UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION

ORIGINAL

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	

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

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I. INTRODUCTION

This case involves a combination of a flawed policy objective and the wrong target for prosecution. The flawed policy objective consists of Complaint Counsel's misguided and unlawful campaign to impose FDA pharmaceutical testing standards on health claims made by natural food advertisers, including imposing an FDA pre-clearance regime. The wrong target is Respondents, who produce safe natural food products with significant health benefits, which they market using advertisements that accurately and responsibly tout those benefits to the public.

At trial, Dr. Dean Ornish, one of the world's leading experts on the relationship of diet to disease, and named by Life Magazine to be one of the 50 most influential people of his generation, pleaded with the ALJ to reject Complaint Counsel's attempt to block public dissemination of scientific information about the health benefits of a healthy food product. "I think the Government is overstepping its role here," Dr. Ornish testified. Elaborating on his concern, Dr. Ornish stated :

> [The Government] is playing the role of big brother, and ultimately, if successful, will keep the American people from valuable information that could make a difference in the quality of their lives and possibly even be life-saving to them. It's one thing when you're talking about the standards of a new drug, because a new drug always has toxicities and side effects. . . . But we're talking about a beverage that's been around since the Bible, for thousands of years, that the only side effects are good ones, and it concerns me that . . . if the standard for a drug is held to a fruit or a beverage, then, in fact, no one can meet that standard.

Ornish, Tr. 2324:15-2325:6.

Dr. Ornish's testimony was not influenced by any financial interest. He refused all but a nominal fee for his testimony. (RFF 1177.) Nor did he appear out of loyalty to the Respondents, with whom he has a fraught relationship. Rather, Dr. Ornish came forward because, based on his own scientific studies and those done by other leading experts in their fields (what he termed

"reliable and credible scientific evidence"), he became convinced that POM Juice improves heart health. Moreover, he is convinced that Complaint Counsel's approach -- the centerpiece of which is a slavish demand for randomized, double-blinded, placebo-controlled human clinical trials ("RCTs") as a prerequisite for any health claims -- was both scientifically unjustified and affirmatively harmful to public health.

Dr. Ornish's impassioned plea has given Complaint Counsel no pause. Nor has the testimony of other highly-regarded experts who stated both that the RCT standard was unjustified and inappropriate and that "credible and reliable" scientific evidence strongly indicated that POM Juice and POMx improve heart and prostate health, including inhibiting the recurrence of prostate cancer, and improve erectile function. And now Complaint Counsel mounts a heedless assault on the ALJ's decision that wisely rejected Complaint Counsel's RCT-based campaign to suppress the advertising of natural food products as well as other significant aspects of its Complaint, including its demand for FDA preclearance as a remedy.

The Commission should not countenance Complaint Counsel's extreme approach. Its Appeal Brief advocates unlawful and unwise legal standards, distorts and often mischaracterizes the record, seeks unlawful and unjustified remedies, and urges this Commission to usurp the functions of other agencies and the Congress. The end result of accepting this approach would not be to vindicate the important goal of ensuring truthful advertising. It would be to deprive millions of Americans of truthful information that leading experts testified would be beneficial to their health.

Specifically, the Commission should reject:

- Complaint Counsel's mischaracterization of Respondents' challenged ads, which finds no comparison in Commission precedent and which would, in effect, rewrite

the meaning of the challenged ads, based on no extrinsic evidence, to suit Complaint Counsel's hyper-aggressive legal theories.

- Complaint Counsel's unprecedented attempt to bring within the ambit of the FTCA limitations on commercial speech statements given during the course of media interviews that Respondents did not pay for. This overreaching would violate Respondents' right to free expression and undermine the First Amendment rights of everyone who runs a business and speaks about that business in a media interview.
- Complaint Counsel's attempt to impose retroactively on Respondents a novel RCT substantiation standard for natural food health claims. Adopting this standard would violate Respondents' First and Fifth Amendment rights, override the views of leading experts in the field, and deprive the public of important information about healthy foods.
- Complaint Counsel's attempt to force Respondents to go through an FDA pre-approval process (again based on RCTs) before exercising their commercial speech rights. Here, Complaint Counsel confuses the statutorily assigned roles of the Commission and FDA and seeks a remedy that is unwarranted.

Respondents sell safe natural food products made 100% from pomegranates. Those products are extremely high in polyphenol antioxidants. Respondents have spent tens of millions of dollars on scientific research that, taken as a whole, amounts to "credible and reliable" evidence that consuming these products is very good for the heart, the prostate and erectile function. Respondents have never marketed their products as substitutes for medical treatment or as curing disease (as the ALJ found); and they have limited their health claims to accurate

information from scientific studies conducted by leading researchers at renowned institutions published in respected peer-reviewed journals.

It is true that Respondents have sought to differentiate their pomegranate products by emphasizing their healthy content. Complaint Counsel deprecates this intent at every turn. Indeed, the subtext of Complaint Counsel's argument is that natural food producers should not be making health claims.

Respondents submit that this is mistaken. The government should be encouraging companies to undertake responsible scientific research to expand public knowledge about the benefits of eating well and thus helping consumers make more informed choices. It is, of course, appropriate and reasonable to have a public debate on this topic. What is not appropriate and not reasonable is to twist enforcement of the FTCA to end that debate in favor of suppressing potentially beneficial health information.

II. COMPLAINT COUNSEL'S CONSTRUCTION OF RESPONDENTS' ADVERTISEMENTS IS FLAWED.

A. Complaint Counsel's Construction Of Respondent's Advertisements Finds No Support In The Record In This Case.

Complaint Counsel's arguments that the ALJ wrongly found some of Respondents' ads not to convey so-called "establishment" or "efficacy" claims is simply a rehash of arguments properly rejected below. As the ALJ found, none of the Challenged Advertisements made explicit claims to "prevent," "treat," or "reduce the risk" of heart disease, prostate cancer, or erectile dysfunction. And in the face of this irrefutable finding, Complaint Counsel is left to argue that the ads the ALJ did not find actionable implicitly convey such disease claims.

Proving an implied claim presents a high bar. To succeed, Complaint Counsel must either show as a facial matter that the alleged implied claim is "clear and conspicuous" on reading the ad or present "reliable" extrinsic evidence about how consumers would understand

the ad, such as consumer surveys, principles derived from market research, and expert testimony. In the final analysis, the Commission must be able to "conclude with confidence that an ad can reasonably be read to contain a particular claim." *In re Stouffer Foods Corp.*, 118 F.T.C. 746, 798 (1994).

Complaint Counsel cannot clear this bar, or even come close. The ALJ opinion cogently explains why:

> Among other reasons, these advertisements: do not mention heart disease, prostate cancer, or erectile dysfunction; use vague, non-specific, substantially qualified, and/or otherwise non-definitive language; use language and/or images that, in the context of the advertisement, are inconsistent with the alleged claim; and/or do not draw a connection for the reader as through explanatory text, between health benefits, or study results, and effectiveness for heart disease, prostate cancer, or erectile dysfunction. In the context of these advertisements, the nature of the transaction, i.e., the purchase of a food product, or a supplement derived therefrom, as opposed to the purchase of a drug, further weighs against interpreting the advertisements as making such claims.

(ALJ Initial Decision [hereinafter "ALJID"] 222 (citations omitted).)

In sum, as the ALJ recognized, the gist of these ads -- their "net effect" -- is to convey the idea that POM's Products are natural foods high in health-enhancing antioxidants, much like other healthy foods, such as broccoli or blueberries, which may improve one's odds of staying in good health but which are not medicine to prevent or treat disease.

Complaint Counsel cannot persuasively contest this textual analysis. Its brief cherry-picks phrases or images from the challenged ads -- references to "prostate studies," millions of dollars in medical research, or "cardiovascular health," as well as fanciful tag lines like "Off to Save Prostates" or dressed up POM bottles. But none of Complaint Counsel's random sampling of phrases or exaggerated descriptions of medical imagery, or humorless interpretation of hyperbolic tag lines can change the self-evident fact that Respondents sold their food products as natural foods, using images touting their products as pure foods (not medicine), while

assiduously avoiding the implication that their products were clinically proven to treat or prevent disease. Complaint Counsel would translate any reference to science or use of medical imagery into a "clinically proven" claim. But that is exactly the kind of "fishing expedition to pin liability on advertisers" that the Commission has decried. *In re Stouffer*, 118 F.T.C. at 777.

Complaint Counsel's resort to extrinsic evidence is also unpersuasive. Complaint Counsel Appeal Brief [hereinafter "CCAB"] 16.) The only expert to analyze the challenged ads testified unequivocally that they did not convey, either explicitly or impliedly, any disease claims and also rejected as wrong or implausible Complaint Counsel's contrived reading of the ads. (RFF 184, 2203-04, 2275, 2302, 2336, 2364-65, 2392, 2524, 2541).[1] He also explained how the use of humorous tag lines and fanciful imagery (such as POM Juice bottles dressed up as superheroes) undercut any reading of the ads as conveying serious medical claims of the sort Complaint Counsel advanced. (RFF 2336, 2364, 2392, 2524, 2541.) Meanwhile, Complaint Counsel did not present its own expert witness on the meaning of the challenged ads. Nor did Complaint Counsel conduct a consumer survey to help elucidate their meaning.

In the absence of these usual modes of proof, Complaint Counsel relies on a 2009 marketing survey that Respondents commissioned -- the "Bovitz Survey" -- that the ALJ dismissed as having "little weight." (ALJID 223.) The ALJ might, more properly, have said no weight at all. The Bovitz Survey suffers from three fatal flaws. First, the participants were not shown any of the challenged ads. Rather, they were shown billboards with imagery similar to (but not identical) to certain challenged ads, shorn of the accompanying ad text. (*Id.*)

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[1] Complaint Counsel's assertion that Respondents' expert, Dr. Butters, recognized that the "Off to Save Prostates" ad might "possibly" be read as claiming that POM Juice "keep[s] you safe from prostate cancer" (CCAB 12) is true only in the sense that he allowed that this interpretation was not 100% impossible. He made abundantly clear that, in his opinion, readers wouldn't interpret the ad that way.

Accordingly, the Bovitz survey cannot speak to the "net impression" created by ads that the survey participants never viewed. Second, the results of the Bovitz Survey do not support Complaint Counsel's reading of the ads; indeed, just the opposite. As the ALJ noted, none of the survey respondents "answered that the main idea of these billboard advertisements was prevention, risk reduction, or treatment of any specific disease." (*Id.*) Third, as Respondents' market research expert testified, the screening questions used for participants, the size of the sample, and the nature of the questions asked all rendered the survey results unreliable as potential evidence in support of Complaint Counsel's implied claims argument. (RFF 582, 2756-2762).

Complaint Counsel objects to the ALJ's ruling that evidence of Respondents' supposed intent when creating the challenged ads could not overcome Complaint Counsel's failure to present facial evidence or traditional forms of extrinsic evidence to show that a substantial minority of reasonable consumers would interpret the ads to contain the claims alleged. (CCAB 17.) This objection is unfounded. The ALJ's decision is both consistent with the Commission's Deception Statement and also follows logically from the fact that the touchstone for liability under the FTCA is whether an ad is deceptive irrespective of intent.[2] As the ALJ correctly recognized, the test for deception focuses on the understanding of reasonable consumers, and an advertiser's intent is, at best, weak corroborative evidence of how reasonable consumers would understand an advertisement. (ALJID 216-17.)

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[2] Complaint Counsel mistakenly asserts that the ALJ "ignored" Commission precedent suggesting that an advertiser's intent may play some role in the analysis. (CCAB 17) citing *In re Telebrands Corp.*, 140 F.T.C. 278, 304 (2005), *In re Novartis Corp.*, 127 F.T.C. 580, 683 (1999))). The ALJ carefully considered these cases and harmonized them with his ruling. (ALJID 216-17.)

The Commission, however, need not resolve the theoretical question of how to view an advertiser's intent because, in this case, the record makes abundantly clear that Respondents never intended to convey the claims alleged by Complaint Counsel. Respondents testified without contradiction that they never intended to convey a claim that their products treat, prevent or reduce the risk of any disease, and certainly not in the sense that a drug performs these functions. (RFF 496, 535, 538, 540, 545-550, 2280, CX1375 (L. Resnick, Trop., Dep at 0079-0081.) Respondents also explained their actual intention, including explaining the thinking behind specific aspects of particular ads. A fair summary of that extensive testimony is that Respondents intended to convey the overall health-promoting qualities of POM products, the serious scientific research program evaluating those qualities, and the specific promising results produced by that program, which consumers could then evaluate for themselves. (Tupper, Tr. 992, 2985, 3004-05, 3018-19, Leow, Tr. 489, S. Resnick, Tr. 1870-71, L. Resnick, Tr. 152, 155-56, 194, 196-97, 218-19, CX1376 (S. Resnick, Ocean Spray Dep. at 135, 155-56, 163-64), CX1375 (L. Resnick Tropicana Dep. at 100-01), CX1363 (S. Resnick Coke Dep. at 81-82), CX1372 (S. Resnick, Tropicana Dep. at 42-43, 48, 52, 56-59), CX1364 (Tupper, Coke Dep. at 297, 299), CX1374 (Tupper, Ocean Spray Dep. at 6).)[3]

[3] Relying on an e-mail authored by Dr. Pantuck, Complaint Counsel suggests that Respondents publicized his study improperly and notwithstanding a "concern" that Complaint Counsel alleges that he had regarding consumer interpretation of Respondent's advertising. (CCAB 5; RRFF 402.) Yet, that very same e-mail shows that Dr. Pantuck was *not* concerned with POM's marketing claims or the further publicizing of his study. A full reading of the cited email reveals that Dr. Pantuck's was actually concerned consumers might attribute POM's use of his quotes *on its website* as evidence that he was a spokesperson for the company. Dr. Pantuck never raised any issue with more aggressive quotes and positive characterizations of his research made in articles featured on WebMD and in the New York Times. (RRFF 402.) Clearly, Dr. Pantuck had no problem with POM's use of and interpretation of the meaning of his research. Rather, he just did not want a close association with POM to affect his reputation as an independent and objective researcher. (*Id.*).

Complaint Counsel maintains that the ALJ neglected "Respondents' admissions that the POM Product ads conveyed serious health and medical messages." (CCAB 17, citations omitted). This misstates the record. Respondents made no such "admissions." The testimony cited by Complaint Counsel has nothing to do with Respondents' ads. (*Id.* at 17; RRFF 281, RFF 502-520, RRFF 282-290.) In that testimony, Respondents were expressing their genuine personal beliefs in the integrity of Respondents' research program and the health of the POM Products. (RRFF 281-90, RFF 506, 510, 515-20.) In any event, an intention to convey "serious health messages" is not the same as an intention to make disease prevention or treatment claims. A claim that drinking POM Juice may benefit your prostate is a serious health claim, but it is not the type of disease claim Complaint Counsel alleges. Moreover, Respondents' personal belief in the health benefits of their products and the validity of their science is evidence of sincerity, not of an intention to deceive consumers. To argue otherwise, as Complaint Counsel does repeatedly (CCAB 17-18), is a non-sequitor.[4]

For all of these reasons, the Commission should reject Complaint Counsel's effort to reverse the ALJ's findings that certain of Respondents' ads did not convey the claims stated in the Complaint. Indeed, Complaint Counsel finds itself in the untenable and somewhat ironic position of arguing that its inferred meaning of the ads is somehow "clear and conspicuous," notwithstanding the fact that the ALJ found no such supposedly clear meaning and the only expert to construe the ads missed it too.

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[4] Similarly, Complaint Counsel seeks to make hay out of the fact that Lynda Resnick considered the healthy qualities of POM's 100% pure pomegranate juice a "unique selling proposition." (CCAB 11 n.6, 17.) So what? Her businesswoman's appreciation for the health benefits of POM Products, especially as compared to the diluted pomegranate products of POM's competitors, is evidence of a desire to capitalize on a positive attribute of POM's products, not an intent to deceive.

No more availing is Complaint Counsel's counter-factual argument that Respondents' advertisements targeted consumers who were especially vulnerable to disease claims. (CCAB 18.) The ALJ appropriately made short shrift of this argument, describing it as "unpersuasive." (ALJID 219.) As the ALJ noted, while Respondents catered to a generally upscale health-conscious audience, it disseminated its ads "in a wide variety of locally and nationally distributed publications, well beyond health-oriented publications." (*Id.*) And as the ALJ further recognized, to the extent that Respondents clientele tended to be more affluent, better educated, health-conscious consumers, that audience, contrary to Complaint Counsel's unsubstantiated argument, was in fact less likely to infer the kind of disease claims alleged by Complaint Counsel. (*Id.*)

It also bears emphasizing that, from the outset of this case, Complaint Counsel launched an aggressive attack on Respondents' advertising as constituting "silver bullet" treatment claims[5] aimed at a "target audience" of sick people suffering from serious diseases. The evidence, of course, did not bear out these accusations.[6] Having opened the door, however, Complaint Counsel cannot now be heard to complain that, because the ALJ specifically rejected these arguments, his findings should be "vacated." (CCAB 36.) The ALJ's observation that Respondents were not marketing the product to a "target audience" of sick people is important to rebut Complaint Counsel's attempt to inject such an argument into ad interpretation in this case. The fact that Respondents did not make claims that their products were a "silver bullet" and should replace conventional therapy was important to distinguish this case from *Daniel Chapter One* and others, in which such evidence supported findings about the interpretation of the ad

[5] *See* http://www.ftc.gov/opa/2010/09/pom.shtm.

[6] The record showed, for example, that POM's customer relations staff was strictly instructed to refer any consumer who mentioned a specific disease to their physician. *See* Respondents' Proposed Findings of Fact and Conclusions of Law at ¶¶524-530.

claims at issue. The ALJ findings that Complaint Counsel argues should be "vacated" are central to this case and should be upheld.

Nor can Complaint Counsel legitimately gripe that the ALJ addressed "imaginary claims" and provided gratuitous observations on the appropriate level of substantiation for such claims. Complaint Counsel has put into the record reams of marketing materials. After reviewing this material, the ALJ correctly found there were no express claims of the type Complaint Counsel had alleged, and attempted to determine whether such claims could be implied. Although Respondents disagree with many of the ALJ's conclusions on these points, and also disagree with the specific formulation of substantiation the ALJ adopted for the supposed implied disease treatment claims, it cannot be said that it was out of bounds for the ALJ to attempt to determine what claims were actually made and whether they were substantiated. Once again, having opened Pandora's Box and put in issue whether Respondents were promoting health benefits for a product without adequate substantiation, Complaint Counsel cannot now create an artificially narrow scope of Commission decision that fits only its predetermined view of the case -- a view that did not bear scrutiny at trial.

B. Complaint Counsel's Construction Of The Advertisements Finds No Support In Commission Precedent.

The advertisement claims construction employed by Complaint Counsel and adopted, in part, by the ALJ is without precedent. Neither Complaint Counsel nor the ALJ have cited a reported decision where the Commission has implied an establishment claim in circumstances like those in this case.

The typical establishment claim case involves a company making a generalized promise, usually explicit or nearly explicit, that its product is proven to produce a particular result: Aspercreme is faster and safer than aspirin and relieves Arthritis pain in minutes. Removatron

can provide permanent hair removal and had been "clinically tested and found superior" to electrolysis. Coral Calcium, by "alkalizing" the body, is clinically shown to cure cancer and other diseases.[7] Moreover, these claims were made in the context of selling a treatment as an alternative to medicine.

Respondents' ads do not claim that their products are clinically proven to prevent or treat any disease; nor are they sold as a treatment or treatment substitute. To the extent the ads reference scientific research, they simply provide an accurate summary of actual test results conducted by eminent scientists and published in leading journals. In general,[8] the ads combine two concepts. First, they accurately state that POM products are extremely high in antioxidants and that antioxidants are thought to promote good health by inhibiting deleterious chemical processes in the body caused by free radicals. The USDA, in recommending various healthy foods, trumpets this very fact. (RFF 755.) Second, the ads accurately reference, with appropriate qualification, scientific research by eminent scientists at renowned institutions that has produced promising results in cardiovascular, prostate, or erectile health -- or, in other words, have shown that POM's antioxidant power likely produces important health benefits. Some of these ads discuss the amount of research money being spent evaluating POM's products; others accurately

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[7] A representative Coral Calcium claim is the following:

Mr. Barrett: And now here's the question: If I alkalize my body, am I going to come up with one of these chronic degenerative diseases?

Dr. Guerrero: No.

[8] Respondents acknowledge that a few "outlier" ads from many years ago, while legally defensible, did go modestly further. (Respondents' Appeal Brief [hereinafter "RAB"] 39. These few moribund ads, however, cannot possibly serve as the basis for injunctive relief. (Id. (citing *Country Tweeds, Inc. v. FTC*, 326 F.2d 144, 149 (2d Cir. 1964).)

summarize particular study results, such as those indicating that POM's products reduce arterial plaque or lengthen PSA doubling times for prostate cancer victims.

It cannot be -- or, at least it should not be -- that putting together these two accurate concepts in the context of selling a food product as a food product somehow converts these factually correct and carefully tailored ads into ads claiming to be prevention or treatment substitutes for diseases not even mentioned in the ads. This is not a case where an advertiser is making a broad claim to prevent or cure a condition or disease, where the proof must be in the pudding of undisclosed scientific evidence. This is a case where the advertiser's ad claim is co-extensive with its scientific substantiation. To the extent that any of Respondents' ads make scientific claims beyond a claim that the product is generally health-promoting, these claims are defined by and limited to the substantiation contained in the ads themselves in the form of accurate summaries of the scientific research. In trying to shoehorn these very specific claims into an overbroad and undifferentiated category of "prevent, treat, reduce risk" establishment claims, Complaint Counsel is ignoring the particularity of what the ads actually say and penalizing Respondents for actually putting forward accurate test result information that could be beneficial to consumers. That defies general advertising principles and makes for bad policy.[9]

It is true, of course, that factually accurate statements can be cleverly juxtaposed to create a deception. That is what happened in the Kraft singles case, where the juxtaposition of the "five ounces of milk in one slice" claim with the company's boast about a "concentrated" calcium

[9] The Commission has repeatedly warned advertisers against overly broad and general claims because such claims are difficult to interpret and may convey a wide range of meanings to consumers, some of which may be difficult to substantiate. *See* Policy Statement Regarding Advertising Substantiation, appended to *In re Thompson Medical Co.*, 104 F.T.C. 648, 839 (1984); "General Environmental Benefit Claims," 16 C.F.R. § 260.7(a). Through such guidance the Commission has previously encouraged more specific, accurate statements in advertising. Complaint Counsel in this case, however, would penalize an advertiser for taking that course.

content or "all the calcium" kids need, created the false impression that the product contained five ounces of milk protein when, in fact, 30% of the protein was lost in processing. *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992). Respondents have engaged in no such trickery. Antioxidants are thought to inhibit deleterious chemical reactions in the body. POM's Products are high in antioxidants. Respondents' reportage of the scientific results is accurate, right down to the qualifiers that the results of some of the studies are preliminary or come from pilot studies. In sum, it is a bridge too far from existing precedents to the facts of this case and, for this reason, among others, Respondents should not be held liable under the FTCA.

III. RESPONDENTS' MEDIA INTERVIEWS ARE NOT ACTIONABLE UNDER THE FTCA.

Complaint Counsel seeks to hold Respondents liable for three media interviews of Lynda Resnick -- on the Martha Stewart Show and the CBS Early Show, and in Newsweek Magazine -- and one media interview of Matthew Tupper -- on the Fox Business Network. (ALJID 207-08.) According to Complaint Counsel, statements about POM Products that Ms. Resnick and Mr. Tupper made during the media interviews constitute commercial speech over which the Commission has jurisdiction under the FTCA. (CCAB 19-20). This is a gross overreach. As the ALJ correctly ruled, these media interviews are not actionable under the FTCA.[10]

Complaint Counsel's attack on the media interviews that Ms. Resnick and Mr. Tupper gave defies the Commission's quarter-century old "understand[ing]" that a fundamental indicia of a commercial speech is that it takes the format of an advertisement that it is paid-for by the speaker or the speaker's company. (ALJID 208 (quoting *In re R.J. Reynolds Tobacco Co.*, 1998

[10] Complaint Counsel's insinuation that Respondents admitted that three of the media interviews are actionable "advertisements and promotional materials" is flat wrong and not supported by Respondents' Answer, to which Complaint Counsel misleadingly cites. (CCAB 19, citing PX0364 ¶9). The Answer *specifically denied* any "inference, characterization, suggestion or legal argument concerning the materials" challenged by Complaint Counsel. (PX0364 ¶9).

FTC LEXIS 9 at *20).)[11] It is undisputed that the Respondents did not pay the Martha Stewart Show, the CBS Early Show, Newsweek Magazine, or the Fox Business Network to secure the interviews of Ms. Resnick and Mr. Tupper. Nor were the media interviews infomercials sponsored by Respondents. (ALJID 208.)

Complaint Counsel argues that the Commission's position set forth in *R.J. Reynolds* that an advertisement must be paid for to be actionable under the FTCA is irrelevant here because *R.J. Reynolds* was a Section 12 case and Complaint Counsel has sued Respondents under both Section 12 and Section 5. (CCAB 19-20.) This is nonsense. The Commission in *R.J. Reynolds* did not limit its understanding of what constitutes a commercial speech advertisement to Section 12 cases. Moreover, in the case that Complaint Counsel says (*id.* at 20) is "more relevant" because it was brought under both Section 12 and Section 5, *In re National Comm'n on Egg Nutrition*, 88 F.T.C. 89 (1976), the speaker paid media organizations and the United States postal service to have its advertisements placed in national newspapers and in the country's mail system. Complaint Counsel cites no case in which the Commission has imposed liability for alleged false statements made in an advertisement that was not paid-for.

Beyond the fact that the media interviews did not take the format of a paid-for commercial advertisement, the ALJ's rejection of Complaint Counsel's characterization of the interviews as commercial speech that is actionable under the FTCA was right for two additional reasons.

First, the Supreme Court has defined commercial speech as expression that is "related *solely* to the economic interests of the speaker and the audience." *See Cent. Hudson Gas &*

[11] The Commission's understanding that a paid-for advertisement is a hallmark of commercial speech is consistent with the Supreme Court's demarcation between commercial speech and noncommercial speech. *See Bolger v. Youngs Drug Corp.*, 463 U.S. 60, 67-68 (1983) (speech in format of a paid advertisement is an indicia of commercial speech).

Elec. v. Pub. Serv. Comm'n., 447 U.S. 557, 561 (1980) (emphasis added). The media interviews at issue here do not meet this definition. Ms. Resnick and Mr. Tupper were not invited by the media outlets to be interviewed for the purpose of promoting POM Products; indeed, the interviews covered a wide-range of matters unrelated to POM Products. (RFF 2552-54, 2536-57, 2567, 2571, 2582, 2586-88, 2596, 2601-03, 2610, 2614-15.) The statements that Ms. Resnick and Mr. Tupper made about POM Products reflected just a portion of the interviews, and they were made only in response to questions posed by the interviewers, not sua sponte. (RFF 2557, 2571, 2587, 2588, 2603, 2615; CX1426, Exh. E-6.)

Second, imposing liability on Respondents for statements that Ms. Resnick and Mr. Tupper made in response to questions posed by media interviewers would raise grave First Amendment concerns. It would mean, for example, that any author, film maker, or entrepreneur could be subject to a Commission enforcement action and attendant penalties for making allegedly false statements about his or her latest book, movie, or invention in interviews on talk shows and in newspapers. While some might go ahead with the interviews anyway, others may be hesitant to speak and thus their expression would be chilled. The Commission was warned about the potential for such constitutional overreach more than half-century ago in *FTC v. Koch*, 206 F. 2d 311, 317 (6th Cir. 1953), where the court said that statements in a medical book on which the Commission's false advertising charges partially rested could not be the basis for liability because that would infringe First Amendment freedoms. Complaint Counsel's attempt to take the Commission down that same path should be rejected here too.

IV. COMPLAINT COUNSEL'S CONTENTION THAT THE RCTs ARE LEGALLY REQUIRED TO SUBSTANTIATE ANY HEALTH CLAIM IN ADVERTISEMENTS FOR FOOD PRODUCTS IS CONTRARY TO COMMISSION POLICIES AND PRECEDENTS.

Complaint Counsel asserts that "the law" mandates that health claims in advertisements for food products must be substantiated through RCTs. (CCAB 23, 26, 37-38). Complaint Counsel is wrong. As reflected in Commission policies and precedents governing the substantiation of health claims, "the law" imposes no such mandate. The ALJ thus was correct to reject Complaint Counsel's position that RCTs are legally necessary to substantiate health claims about food products. As the Supreme Court recently observed, even when it comes to analyzing the health effects of pharmaceutical drugs, "medical professionals and researchers do not limit the data they consider to the results of randomized clinical trials," and the FDA itself "does not apply any single metric for determining" if a drug is safe and effective. *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1320 (2011) (citation and internal quotation marks omitted). If the law does not make RCTs indispensable to substantiating the health effects of drugs, it certainly does not make RCTs indispensable to substantiating the health effects of safe natural foods. The Commission's policies and precedents bear that out.

A. Commission Policies

The Commission's standard for the substantiation of health claims in advertisements for food products is codified in the 1994 Enforcement Policy Statement on Food Advertising. Under that standard, an advertiser making a health claim about a food product must have "competent and reliable scientific evidence sufficient to support the claim . . . ." 59 Fed. Reg. 28388, 28389 (June 1, 1994) [hereinafter "Policy Statement"]. As the Policy Statement makes clear, this is a flexible standard. It can met through *any* type of "tests, analyses, research, studies or other evidence," so long as they "have been conducted and evaluated in an objective manner

by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *Id.* at 28393.

The Policy Statement does not require health claims in advertisements for food products to be substantiated through RCTs. In fact, it says not one word about RCTs. The Policy Statement does refer to the substantiation of health claims in advertisements for foods through "clinical research" generally. *Id.* But it states that clinical research constitutes just one method by which the substantiation standard can be satisfied: "other forms of reliable and probative scientific evidence" may also be more than adequate. *Id.*

Now nearly two decades old, the Policy Statement is a critical part of the law on the substantiation of health claims about food products. While the Policy Statement may not itself be binding law, it has long provided guidance to food advertisers on how the law will be enforced. It thus is an important source for determining what the law on substantiation is.[12] Yet, the Policy Statement barely rates a mention in Complaint Counsel's brief. Complaint Counsel cites the Policy Statement only twice, and both times for the proposition that the Commission and FDA substantiation standards for health claims regarding food are largely identical. (CCAB 34, 38.) As set forth more fully below, however, the Policy Statement does not support that notion, and instead, it actually highlights important differences between the two agencies' respective substantiation standards.

Complaint Counsel also largely ignores the Commission's guidelines on the substantiation of health claims advertisements for dietary supplements. FTC, Dietary

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[12] The Policy Statement says that its purpose is to clarify how the Commission will enforce the FTCA in the area of food advertising. Policy Statement, 59 Fed. Reg. at 28388. Whether that recitation of purpose gives the Policy Statement binding effect is not relevant here. What is important is that the Policy Statement contains consistent enforcement principles that have served to "facilitate[e] long range planning" for food advertisers *PG&E*, 506 F.2d at 38.

Supplements: An Advertising Guide for Industry 6 (2001) [hereinafter "Dietary Supplement Guidelines"]. Unique concerns about the safety and quality of dietary supplements are the foundation of a special FDA regulatory scheme covering such products that does not apply to conventional foods. *See Alliance for Natural Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 128-29 (D.D.C. 2011) (discussing Dietary Supplements Health and Education Act). Given those concerns, one might assume that the Commission's guidelines would mandate RCTs to substantiate health claims in advertisements for dietary supplements. But they do not. Under the guidelines, a dietary supplement advertiser that makes a health claim about its product must have "competent and reliable scientific evidence" to substantiate the claim. Dietary Supplement Guidelines at 7-8. And as is the case with health claims in advertisements for food products, this standard for health claims in advertisements for dietary supplements is flexible: "[t]here is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration." *Id.* Rather, "[t]he FTC will consider all forms of competent and reliable scientific research when evaluating" health claims in advertisements for dietary supplements." *Id.*

While RCTs may be helpful in some contexts, Commission guidelines state that the substantiation standard for health claims about dietary supplements also can be met through animal and in vitro studies. Dietary Supplement Guidelines at 7-8. The Commission has recognized that "[t]his flexibility allows advertisers to provide truthful information to consumers about the benefits of supplement products, and at the same time, preserves consumer confidence by curbing unsubstantiated, false, and misleading claims," *id.* at 18, and it has touted the advantages of its flexible approach in public comments to the FDA on the substantiation of health claims about dietary supplements. *See* Comment of the Staff of Bureau of Economics, the

Bureau of Consumer Protection, and the Office of Policy Planning of the Federal Trade Commission in the Matter of Request for Comment on First Amendment Issues, FDA Docket No. 02N-0209, Sept. 13, 2002, at 22 [hereinafter "FTC Staff Comment"]. At the same time, the Commission also has resisted the adoption of "a more rigid standard" for health claims about dietary supplements on the grounds that such a policy change could lead to a higher standard than is necessary to ensure adequate substantiation. Letter from Donald Clark to Jonathan W. Emord, Denying Petition for Rulemaking, November 30, 2000, *available at* http://www.ftc.gov/os/2000/12/dietletter.htm.

In sum, the Commission's policies on the necessary level of substantiation for health claims in advertisements for food products and dietary supplements run directly counter to Complaint Counsel's contention that RCTs are a legal must for such claims.

B. Commission Precedents

The law set forth in Commission precedents is not on Complaint Counsel's side either. As the ALJ recognized, there is *no* Commission precedent holding that RCTs are always required for the substantiation of health claims in advertisements for food products.[13] Complaint Counsel's handling of the Commission's precedents is flawed in multiple respects.

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[13] Complaint Counsel says, notwithstanding the ALJ's contrary conclusion (ALJID 238), that it is not contending "that RCTs are automatically required for *any* health efficacy claim," as opposed to establishment claims. CCAB 26 (emphasis in original). In its submissions to the ALJ, however, Complaint Counsel made blanket statements about the need for RCTs for any and all health claims. For example, in its post-trial brief, Complaint Counsel stated unequivocally that "[c]ourts have consistently found or upheld that . . . RCTs are required to provide adequate substantiation for the truthfulness of *health-related claims*." (CC Post-Trial Brief 32 (emphasis added)). A nearly identical sweeping statement appears in Complaint Counsel's Conclusion of Law Number 68. It was then followed immediately by the statement in Conclusion of Law Number 69 that "[t]he need for [RCTs] is *even clearer* in cases which involve establishment claims. (CC Conclusion of Law # 69 (emphasis added)).

First, none of the Commission precedents on which Complaint Counsel relies involved a food product. Complaint Counsel argues that this fact is irrelevant. It says that the POM Products at issue here should be treated like drugs for purposes of the level of substantiation. CCAB 32 n. 27. Unlike drugs, however, the POM Products cause no side effects -- they are perfectly healthy products, and Respondents did not market them as a substitute for drugs or for medical treatment. (ALDID 234-45.) Thus, the level of substantiation required to support health claims about drugs has no bearing here.

For these reasons, Complaint Counsel's reliance on *In re Thompson Medical Co.*, 104 F.T.C. 648 (1984), *petition for review denied sub nom. Thompson Med. Co . v. FTC,* 791 F.2d 189 (1986), is misplaced. That case involved an over-the-counter drug, not a healthy food product, the advertisements for which expressly stated that the drug's effectiveness had been clinically proven. The Commission held that the appropriate level of substantiation for efficacy and establishment claims about that particular drug was two RCTs. Notably, however, the Commission did not hold in *Thompson Medical* that two RCTs amounted to the rule for every case and for every product. It stated that other types of scientific evidence may be used to satisfy the substantiation requirement for efficacy claims, 104 F.T.C. at *79-80, and as to establishment claims, the D.C. Circuit recognized in affirming the Commission's decision that the Commission does not always require RCTs. 791 F.2d at 194.

Second, Complaint Counsel cites two recent Commission consent decrees in food advertising cases that required companies to conduct RCTs before making health claims about their foods. (CCAB 39 (citing *Nestle HealthCare Nutrition, Inc.,*, 151 F.T.C. 1 (2011), and *Dannon Co.*, 151 F.T.C. 62 (2011)) It is axiomatic, however that consent decrees do not constitute "the law." Therefore, the *Nestle* and *Dannon* consent decrees furnish no precedential

support for the notion that RCTs are legally required to substantiate health claims in advertisements for foods. *See United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 331 n.12 (1961) (because they do not resolve the merits of a controversy, consent decrees "cannot be persuasively cited in a litigation context"); *United States v. City of Jackson*, 519 F.2d 1147, 1151-52 (5th Cir. 1975) (consent decrees are not a judicial determination on the merits of the matters resolved in the decree). Indeed, the *Nestle* and *Dannon* consent decrees themselves contain the familiar, boilerplate recital generally found in settlement agreements that the decrees were entered into "for settlement purposes only and do[] not constitute an admission . . . that the law has been violated." *Nestle*, 151 F.T.C. at 10; *Dannon*, 151 F.T.C. at 91.

Third, Complaint Counsel cites a handful of consumer product and dietary supplement precedents of the Commission, but they do not set forth an "RCTs are necessary" standard of substantiation for health-related claims for even those products. Complaint Counsel is playing it fast and loose in suggesting otherwise. This problem is underscored by Complaint Counsel's insistence on citing the district court decisions in *FTC v. QT, Inc.*, 448 F.Supp.2d 908 (N.D. Ill. 2006), and *FTC v. Directing Marketing Concepts, Inc.*, 569 F.Supp.2d 285 (D. Mass 2008), for the proposition that RCTs are required to substantiate health efficacy claims. (*See* CCAB 33; CC Post-Trial Brief 32; CC Conclusions of Law # 68, at 1045). It is true that the district courts in those cases said that. But the appellate courts in both cases said just the opposite. On appeal in *QT*, the Seventh Circuit (per Judge Easterbook) concluded that RCTs are not "a legal requirement for consumer products" specifically, and that "[n]othing in the Federal Trade Commission Act . . . requires [RCTs]" more generally for any kind of product. *FTC v. OT, Inc.*, 858, 861 (7th Cir. 2008). And on appeal in *Direct Marketing Concepts*, the First Circuit noted that while the expert testimony in that case indicated that the claims at issue needed to be

substantiated through RCTs, that was not always going to be true in every case. The First Circuit recognized that, in other cases, "there may be other scientific evidence that could be sufficient" to substantiate health claims, and therefore RCTs are "not necessarily required" in all instances. *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010).

One would not know from reading Complaint Counsel's briefs that the Seventh Circuit in *QT* and the First Circuit in *Direct Marketing Concepts* rejected Complaint Counsel's "RCTs are required" theory because those briefs cite only the district court decisions in *QT* and *Direct Marketing Concepts* on the subject of whether RCTs are required, to the exclusion of the appellate decision in the two cases. Significantly, there is no federal appellate decision that diverges from the Seventh and First Circuits and adopts Complaint Counsel's theory. Thus, were the Commission to impose an RCT mandate, it would be acting in derogation of the only two federal appellate decisions on point.[14]

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[14] *In re Removatron Int'l Corp.*, 111 F.T.C. 206 (1988), *petition for review denied sub nom. Removatron Int'l Corp v. FTC*, , 884 F.2d 1489 (1st Cir. 1989) and *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994) are not to the contrary. As the ALJ here correctly observed, the imposition of a single RCT requirement in *Removatron* was based on the evidence that was presented at trial, not on an absolute, one-size-fits-all rule. (ALJID 240, citing 884 F.2d at 1498.) But even when presented with undisputed, unrebutted expert testimony that multiple RCTs would be "preferable" to substantiate the claim, the Commission was unwilling to impose such a requirement. *Removatron*, 111 F.T.C. at 311. Furthermore, in one sentence of the First Circuit's opinion in *Removatron*, the court stated that "a 'reasonable basis'" in scientific evidence for an establishment claim "means well-controlled scientific studies." 884 F.2d at 1498. Elsewhere, however, the First Circuit expressed a different (and the correct) understanding of the law: citing *Thompson Medical*, it recognized that the Commission does not always require well-controlled studies. *Id.* at 1492 n.3. In *Pantron*, the Ninth Circuit did not hold that RCTs are always legally required for any establishment claim, as the an RCT mandate there clearly was fact-specific. 33 F.3d at 1097-99. The same is true of *FTC v. National Urological Group*, 645 F.Supp.2d 1167 (N.D. Ga. 2008), which involved weight loss and erectile dysfunction dietary supplements. (*See* ALJID 239 (discussing fact-specific holding in *National Urological Group.*))

The Seventh and First Circuits were right to reject Complaint Counsel's rigid approach to substantiation. There is simply no legitimate scientific basis to require RCTs for any and all claims made about any and all products. The expert testimony in this case, which is canvassed more fully below, conclusively shows that RCTs are not always the most practical or most effective method of substantiating a claim. Further, as that testimony also shows, in some instances RCTs may be prohibitively expensive to conduct. Under a regime in which RCTs are necessary before health claims are made, a business that makes a healthy product but that cannot afford the cost of RCTs will be precluded from imparting potentially valuable information to consumers. In such cases, an RCT mandate will serve only to frustrate the strong public interest in the broad dissemination of medical and health information. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011) (stressing importance of limiting government interference with the communication of commercial information regarding "the fields of medicine and public health").

V. PENALIZING RESPONDENTS FOR FAILURE TO MEET AN RCT SUBSTANTIATION REQUIREMENT WOULD VIOLATE THE CONSTITUTION.

Even assuming that RCTs should be required from this day forward to substantiate health claims in advertisements for food products, Complaint Counsel's call for the punishment of Respondents for failing to substantiate its health claims through RCTs should be rejected. The retroactive application of an RCT standard to penalize Respondents for the studies it undertook and the expression about those studies in which it engaged would violate Respondents' due process and First Amendments rights.

A. Penalizing Respondents For Failure To Meet An RCT Substantiation Requirement Would Violate Respondents' Right To Due Process Of The Law.

As the Supreme Court reconfirmed this past Term, the constitutional guarantee that liberty cannot be deprived without due process of the law means that the government "must give

fair notice of conduct that is forbidden or required" by the law. *FCC v. Fox Television Stations,* 132 S. Ct. 2307, 2317 (2012). A punishment meted out by the government violates the right to due process if the law under which the punishment is obtained does not provide adequate notice of what the law prohibits. *Id.* This fundamental principle, the Court stressed, solves two related due process problems. First, it ensures that persons regulated by a government agency "know what is required of them so they may act accordingly," and second, it cabins agency discretion by limiting the authority of the agency to impose penalties for violations of its regulations. *Id.* The Court also reiterated in *Fox Television Stations* that these twin due process problems loom especially large when the government's action threatens First Amendment freedoms. In such cases, the Court admonished, "rigorous adherence" to the requirement that the government provide adequate notice of what the law prohibits before penalizing anyone for breaches of the law is necessary to ensure that the exercise of free speech rights is not chilled. *Id.*

The Supreme Court applied these teachings to the facts of *Fox Televisions Stations* itself. It held in that case that the FCC deprived broadcasters of their constitutional right to due process of the law when the FCC punished the broadcasters for violating the agency's "indecency" regulations. 132 S. Ct. at 2320. In describing how the FCC violated due process requirements, the Court observed that the FCC's rules that were "in place at the time of the broadcasts" in question did not render a fleeting expletive or a brief shot of nudity actionably indecent. *Id.* at 2318. Subsequent to the broadcasts, however the FCC changed the rules. It issued an order proclaiming that a fleeting expletive or a brief shot of nudity could be deemed indecent under the agency's indecency regulations. The FCC then retroactively applied its new rules to pre-rule-change broadcasts that contained a fleeting expletive or a brief shot of nudity and punished the broadcasters for airing this. *Id.* The Court refused to let that punishment stand. It held that the

FCC could not sanction the broadcasters for violating rules that were not operative when the broadcasts aired. *Id.* Linking due process protections to free speech protections, the Court observed that the FCC's abrupt change of its rules was particularly offensive to the Constitution because the FCC's action "touch[ed] upon sensitive areas of basic First Amendment freedoms." *Id* at 2318 (citation and internal quotation marks omitted).

The Supreme Court's decision in *Fox Television Stations* forecloses Complaint Counsel's quest to punish Respondents for their prior expression. As indicated above, under the prevailing Commission policies and precedents, Respondents needed to have competent and reliable scientific evidence to substantiate its claims, and under those policies and precedents, Respondents could satisfy this standard through a variety of scientific methods, and were not tethered to an RCT mandate. With those policies and precedents as its guideposts, nearly a decade ago, Respondents carefully mapped out a strategy to meet that standard. They invested over $30 million of their own money in sponsoring study upon study, many of which were eventually published in peer-reviewed scholarly journals, conducted by some of the world's leading experts in their respective fields at some of the world's leading research institutions. Respondents then engaged in commercial expression that was tied to the specific findings of the studies. As set forth in Respondents' opening brief in their separate appeal, this impressive body of scientific evidence more than substantiates Respondents' health claims and should be the end of this case.

Complaint Counsel now seeks to change the rules under which Respondents operated all along. It contends that everything that Respondents did over the years was not enough, and that Respondents instead were required to strive for and surmount an entirely different substantiation standard. According to Complaint Counsel, because Respondents did not meet that standard,

they are prohibited altogether from speaking about the studies that they conducted and what those studies show.

Complaint Counsel's attempt to hold Respondents liable for failing to satisfy a new set of rules raises the very same constitutional red flags that compelled the Supreme Court to invalidate as a violation of due process protections the FCC's punishment of the broadcasters in *Fox Television Stations*. The Commission will follow on the FCC's heels and stumble into its own due process violation if it were to penalize Respondents for failing to meet an RCT substantiation standard that simply was not the rule at the time that Respondents engaged in the expression that Complaint Counsel challenges.

Whether going forward the Commission constitutionally could require RCTs as the substantiation barometer for all health claims in advertisements for food products is doubtful because that would create its own set of free speech problems. But what the Commission surely cannot constitutionally do under *Fox Television Stations* and the basic due process principles it reinforces is penalize Respondents for violating a rule without ever having given notice of the existence of the rule and what it requires or forbids.

Complaint Counsel compounds the due process problem by seeking to establish its RCT standard through adjudication. As a general matter, agencies have discretion under the Administrative Procedure Act to determine whether to proceed through adjudication or rule-making. *See Time Warner Entertainment Co. v. FCC*, 240 F.3d 1126, 1141 (D.C. Cir. 2001). But an agency may abuse its discretion when it deviates from past policies and precedents in imposing a new standard through adjudication "that operates retroactively and disturbs settled expectations." *Miguel-Miguel v. Gonzalez*, 500 F.3d 941, 950 (2007) (9th Cir. 2007). The retroactive application of a new rule instituted in an adjudication thus "must be balanced against

the mischief of producing a result which is contrary to . . . .legal and equitable principles." *SEC v. Chenery Corp.*, 332 U.S. 194, 203 (1947). Retroactive application of a new standard here would cause that very sort of administrative law "mischief" by upsetting Respondents' expectations. At minimum, if the Commission wishes to declare a new RCT standard for health claims about foods, it should act through a revision to the Policy Statement and announce therein its intent to enforce this new standard in future adjudications. *See PG&E v. FPC*, 506 F.2d at 38 ("A general statement of policy . . . announces the course which the agency intends to follow in future adjudications."). The APA's limitation on an agency's discretion to act through adjudication thus reinforces due process values -- values that would be compromised if the Commission instituted an RCT mandate in this adjudication. *See NetworkIP, v. FCC*, 548 F.3d 116, 122-23 (D.C. Cir. 2008) ("[T]raditional concepts of due process [that are] incorporated into administrative law preclude an agency from penalizing a private party for violating a rule without first providing adequate notice of the substance of the rule.") (internal quotations omitted).

B. Penalizing Respondents For Failure To Meet An RCT Substantiation Requirement Would Violate Respondents' First Amendment Rights To Engage In Commercial Expression.

Penalizing Respondents for failing to meet an RCT mandate that was not the rule at the time they made their health claims also would lead the Commission smack into an independent First Amendment violation, one that stands separate and apart from the due process violation that such action would create. The plain fact is that Complaint Counsel seeks to hold Respondents liable for having spoken. The First Amendment forbids that.

Complaint Counsel pays it no heed, but the First Amendment firmly protects commercial advertising. *See Virginia State Bd. of Pharmacy v. Virginia Consumer 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 First Amendment does not protect advertisements that are false or are misleading. *Virginia Pharmacy*, 425 U.S. at 771. From there, Complaint Counsel makes the blunderbuss argument that because the health claims in Respondents' advertisements were not substantiated through RCTs, the advertisements necessarily are false or misleading and thus unprotected by the First Amendment. (CCAB 22.) The First Amendment is not that simple or so easily sidestepped. Even if the Commission were to conclude that RCTs are necessary to substantiate health claims about a food, this would not give the agency constitutional license to ban outright the health claims in Respondents' advertisements. Respondents' opening brief in their separate appeal sets forth a comprehensive First Amendment analysis, which demonstrates that Respondents' advertisements are constitutionally protected, notwithstanding the dispute between Respondents and Complaint Counsel on the level of scientific evidence that is required to substantiate the health claims in the advertisements. We summarize the key points of that analysis here.

First, as the ALJ correctly found, the statements in the advertisements regarding Respondents' studies are all literally true: they contain accurate and verifiable information on what the studies found. (RAB 21-22.)

Second, a literally true advertisement may be actually misleading if there is evidence that consumers were in fact deceived by it. Here, however, there is no credible evidence in the record that anyone actually was deceived by Respondents' advertisements. (RAB 20.)

Third, First Amendment caselaw draws a clear distinction between "inherently misleading" commercial speech, which is constitutionally unprotected and thus can be proscribed altogether, and "potentially misleading" commercial speech, which is constitutionally protected and thus cannot be proscribed altogether; any regulation attempting to prevent consumers from being deceived by potentially misleading commercial advertisements must satisfy the Supreme Court's stringent test for evaluating the constitutionality of restrictions on commercial speech. (RAB 18, 19.)

Fourth, an advertisement is not inherently misleading just because the government is convinced that consumers lack sophistication to understand the nuances of the advertisement and thus will be duped by it. The First Amendment caselaw adopts a different and less jaundiced view of consumer behavior: people will act in their own best interests the more information they receive about the products available to them in the marketplace. (RAB 34.)

Fifth, the lack of significant agreement about the necessary level of scientific substantiation for a health claim in a dietary supplement or food product advertisement does not allow the government to declare the advertisement inherently misleading and ban it outright. The First Amendment stands in the way of that. At most, the lack of significant scientific agreement may render the advertisements potentially misleading. But even in that event, the government may not ban the advertisement outright. The government may only restrict the advertisement consistent with First Amendment strictures, such as through carefully tailored

disclaimers that qualify and explains the nature and limits of the studies. (RAB 35-36 (citing *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999).)

Applying these principles here, the First Amendment bars the Commission from branding Respondents' advertisements inherently misleading based on an assumption that consumers will not understand the limits of the science referenced in the advertisements.

If Respondents' advertisements somehow are potentially misleading solely because the science on which Respondents relied was not RCT-based, then the Commission may seek to address that concern by requiring Respondents to incorporate into the advertisements statements about the difference between RCTs and other types of studies. But the Commission cannot use the absence of RCTs to completely bar Respondents from engaging in commercial expression about their studies. That would constitute a hands-down violation of the First Amendment.

VI. THE EVIDENCE PRESENTED AT TRIAL DEMONSTRATES THAT RCTs ARE NOT REQUIRED TO SUBSTANTIATE HEALTH CLAIMS ABOUT NATURAL FOOD PRODUCTS THAT ARE NOT MARKETED AS SUBSTITUTES FOR MEDICAL TREATMENT.

Complaint Counsel is not only wrong on the law with respect to its asserted RCT requirement, it is wrong on the facts. As the ALJ found, "[t]he greater weight of the persuasive expert testimony" shows that "RCTs are not required . . . where, as here, the safety of the product is known; the product causes no material risk of harm; and the product is not being advocated as an alternative to medical advice." (ALJID 242-43.) This finding is supported by the overwhelming weight of the expert testimony, including testimony from several of Complaint Counsel's own experts, and it has the additional benefit of comporting with common sense. Safe natural food products not sold as replacements for medical treatment are fundamentally different from supplements, drugs, or other products that can either have significant side effects or are touted as medical substitutes. The proper balance between public disclosure of health information and protecting public health is completely different in the two circumstances. In the case of safe natural food products it makes no sense to suppress positive health news that does not meet Complaint Counsel's arbitrary standard of extremely expensive and potentially inappropriate RCTs. The long-established *Pfizer* factors reflect this very distinction by requiring an analysis of the type of product at issue, the possible consequences of false claims, and the cost of developing substantiation for the claim. *In re Pfizer Inc.*, 81 F.T.C. 23, 30 (1972).

At trial, experts from *both sides* testified the RCTs are not necessary to evaluate the health benefits of a food or nutrient, and sometimes are not even the best evidence. Respondents' case on this point began with Dr. Denis Miller, who had served as an expert for the Commission *in Daniel Chapter One*. Dr. Miller testified that, when a food product is safe and where there is no suggestion that the product be used as a substitute for conventional medical

treatment, then a more flexible standard that does not require RCTs is appropriate, and basic science alone can be enough to substantiate health claims. (RFF 744.)[15]

In addition to Dr. Miller, Dr. David Heber, a practicing physician and Professor of Medicine and Public Health at UCLA (among other prominent positions), testified that most experts in the field of nutrition consider competent and reliable science to support health claims for pomegranate juice based upon the totality of evidence, which does not necessarily include RCTs. (RFF 652; Heber, Tr. 1948-49, 2166, 2182). Dr. Jean deKernion, the Chairman of the Department of Urology at UCLA School of Medicine, testified that in the case of fruit juice, such as POM Juice, that has low or no toxicity, it is not necessary to have an RCT. (RFF 1784; deKernion, Tr. 3060.)

Respondents' erectile and nitric oxide experts, Dr. Irwin Goldstein (an expert in sexual medicine) and Dr. Arthur Burnett (Professor of Urology at Johns Hopkins University School of Medicine), also testified that urologists who treat men with erectile health concerns would not require that pomegranate juice be subjected to RCTs before concluding that pomegranate juice has a beneficial effect on preserving erectile function and on erectile dysfunction. (RFF 650-651; 2122, 2123, 2164; PX0149-0006-0007; Burnett, Tr. 2272-74, 2303 (testifying RCTs are not necessary to deal with studies of drinking pomegranate juice); PX0189-0003, 0014; PX0352 (Goldstein, Dep. at 50-52, 61) (testifying that pharmaceutical type trials should not be applied to

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[15] With no hint of irony, Complaint Counsel seeks to denigrate Dr. Miller's qualifications, notwithstanding his prior service for the Commission. (CCAB 31, n. 25). Dr. Miller offered his expert opinion based on more than 40 years of practicing medicine and being involved in clinical research in academia and for industry. He is currently the Global Therapeutic Area Leader of Oncology/Hematology at PAREXEL International, one of the world's leading contract research organizations, and Clinical Professor of Pediatrics at Robert Wood Johnson School of Medicine. (RFF 110, 660, 671).

nutraceuticals—natural, safe, food products from a plant, with health promoting characteristics); Goldstein, Tr. 2600-2620.)

Furthermore, Respondents' cardiovascular expert, Dr. Ornish, opined in his expert report that "it is an extreme position to state that the therapeutic efficacy of a fruit juice or extract of pomegranate juice should be held to the same standard of evidence as a new drug." (RFF 1192; PX0025-0008). Echoing the views of the other experts, Dr. Ornish stated that the studying of pomegranates or pomegranate juice is different than studying a new drug, which typically involves harmful side-effects, both short-term and long-term. (RFF 1195; PX0025-0008.)[16] In the context of safe natural foods, Dr. Ornish made clear that an RCT standard would dangerously inhibit the promulgation of important scientifically-supported health benefit claims. (RFF 142-143, 1179-80.)

The testimony of Respondents' experts reflected not only the fact that requiring RCTs in the context of safe natural foods will chill the dissemination of important public health information, but also the fact that requiring RCTs is an extreme view unsupported by the

[16] Complaint Counsel is wrong in suggesting that Dr. Ornish "did not speak to the Challenged Claims." (CCAB 30.) In fact, in his expert report, Dr. Ornish testified: "Taken as a whole, the preponderance of the scientific evidence from basic scientific studies, animal research, and clinical trials in humans reveals that the pomegranate in its various forms (including POM Wonderful 100% Pomegranate Juice, POMx Pills, or POMx Liquid) is likely to be beneficial in maintaining cardiovascular health and is likely to help reduce the risk of cardiovascular disease. (RFF 1206; PX0025-0005.) Both Dr. Ornish and Dr. Heber have testified that the POM Products are likely to help prevent or reduce the risk of heart disease by (1) decreasing arterial plaque; (2) lowering blood pressure; and/or (3) improving blood flow to the heart. (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42); PX0192-0045; PX0353 (Heber, Dep. at 76-80).) Dr. Ornish stated that pomegranate juice "actually improves the blood flow in people who already had heart disease" and if you can "begin to reverse a disease, it would only make sense that it would work even better to help prevent it in the first place." (RFF 1211; Ornish, Tr. 2354-55.) Finally, Dr. Ornish expressly stated "it is my expert opinion that clinical studies, research and trials, provide significant evidence that pomegranate juice is likely to reduce blood pressure, improve blood flow, and reduce arterial plaque, period." (RFF 1210; PX0025-0005; Ornish, Tr. 2374-75; PX0355 (Ornish, Dep. at 42).)

scientific community. There is widespread scientific agreement that RCTs are problematic for evaluating the health benefits of a food or nutrient. (RFF 618-24).[17]

Complaint Counsel's own experts confirmed the many problems with using RCTs in the context of evaluating the health benefits of foods. For example, according to Professor Meir Stampfer, RCTs are not the best source of valid and reliable information on nutrition. He gave no fewer than five reasons: First, ethical principles do not permit randomizing individuals to diets that may have negative health effects. (RFF 634, 636; RX5007). Second, it is very difficult to ensure that large numbers of participants adhere to an altered diet over long-term periods. (*Id.*. Third, the cost of such studies forms an almost insurmountable barrier, given that no exclusive intellectual property rights (like a pharmaceutical patent) will result from a nutritional trial. (RFF 635). Fourth, in a nutritional context, a hypothesis about disease causation can rarely be directly tested in humans using the RCT design. (RFF 640). Finally, Professor Stampfer even conceded that "there are situations where you would determine causality in the absence of a randomized trial," (PX0362 (Stampfer Dep. at 73), and that a randomized, double blind, and placebo-controlled clinical trial is not required to conclude a causal link regarding a nutrient and disease. (PX0362 (Stamper Dep. at 98)). If RCTs were required before it could be said that scientific evidence supports a particular claim about the health benefits of food, the field of nutrition science would be almost eliminated. (RFF 639-40, 642, 740). According to Professor Stampfer, when there is little risk and little cost involved and a potential benefit, we should "definitely" make that information available to the public rather than withhold it. (Stamper, Tr. 838).

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[17] *See* Robert Heaney, Connie Weaver, Jeffery Blumberg, *EBN (Evidence-Based Nutrition) Ver. 2.0,* Nutrition Today, Vol. 46, No. 1, (Jan/Feb. 2011); Roger Clemens, *Dietary Guidelines May Produce Unintended Health Consequences*, Food Technology, (Feb. 2011).

This testimony echoed Professor Stampfer's writings. For example, Professor Stampfer has asserted that the general principles of evidence-based nutrition "can provide a sufficient foundation for establishing nutrient requirements and dietary guidelines in the absence of RCTs for every nutrient and food group." (RFF 630). Professor Stampfer further stated in that article that "requiring RCT-level evidence to answer questions for which the RCT may not be an available study design will surely impede the application of nutrition research to public health issues." (RFF 642).

Another of Complaint Counsel's experts, Dr. Frank Sacks, also backed away from the strict RCT requirement, conceding that a casual influence can be demonstrated between an agent and its effects on humans without the use of RCTs. (RFF 647; PX0361 (Sacks, Dep. at 134-135)). Dr. Sacks testified that in vitro studies can be competent and reliable evidence of an agent's effect on a particular mechanism and that he considers all levels of science in issuing national guidelines for the prevention or treatment of cardiovascular disease. (RFF 576, 579). Dr. Sacks also testified that RCT trials are unnecessary to test the benefits of food categories that are included in a diet already tested, like the DASH diet, which includes pomegranates. (RFF 648.) Dr. Sacks went so far as to concede that a causal influence can be demonstrated between an agent and its effect in humans without the use of RCTs. Dr. Sacks had little choice but to make these concessions -- most of his own published studies have been epidemiological and observational in nature, rather than RCTs. (RFF 1186; PX0025-0007.)

It is true that Complaint Counsel's last expert, Dr. Arnold Melman, stood up for the RCT requirement. But he could only do so by taking the extreme position that "pomegranate juice is a drug." (Melman, Tr. 1141.) Of course he practically characterized water as drug too, as it is composed of hydrogen and oxygen molecules. (*Id.*) It is perhaps emblematic of Complaint

Counsel's case that this testimony came from someone trying to patent a potentially dangerous gene therapy for erectile dysfunction that he has publicly touted as a "fountain of youth" and "modifying the aging process" -- all, of course, without the benefit of RCT testing. (RFF 2141-43.) It is not a small wonder that the ALJ found the weight of the evidence to be against Complaint Counsel's approach.

The right approach to substantiation is to recognize that the scientific evidence, including basic science, animal research, pilot studies, and, sometimes, RCTs,[18] should be evaluated in their totality as appropriate to each specific circumstance, and that in some circumstances basic science alone may be sufficient. (PX206-0010-0011; Miller, Tr. 2194). Properly viewed, there can be no doubt, as discussed further in the briefs attendant to Respondents' appeal, that Respondents' substantiation was more than sufficient for the claims they actually made.

VII. REQUIRING FDA APPROVAL OF THE SUBSTANTIATION OF RESPONDENTS' HEALTH CLAIMS WOULD EXCEED THE COMMISSION'S STATUTORY AUTHORITY AND IS UNWARRANTED.

If the Commission were to impose liability on Respondents, it should reject the remedy that Complaint Counsel urges: FDA preclearance of the substantiation of Respondents' health claims. The Commission lacks the statutory authority to impose such a remedy. And in any event, the remedy is wholly unwarranted.

A. The Commission Lacks Statutory Authority To Require FDA Preclearance.

Complaint Counsel quotes chapter and verse on the broad remedial authority of the Commission. But that authority does not encompass the power to task another agency with

[18] In yet another overreach, Complaint Counsel appears to argue that the fact that Respondents, in their vigilant search for medical evidence, conducted some RCTs is evidence in favor of an RCT prerequisite for substantiation. No one disputes that RCTs are a valid scientific method or that they cannot produce important results. But the question at issue is whether this flawed (and sometimes impossible) methodology should be the sine qua non of making health claims.

responsibilities and enforce that agency's statutes. That is precisely what is contemplated by Complaint Counsel's remedy of FDA preclearance. Complaint Counsel would put the Commission in the odd posture of dictating to the FDA that it needs to preclear any health claims in Respondents' advertisements on the grounds that those claims supposedly trigger the FDA's statutory authority. The FDA can determine for itself if and when such action is warranted. If the FDA concludes that Respondents' claims fall within the rubric of its statutes, it presumably will say so and thus take steps to require that it approve the claims before they are made. It is up to the FDA, and no other agency, to make this call, however. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 (2001). For good reason, the Commission has not previously sought to intrude on the FDA's domain in the fashion that Complaint Counsel urges. As the ALJ observed, Complaint Counsel cites no precedent in which the Commission has required FDA preclearance of the substantiation of a claim. (ALJID 316.)[19] And there is no evidence in the record of any coordination between the Commission and the FDA or of FDA acceptance of the pre-clearance requirement that the Commission seeks to impose here. (*Id.* at 321 n.30.)

Complaint Counsel seeks to pass off the unprecedented nature of the FDA preclearance remedy by claiming that the Commission already has "harmonized" its approach to advertising interpretation and substantiation with the FDA's approach to food labeling, and so the remedy it seeks here is not a bolt from the blue. (CCAB 34, 38.) This claim of inter-agency harmony, however, rests on misleading, selective quotations from the Policy Statement, and misstates the actual holdings of various cases.

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[19] Complaint Counsel cites the *Nestle* and *Dannon* consent decrees, but, as discussed above, those orders are not legal precedents and thus lend no support to the notion that the Commission has the statutory authority to require FDA preclearance.

For example, while the Policy Statement does say that "[t]he Commission's standard for substantiation of health claims in food advertising shares many elements with FDA's approach to such claims in labeling," Complaint Counsel fails to note the caveat, which is made repeatedly in the same section of the Policy Statement from which Complaint Counsel quotes: namely, that the Commission operates under a different statute than the FDA, applies different standards than the FDA, and that there accordingly will be instances in which it is possible for an advertiser to craft a truthful, and non-misleading health claim even if the claim does not meet the FDA's standards. Policy Statement, §IV(A); see also Dietary Supplement Guidelines at 1-2; Commissioner Mary Azcuenaga, "Advertising: Interpretation and Enforcement Policy," Remarks before AAF 1994 National Government Affairs Conference (pointing out differences between FDA regulation of health claims and Section 5 jurisprudence), *available at* http://www.ftc.gov/speeches/azcuenaga/aaf94.shtm.

Furthermore, as Complaint Counsel is well aware, the Commission and the FDA have at times in the recent past taken very different approaches to health claims, and, in particular, the extent to which information on the health benefits of foods, even if not established to pharmaceutical levels of proof, is useful and important to consumers and should not be restricted. *See* FTC Staff Comment, *supra*. The FDA's more restrictive approach has not only embroiled that agency in extensive First Amendment litigation,[20] but also has resulted in a paucity of FDA-approved health claims, which is directly contrary to Congressional intent. See GAO, Report: Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers From False or Misleading Claims 12, GAO-11-102 (Jan. 14, 2011) [hereinafter "GAO Report"].

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[20] *Pearson, supra*, 164 F.3d 650; *Pearson v. Shalala*, 130 F. Supp. 2d 105 (D.D.C. 2001); *Pearson v. Thompson*, 141 F. Supp. 2d 105 (D.D.C. 2001); *Whitaker v. Thompson*, 248 F. Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health v. Sebelius*, 714 F. Supp. 2d 48 (D.D.C. 2010).

Complaint Counsel says that the Commission and the FDA nevertheless "share a common goal of "preventing injury and deception of the consumer." (CCAB 39, n. 32.) So, of course, do the SEC, CPSC, and many other federal agencies. It would equally nonsensical to blend the enforcement jurisdiction of those agencies with that of the Commission as to do so with the FDA.

Complaint Counsel's reliance on *Thompson Medical* to support its "FTC-FDA are in harmony thesis" is misplaced. The D.C. Circuit stressed in *Thompson Medical* that the FTC and FDA operate under "different regulatory scheme[s]," and it rejected the attempt of respondents in that case to force the Commission to defer to a pending FDA review of its claims. 791 F.2d at 192-195. The Second Circuit struck the same chord in *Bristol-Myers Co. v. FTC*, 738 F.2d 554 (2d Cir. 1984). The Commission argued there that FDA standards should apply to the claims at issue. The Second Circuit said no. "FDA requirements and regulations . . . do not govern," the Second Circuit stated, "[because] [n]ot only is a different regulatory scheme involved, but generally speaking, the FDA is concerned only with evaluating absolute safety and efficacy, not with questions of comparative safety and efficacy that arise in [over-the-counter] drug advertising." *Id.* at 559. The fundamental difference between FTC and FDA standards and functions that the D.C. Circuit and the Second Circuit recognized three decades ago remains true today.

B. The FDA Preclearance Remedy Is Unwarranted.

Even if the Commission had the statutory authority to require FDA preclearance of the substantiation of Respondents' health claims, that remedy would be unwarranted here.

Complaint Counsel's primary argument is that the "bright line" of FDA preclearance is warranted because, according to Complaint Counsel, Respondents have "demonstrated [a] willingness to flout the law." (CCAB 41.) As one illustration of this supposed misbehavior,

Complaint Counsel cites Respondent's alleged "fail[ure] to "heed warnings" in a 2008 letter from Commission staff. (*Id.* at 42.) But as the ALJ found, what Complaint Counsel calls Respondents' willingness to flout the law" is, more accurately, simply the unwillingness of Respondents to cave in under pressure from Complaint Counsel and settle on Complaint Counsel's terms. That Respondents chose to litigate follow receipt of the 2008 Commission staff letter and the subsequent negotiations with Complaint Counsel is not evidence that Respondents flouted the law. Rather, it merely reflects the fact the Respondents disagreed with Complaint Counsel on what the law requires.

The other evidence that Complaint Counsel cites as proof that Respondents "flouted the law" is equally flimsy. First, Complaint Counsel faults Respondents' decision not to seek FDA approval of a qualified health claim for their products. (CCAB 41-42.) Respondents were not required to take that step, however. Indeed, Complaint Counsel does not contend otherwise. In any event, Respondents carefully considered whether to seek FDA approval. Respondents made a good faith decision not to do so because of the attendant time and expense and because Respondents genuinely believed that the science behind their health claims was more than sufficient, especially given that they were not marketing their products as substitutes for medical treatment. (RFF 521-30.)

A second item in Complaint Counsel's parade of horrors is a 2010 letter from the FDA to Respondents in which the FDA stated that certain aspects of POM's website raised the possibility that the POM Products were being promoted as if they were drugs. (CCAB 33 n.29 (citing CX0344_0001).) The FDA letter did not, however, say anything about the appropriate level of substantiation for the health claims that Respondents made. Nor did it take issue with the studies on which Respondents relied in making those claims. (See CX0344.) Furthermore,

the FDA letter does not qualify as a legal ruling as the FDA's regulations and internal procedures specify. *See* 21 C.F.R. § 10.85(k); FDA Regulatory Procedures, §4-1-1, available at http://www>fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucml76870.html. And so, Respondents could not have "flouted the law" when reacting to the FDA's letter. In any event, as the record indicates, after receiving the letter from the FDA, Respondents modified the POM website to address the FDA's concerns. Since then, the FDA has expressed no further concern about the marketing of the POM Products. (Tupper, Tr. 2981-83.)

Third, Complaint Counsel finds it sinister that Respondents did not file an Investigational New Drug Application ("IND") with the FDA in response to requests on that subject from university Institutional Review Boards. (CCAB 42.) Complaint Counsel elides the fact the Respondents engaged in a constructive dialogue with the Institutional Review Boards in which Respondents explained that they were not marketing the POM Products as drugs. All but one of the Boards were satisfied with what they heard from Respondents on this issue.[21] (CX07774; CX0811; CX0936; CX0975; CX1020; CX1056; CX 1340; Carducci Dep. at 179-80.) Furthermore, Complaint Counsel ignores the function of Institutional Review Boards. Their responsibility is to review protocols associated with scientific studies to ensure the safety of the participants in the studies. They do not, however, review the substantiation of health claims in advertising. Given their limited charter, none of the Boards involved here sat in judgment on whether Respondents' advertisements were adequately substantiated. (Dreher, Tr. 578.)

[21] The Institutional Review Board at Johns Hopkins required POM to file an IND for reasons totally unrelated to POM's marketing. As a result of another study being conducted at Johns Hopkins, the University decided to require INDs for *all studies* involving natural products, across the board, regardless of statements in the protocols or in the company's marketing history. (CX1350 (Liker, Dep. at 250)) (emphasis added).

In sum, the evidence on which Complaint Counsel relies to support its demand for an FDA preclearance remedy demonstrates that Respondents are hardly the scofflaws that Complaint Counsel makes them out to be. As the ALJ pointed out, and which Complaint Counsel ignores, it is telling that the Commission did not require FDA preclearance of the substantiation of health claims as a remedy for the violations found in *Daniel Chapter One*. (ALJID 316.) The health claims made in *Daniel Chapter One* were "so strongly implied as to be virtually express"; the claims were based on no scientific studies whatsoever; and the claims urged consumers to use the advertised products as a substitute for medical treatment. (*Id.* at 317.) None of this is true of the health claims at issue here. In short, if ever there were a case in which FDA preclearance was warranted, it would be *Daniel Chapter One* because the violations were so egregious. If that remedy was considered unwarranted in *Daniel Chapter One*, it certainly is unwarranted here.

Complaint Counsel's secondary argument for an FDA preclearance remedy is that it is said to provide a "clear and precise" standard, with no ambiguities. (CCAB 41, 43.) This argument, too, does not bear scrutiny. For decades, the Commission has been able to enforce the FTCA's substantiation requirement through the tried and true "competent and reliable" evidence standard. Complaint Counsel has failed to articulate why that standard is no longer sufficiently clear and precise to guide advertisers.

Nor does Complaint Counsel's FDA preclearance remedy take into account the sheer difficulty of obtaining FDA approval. Each of the four forms of FDA approval listed in Complaint Counsel's proposed order (CCAB 45) either carries substantial monetary costs, takes an exceptionally long time, or has been essentially closed off because of lack of FDA action (or combinations of these obstacles). *See Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011)

(process for obtaining approval of a new drug application is "costly and lengthy"); GAO Report at 12 (criticizing FDA for failing to approve at a meaningful pace proposed qualified health claims under the Nutrition Labeling and Education Act). Even a senior FDA official has said to the business community, "I can't stress this enough but avoid interacting with the monograph process." Jessica Lake, *OTC Monograph Route More Onerous Than NDA Process -- ONP Official*, The Tan Sheet, May 21, 2007, at 14.

Because drug manufacturers can recoup the expense of FDA approval through the exploitation of intellectual property rights, they have a financial incentive to run the gauntlet at the FDA and wait out the long approval process. That is just not the case for sellers of healthy food products. An FDA approval requirement is totally impractical for them. (RFF 367, 369, 373, 375.) Given the high hurdles to obtaining FDA approval, many sellers of healthy food products will simply not bother making health claims. This will chill the exercise of First Amendment freedoms and deprive consumers of potentially valuable health and medical information. As the ALJ found, the "competent and reliable" evidence standard, not FDA standards, is the most practical and effective standard for the substantiation of health claims about healthy foods. (ALJID 318-320.)

VIII. CONCLUSION

For the foregoing reasons and for the reasons set forth in Respondents' opening brief in their appeal, 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 submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this is a true and correct copy of the **ANSWERING BRIEF OF RESPONDENTS POM WONDERFUL LLC, ROLL GLOBAL, STEWART A. RESNICK, LYNDA RAE RESNICK, and MATTHEW TUPPER** and that on this 18th day of July, 2012, I caused the foregoing to be served by hand delivery and email on the following:

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The Honorable D. Michael Chappell
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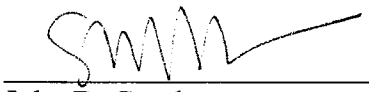

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