoprotein e-deficient mice attenuates atherosclerosis development as a result of decreased macrophage oxidative stress and reduced cellular uptake of oxidized low-density lipoprotein, J *Agric Food Chem.* 2006 Mar 8;54(5):1928-35. (CX0053) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POMx	*In vitro* and Apo E-deficient mice	Consumption of POMx by atherosclerotic mice E-deficient mice resulted in a significant reduction in the mouse macrophage oxidative stress and in the atherogenic oxidized LDL uptake by the cells, and these effects were associated with a significant attenuation atherosclerotic lesion development. The results showed that POMx significantly attenuates atherosclerosis development by its antioxidant properties in vitro and in E-deficient mice.
2006	Ignarro, *et al.*, Pomegranate juice protects nitric oxide against destruction and enhances the biological actions of nitric oxide, 15 *Nitric Oxide* 93-102. (PX0058) Researcher/Affiliation Dr. Ignarro UCLA	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice is more potent in preserving nitric oxide than red wine, concord grape and blueberry juice. Pomegranate polyphenols retard vascular smooth muscle growth.
2006	de Nigris, *et al.*, Pomegranate juice reduces oxidized low-density lipoprotein down regulation of endothelial nitric oxide synthase in human coronary endothelial cells, 15 *Nitric Oxide* 259-263 (2006). (PX0055) Researcher/Affiliation Drs. Napoli & Ignarro University of Naples & UCLA	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice can revert the potent down regulation of the expression of endothelial nitric oxide synthase induced by oxidized LDL cholesterol in human endothelial cells via a significant dose dependent pathway.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2006	Rozenberg, *et al.*, Pomegranate juice sugar fraction reduces macrophage oxidative state whereas grape juice fraction increases it, 188 *Atherosclerosis* 68-76. (PX0022) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Male balb/C mice	PJ sugar fraction decreases macrophage oxidative stress by up to 72% whereas white grape juice increases oxidative stress by up to 37% vs. control group.
2007	deNigris, *et al.*, The influence of pomegranate fruit extract in comparison to regular pomegranate juice and seed oil on nitric oxide and arterial function in obese Zucker rats, *Nitric Oxide* 17 (2007) 50–54. (PX0057) Researcher/Affiliation Dr. Napoli University of Naples	POM Juice, POMx Pills, and POM seed oil	Zucker rats	POM Juice and POMx Pills significantly reduce the expression of vascular inflammatory markers as well as significantly increasing nitric oxide levels.
2007	de Nigris, *et al.*, Effects of a Pomegranate Fruit Extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis, *Cardiovascular Research* 73 (2007) 414–42. (PX0056) Researcher/Affiliation Dr. Napoli University of Naples	POM Wonderful 100% pomegranate juice and POMx Liquid	*In vitro*	Results showed that proartherogenic effects induced by perturbed sheer stress is reduced by POMx and POM Juice.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2007	Shiner, *et al.*, Macrophage paraoxonase 2 expression is up-regulated by pomegranate juice phenolic antioxidants via PPARy and AP-1 pathway activation, 195 *Atherosclerosis* 313-321. (PX0007) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	*In vitro*	Pomegranate juice up-regulates arterial macrophage PON2 expression and protects against cellular lipid peroxidation.
2008	Aviram, *et al.*, Pomegranate Phenolics from the Peels, Arils, and Flowers Are Antiatherogenic: Studies in Vivo and in Atherosclerotic Apolipoprotein Edeficient (E) Mice and in Vitro in Cultured Macrophages and Lipoproteins, *J. Agric. Food Chem.* (2008), 56, 1148-1157. (PX0008) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Juice, POMx Liquid, POMx Pills, POM oil, POM seeds, POM flowers, POM arils	*In vitro* and *in vivo*	All POM extracts possess antioxidant activity *in vitro*. After consumption of PJ, POMxl, POMxp, POMf, or POM arils by Apo E mice, the atherosclerotic lesion area was significantly decreased by 44, 38, 39, 6 or 70%, respectively as compared to placebo, while POMo had no effect and POMf reduced serum lipids and glucose levels by 18-25%.
2009	Mattiello, *et al.*, Effects of Pomegranate Juice and Extract Polyphenols on Platelet Function, *J. Medicinal Foods* 12 (2) (2009). (PX0017) Researcher/Affiliation Dr. Mattielo Sapienza University of Rome	POM Wonderful 100% pomegranate juice and POMx Pills	*In vitro*	POM Juice and POMx reduce all platelet responses studied. Results demonstrated that cardiovascular health benefits of pomegranate may in part be related to the ability of polyphenols to inhibit platelet function.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Basic Science				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2010	Fuhrman, *et al.*, Pomegranate juice polyphenols increase recombinant paraoxonase-1 binding to high-density lipoprotein: studies in vitro and in diabetic patients, *Nutrition*. 2010 Apr; 26(4):359-66. (PX0009, unpub. manuscript) Researcher/Affiliation Drs. Aviram and Fuhrman The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	*In vitro*	Oxidative stress impairs binding of PON1 to HDL. POM Juice polyphenols increase the binding beyond their anti-oxidative effect. These effects could be related to a POM Juice-mediated reduction in oxidative stress and to a direct effect of POM Juice polyphenols on the HDL-PON1 association.
2010	Khateeb, *et al.*, Paraoxonase 1 (PON1) expression in hepatocytes is upregulated by pomegranate polyphenols: a role for PPAR-gamma pathway, *Atherosclerosis*. 2010 Jan; 208(1):119-25. (PX0002, unpub. manuscript) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center	POM Wonderful 100% pomegranate juice	*In vitro*	The anti-atherogenic characteristics of POM Juice polyphenols are modulated, at least in part, via PON1 upregulation and its subsequent release to the medium.
2011	Rosenblat, *et al.*, Pomegranate Juice Protects Macrophages from Triglyceride Accumulation: Inhibitory Effect on DGAT1 Activity and on Triglyceride Biosynthesis, Ann. Nutr. Metab. (2011), 58:1-9. (PX0010) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center	POM Wonderful 100% pomegranate juice	*In vitro*	When macrophages were treated with pomegranate juice or punicalagin, the content and formation of triglycerides were reduced by at least 30%. The accumulation of lipids, to include triglycerides, within macrophages has been linked to the formation of atherosclerotic plaques. The authors concluded that the ability of POM Juice polyphenols to protect against macrophage triglyceride accumulation is an important contributor to the anti-artherogenic properties of pomegranate.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2000	Aviram, *et al.*, Pomegranate juice consumption reduces oxidative stress, atherogenic modifications to LDL, and platelet aggregation: studies in humans and in atherosclerotic apolipoprotein E-deficient mice, 71(5) *Am. J. Clinical Nutrition* 1062-76 (2000). (PX0004) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans (and Apo E-deficient mice)	In humans, pomegranate juice consumption decreased LDL susceptibility to aggregation and retention and increased the activity of serum paraoxonase (an HDL-associated esterase that can protect against lipid peroxidation) by 20%. In mice, oxidation of LDL by peritoneal macrophages was reduced by up to 90% after pomegranate juice consumption and this effect was associated with reduced cellular lipid peroxidation and superoxide release. The uptake of oxidized LDL and native LDL by mouse peritoneal macrophages obtained after pomegranate juice administration was reduced by 20%. Pomegranate juice supplementation of mice reduced the size of their atherosclerotic lesions by 44% and also the number of foam cells compared with control mice supplemented with water.
2001	Aviram, *et al.*, Pomegranate juice consumption inhibits serum angiotensin converting enzyme activity and reduces systolic blood pressure, 158 *Atherosclerosis* 195-98 (2001). (PX0005) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans	Ten patients, ranging in age from 62 to 77, with an average blood pressure of over 155/83 drank 8 oz of POM Wonderful pomegranate juice each day for 2 weeks. This resulted in a 5% decrease in systolic blood pressure. ACE (angiotensin converting enzyme), which helps to lower blood pressure was also reduced by 36%.
2004	Aviram, *et al.*, Pomegranate juice consumption for 3 years by patients with carotid artery stenosis reduces common carotid intima-media thickness, blood pressure and LDL oxidation, 23 *Clinical Nutrition* 423-33 (2004). (CX0611) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans	Ten patients consumed 8 oz a day of POM Wonderful pomegranate juice for 1 year. Nine patients did not consume pomegranate juice (controls). The intima-media thickness (IMT) of the carotid artery wall was measured at 3 month intervals. After 1 year, those patients who did not consume pomegranate juice showed a 9% increase in IMT, while those consuming juice showed a decrease in IMT of up to 30%. Furthermore, those consuming juice had a significant reduction in systolic blood pressure and a reduction of LDL oxidation by 90%. Benefits were maintained in 5 patients that continued to drink juice for 2 additional years.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2004	Esmaillzadeh, *et al.*, Concentrated pomegranate juice improves lipid profiles in diabetic patients with hyperlipidemia, 7 *J. Med. Food* 3 (2004). (PX0038) Researcher/Affiliation Dr. Esmaillzadeh Shaheed Beheshti University of Medical Sciences Tehran, Iran	POMx Liquid	Humans	The authors concluded that concentrated pomegranate juice consumption may modify heart disease risk factors in hyperlipidemic patients, and its inclusion therefore in their diets may be beneficial.
2005	Sumner, *et al.*, Effects of pomegranate juice consumption on myocardial perfusion in patients with coronary heart disease, 96 *Am. J. Cardiol.* 810-14 (2005). (PX0023) Researcher/Affiliation Dr. Ornish The Preventive Medicine Research Institute in Sausalito, California	POM Wonderful 100% pomegranate juice	Humans	After 3 months, the extent of stress-induced ischemia decreased in the pomegranate juice group by 18%, but increased in the control group for a significant change by 17%. The comparative benefit of the pomegranate juice group to the placebo group was about 35 percent.
2006	Rosenblat, *et al.*, Anti-oxidant effects of pomegranate juice consumption by diabetic patients on serum and on macrophages, 187 *Atherosclerosis* 363-371. (PX0020) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans	Pomegranate juice resulted in significant reduction in serum peroxides, TBAR levels by 56% and 28%, and cellular peroxides by 71% and increased glutathione levels by 141% in patients with diabetes. Juice resulted in significant antioxidant benefit for people with diabetes.
2007	Heber, *et al.*, Safety and antioxidant activity of pomegranate ellagitannin-enriched polyphenol dietary supplement in overweight individuals with increased waist size, *J. Agric. Food Chem.* 2007, 55, 10050–10054. (PX00139) Researcher/Affiliation Drs. Heber and Hill UCLA & University of Colorado	POMx Pills	Humans	No adverse events related to POMx were observed. After one month, a significant 13% percent reduction in plasma TBARS compared to baseline was observed.

RESPONDENTS' PUBLISHED CARDIOVASCULAR HEALTH STUDIES				
Respondents' Human Clinical Trials				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2008	Rock, *et al.*, Consumption of wonderful variety pomegranate juice and extract by diabetic patients increases paraoxonase I association with high-density lipoprotein and stimulates its catalytic activities, 56 *J. Agric. Food Chem.* (2008). (PX0127) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice and POM Liquid	Humans	After 4 weeks, there was a significant 30% improvement in HDL paraoxonase 1 (PON1) and an overall lowering of oxidative stress associated with reduced atherosclerosis risk. POM Juice and POMx had similar efficacy. The beneficial effects of pomegranate juice consumption on serum PON1 stability and activity could lead to retardation of atherosclerosis development in diabetic patients.
2009	Davidson, *et al.*, Effects of Consumption of Pomegranate Juice on Carotid Intima-Media Thickness in Men and Women at Moderate Risk for Coronary Heart Disease, 104 *Am. J. Cardiology* 936 (2009). (PX0014) Researcher/Affiliation Dr. Davidson Radiant Research University of Chicago	POM Wonderful 100% pomegranate juice	Humans	A randomized, placebo-controlled, double-blind clinical trial followed 289 subjects at moderate risk for coronary heart disease. These subjects consumed 8 ounces per day of either Wonderful variety 100% pomegranate juice or a placebo beverage. At 12 months, data showed a statistically significant reduction in CIMT in the group consuming pomegranate juice versus the placebo group in composite measurements, but statistical significance between the two groups was not evident at 18 months. Further analysis revealed that the rate of CIMT progression slowed in nearly one third of 100% pomegranate juice subjects, those with elevated cardiovascular disease risk factors.
2010	Rosenblat, *et al.*, Consumption of polyphenolic-rich beverages (mostly pomegranate and black currant juices) by healthy subjects for a short term increased serum antioxidant status, and the serum's ability to attenuate macrophage cholesterol accumulation, *Food Funct.* 2010, 1, 99-109. (PX0021) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory Technion Faculty of Medicine Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans	100% pomegranate juice and 100% black currant juice demonstrated the highest total polyphenol content and antioxidant potency in a comparative study of 35 U.S. beverages including red wine, green tea, and several deeply colored fruit juices. In addition, the blood serum of healthy subjects who drank 100% Wonderful-variety pomegranate juice and 100% black currant juice for one week exhibited several measures of increased antioxidant activity.

RESPONDENTS' PUBLISHED PROSTATE HEALTH STUDIES				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2001/ 2003	Agensys, Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cancer (Unpublished Study Results, 2001) (PX0065); Agensys, Investigation of the Effect of Pomegranate Juice (PJC) on Human Prostate Cancer, Final Power Point Presentation (2003) (PX0066); Agensys, PJC Reduces Subcutaneous Growth of Prostate Tumors (11/20/2001). (PX0067). Researcher/Affiliation Dr. Markovitz Agensys, Inc. Santa Monica, California	POM Wonderful 100% pomegranate juice	*In vitro* and *In vivo*	Pomegranate juice was found to substantially inhibit prostate cancer cell growth *in vitro*. *In vivo* research found that pomegranate juice consumption retarded the growth of subcutaneous and orthotopic prostate tumors in mice.
2006	Pantuck, *et al.*, Phase II Study of Pomegranate Juice for Men with Rising Prostate-Specific Antigen following Surgery or Radiation for Prostate Cancer, *Clin. Cancer Research* 12 (13): 4018-4026 (2006). (PX0060). Researcher/Affiliation Dr. Pantuck UCLA, David Geffen School of Medicine	POM Wonderful 100% pomegranate juice	Humans	Researchers 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 both 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 increased by 23% in men that consumed POM. Nitric oxide is a molecule that has been found to inhibit inflammation, which is correlated with higher risk of cancer.
2007	Seeram NP, *et al.*, Pomegranate Ellagitannin-Derived Metabolites Inhibit Prostate Cancer Growth and Localize to the Mouse Prostate Gland, *J. Agric. Food Chem.* 2007, 55, 7732-7737. (PX0069). Researcher/Affiliation Dr. Seeram UCLA, David Geffen School of Medicine	POMx Liquid	*In vitro* and *in vivo*	Researchers evaluated the effects of pomegranate extract on prostate cancer growth in immune deficient mice injected with human prostate cancer cells and on prostate cancer cells *in vitro*. The study showed that pomegranate extract significantly inhibited the growth of the human prostate cancer in the mouse as compared to the control and significantly inhibited the growth of human prostate cancer cells *in vitro*.
2008	Hong, *et al.*, Pomegranate polyphenols down-regulate expression of androgen synthesizing	POM Wonderful 100%	*In vitro*	POM polyphenols from either POMx Pills or POM Juice were found to significantly inhibit gene expression and androgen

RESPONDENTS' PUBLISHED PROSTATE HEALTH STUDIES				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	genes in human prostate cancer cells overexpressing the androgen receptor, *Journal of Nutritional Biochemistry* 19 (2008) 848-855. (PX0068). Researcher/Affiliation Dr. Hong UCLA, David Geffen School of Medicine	pomegranate juice and POMx Pills		receptors as a potential mechanism for maintaining healthy prostate cells. The researchers concluded that, "these results suggest that pomegranate polyphenols may be particularly helpful in the subgroup of patients with androgen-independent prostate cancer."
2008	Rettig, *et al.*, Pomegranate extract inhibits androgen-independent prostate cancer growth through a nuclear factor-κB-dependent mechanism, *Molecular Cancer Therapy* 7 (9): 2662-2671 (2008). (PX0070). Researcher/Affiliation Dr. Rettig UCLA, David Geffen School of Medicine	POM Wonderful 100% pomegranate juice and POMx Pills	*In vitro and in vivo*	Consumption of POM Juice and POMx in immune deficient mice with human prostate cancer grafts led to cancer cell growth reduction and decreased PSA levels. POMx was found to inhibit NF-kB and cancer cell viability in a dose response fashion in vitro and in the human prostate cancer graft mice model. Based on these results, the researchers concluded that pomegranate juice could have potential as a dietary agent to prevent the emergence of androgenindependence, thus potentially prolonging life expectancy of prostate cancer patients, and suggested that this may be a high priority area for future clinical investigation.
2008	Sartippour, *et al.*, Ellagitannin-rich pomegranate extract inhibits angiogenesis in prostate cancer in vitro and in vivo, *International Journal of Oncology* 32: 475-480, 2008. (PX0071). Researcher/Affiliation Dr. Sartippour UCLA, David Geffen School of Medicine	POMx Pills	*In vitro and in vivo*	POMx significantly inhibited angiogenesis (blood vessel growth) both *in vitro* on human prostate cancer tissue and in immune deficient mice grafted with human prostate cancer tissue. 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."
2009	Pantuck, *et al.*, Long Term Follow Up of Phase 2 Study of Pomegranate Juice for Men with Prostate Cancer Shows Durable Prolongation of PSA Doubling Time, *J. of Urology*, Vol. 181 No. 4, Supplement, 2009 (PX0061). Researcher/Affiliation Dr. Pantuck (Radiant)	POM Wonderful 100% pomegranate juice	Humans	With a median follow-up of 56 months, the mean PSADT for all 15 patients still in the study continued to show a significant increase from 15.4 months at baseline to 60 months post-treatment with the median PSA slope decreasing 60%. When compared to those patients no longer in the study, the mean PSADT prolongation was greater and the decline in median PSA slope was larger in the active patients.

RESPONDENTS' PUBLISHED PROSTATE HEALTH STUDIES				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
	UCLA, David Geffen School of Medicine			These results demonstrated that PJ has a durable effect on increasing PSADT and suggests that a sub-set of patients may be more sensitive to its effects.
2009	Kasimetty, *et al.*, Effects of Pomegranate Chemical Constituents/Intestinal Microbial Metabolites on CYP1B1 in 22Rv1 Prostate Cancer Cells, *J. Agric. Food Chem.* 2009, *57*, 10636-10644. (PX0072). Researcher/Affiliation Dr. Kasimetty The University of Mississippi	POMx Pills	*In vitro*	Systemically available metabolites of pomegranate juice were found to be effective inhibitors of CYP1B1 enzyme activity/expression and could lower the incidence of prostate cancer initiation and sustenance. Pomegranate juice consumption, thus, may be of considerable advantage in prostate cancer chemoprevention, not only in patients with a genetic predisposition toward prostate cancer but also in patients undergoing cancer therapy.
2010	Koyama, *et al.*, Pomegranate Extract Induces Apoptosis in Human Prostate Cancer Cells by Modulation of the IGF-IGFBP Axis, *Growth Horm IGF Res.* 2010 Feb; 20(1): 55-62. (PX0183). Researcher/Affiliation Dr. Koyama UCLA, David Geffen School of Medicine	Pomegranate extract	*In vitro*	Treatment of LAPC4 prostate cancer cells with POMx extract resulted in inhibition of cell proliferation and induction of apoptosis.
2011/ 2012	Carducci, *et al.*, A Phase II Study of Pomegranate Extract for Men with Rising Prostate-Specific Antigen Following Primary Therapy, *J Clin Oncol* 29: 2011 (suppl 7; abstr 11) (PX00175); *Prostate Cancer and Prostatic Diseases*, June 2012. Researcher/Affiliation Dr. Carducci (Essential) Johns Hopkins Medical Institutions	POMx Pills	Humans	In this clinical 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. Their PSADT was measured over that time and it was found that there was a significant effect of POMx Pills on PSADT independent of dose--it lengthened it significantly--nearly doubling it.

RESPONDENTS' PUBLISHED ERECTILE HEALTH STUDIES				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
200	Aviram, *et al.*, Pomegranate Juice Consumption Reduces Oxidative Stress, Atherogenic Modifications to LDL, and Platelet Aggregation: Studies in Humans and in Atherosclerotic Apolipoprotein E-Deficient Mice, *Am J Clin Nutr* 2000; 71: 1062-1076. (PX0004) Researcher/Affiliation Dr. Aviram The Lipid Research Laboratory, Technion Faculty of Medicine, Rambam Medical Center	POM Wonderful 100% pomegranate juice	Humans, and Apo E-deficient mice	This study demonstrates that antioxidant activity in the blood of 13 healthy male volunteers who drank POM Wonderful pomegranate juice for 2 weeks increased by 9%, and the amount of LDL cholesterol oxidation decreased by 20%. The study also measured similar effects on mice with abnormal fatty deposits in their arteries. It was found that plaque build-up was 44% less than these mice than in the mice who did not receive pomegranate juice.
2005	de Nigris, *et al.*, Beneficial Effects of Pomegranate Juice On Oxidation-Sensitive Genes and Endothelial Nitric Oxide Synthase Activity at Sites of Perturbed Shear Stress, *PNAS* 2005; 102: 4896-4901. (PX0059) Researcher/Affiliation Drs. Napoli and Ignarro University of Naples and UCLA	POM Wonderful 100% pomegranate juice concentrate	*In vitro* and *in vivo*	Pomegranate juice significantly increased levels of nitric oxide in cell culture, as well as decreased the expression genes that are associated with stress and progression of atherosclerosis. These results were also seen in mice both when juice was used as a preventative and a therapeutic treatment.
2005	Azadzoi, *et al.*, Oxidative Stress in Arteriogenic Erectile Dysfunction: Prophylactic Role of Antioxidants, J Urol 2005; 174: 386-393. (PX0051) Researcher/Affiliation Dr. Azadzoi Boston University School of Medicine and Director of Urology Research at the Veterans Affairs Boston Healthcare System	POM Wonderful 100% pomegranate juice and concentrate	*In vivo*	Study found pomegranate juice demonstrated the highest free radical scavenging capacity among known antioxidant beverages. Study also found that long term pomegranate juice intake increased intracavernosal blood flow, improved erectile responses, improved smooth muscle relaxation, and decreased erectile tissue fibrosis. Furthermore, the study found antioxidant therapy may be useful as a prophylactic for preventing smooth muscle dysfunction and fibrosis in erectile dysfunction.
2006	Ignarro, *et al.*, Pomegranate juice protects nitric oxide against destruction and enhances the biological actions of nitric oxide, *Nitric Oxide* 2006; 15: 93-102. (PX0058) Researcher/Affiliation Dr. Ignarro UCLA	POM Wonderful 100% pomegranate juice	*In vitro*	Study found that pomegranate juice was found to possess more antioxidant activity than grape juice, blueberry juice, red wine, and ascorbic acid. Furthermore, the study found that pomegranate juice possesses potent antioxidant activity that results in marked protection of nitric oxide against oxidative destruction, thereby augmenting the biologic actions of nitric oxide.

RESPONDENTS' PUBLISHED ERECTILE HEALTH STUDIES				
Year	**Publication/Researcher**	**Product Tested**	**Method**	**Findings**
2007	de Nigris, *et al.*, Effects of a pomegranate fruit extract rich in punicalagin on oxidation-sensitive genes and eNOS activity at sites of perturbed shear stress and atherogenesis, *J.Cardiores*; 2007, 73: 414-423. (PX0056) Researcher/Affiliation Drs. Napoli & Ignarro University of Naples & UCLA	POM Wonderful 100% pomegranate juice concentrate and POMx	*In vitro* and *in vivo*	Study showed that pomegranate juice and extract reduced the activation of oxidation-sensitive genes and increased endothelial nitric oxide synthase expression. The study also showed that that pomegranate fruit extract and juice increased cyclic GMP levels and that pomegranate juice reduced the progression of atherosclerosis in hypercholesterolemic mice.
2007	deNigris, *et al.*, The influence of pomegranate fruit extract in comparison to regular pomegranate juice and seed oil on nitric oxide and arterial function in obese Zucker rats, *Nitric Oxide*; 2007, 17: 50–54. (PX0057) Researcher/Affiliation Dr. Napoli University of Naples	POM Wonderful 100% pomegranate juice, POMx, and seed oil	*In vitro* in Zucker rats	POM Juice and POMx Pills significantly increased the biological actions of nitric oxide and prevented its degradation.
2007	Padma-Nathan, Forest, *et al.*, Efficacy and Safety of Pomegranate Juice on Improvement of Erectile Dysfunction in Male Patients with Mild to Moderate Erectile Dysfunction: A Randomized, Placebo-Controlled, Double Blind, Crossover Study, *Int. Journal of Impotence Research*; 2007 19: 564-567. (CX0908) Researcher/Affiliation Drs. Padma-Nathan, Forest, & Liker The Male Clinic & UCLA	POM Wonderful 100% pomegranate juice	Humans	The *Forest/Padma-Nathan RCT Study* found that participants rated pomegranate juice 50% more effective than placebo at improving erections. The GAQ results achieved a 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. The study has major clinical significance in showing a benefit from pomegranate juice on erectile tissue physiology and health and also demonstrates pomegranate juice is a potential treatment for ED.

CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the **REPLY BRIEF OF RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART A. RESNICK, and LYNDA RAE RESNICK** and that on this 27 day of July, 2012, I caused the foregoing to be served by hand delivery and email on the following:

Donald S. Clark
The Office of the Secretary
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-159
Washington, DC 20580

The Honorable D. Michael Chappell
Administrative Law Judge
Federal Trade Commission
600 Pennsylvania Avenue, NW
Rm. H-110
Washington, DC 20580

I hereby certify that this is a true and correct copy of the **REPLY BRIEF OF RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART A. RESNICK, and LYNDA RAE RESNICK** and that on this 27th day of July, 2012, I caused the foregoing to be served by e-mail on the following:

Mary Engle
Associate Director for Advertising Practices
Bureau of Consumer Protection
Federal Trade Commission
601 New Jersey Avenue, NW
Washington, DC 20580
E-mail: mengle@ftc.gov

Mary Johnson, Senior Counsel
Heather Hippsley
Tawana Davis
Federal Trade Commission
Bureau of Consumer Protection
601 New Jersey Avenue, NW
Washington, DC 20580
E-mail: mjohnson1@ftc.gov
hhippsley@ftc.gov
tdavis@ftc.gov

Counsel for Complainant

John D. Graubert
Skye L. Perryman
COVINGTON & BURLING LLP
1201 Pennsylvania Ave. NW
Washington, DC 20004-2401
Telephone: 202.662.5938
Facsimile: 202.778.5938
E-mail: JGraubert@cov.com
SPerryman@cov.com

Kristina M. Diaz
Johnny Traboulsi
Brooke Hammond
Alicia Mew
Roll Law Group P.C.
11444 West Olympic Boulevard, 10th Floor
Los Angeles, CA 90064
Telephone: 310.966.8775
E-mail: kdiaz@roll.com

Edward P. Lazarus, Esq.
5193 Watson Street, N.W
Washington, D.C. 20016
Tel: 323.244-6831
E-mail: lazarus.eddie@gmail.com

Bertram Fields, Esq.
Greenberg Glusker Fields Claman &
Machtinger, LLP
1900 Avenue of the Stars, Suite 2100
Los Angeles, CA 90067
Telephone: 310.553.0687
Email: bfields@greenbergglusker.com

Michael C. Small, Esq.
Akin Gump Strauss Hauer & Feld
2029 Century Park East, Suite 2400
Los Angeles, CA 90067
Tel: 310.229.1000
Fax: 310.229.1001
Email: msmall@akingump.com

Counsel for Respondents