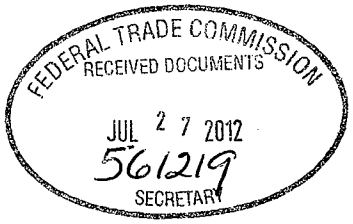
ORIGINAL



UNITED STATES OF AMERICA
BEFORE THE FEDERAL TRADE COMMISSION

COMMISSIONERS: **Jon Leibowitz, Chairman**
J. Thomas Rosch
Edith Ramirez
Julie Brill
Maureen K. Ohlhausen

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

COMPLAINT COUNSEL'S REPLY BRIEF TO RESPONDENTS' ANSWERING BRIEF

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Dated: July 27, 2012

RECORD REFERENCES

CCAB – Complaint Counsel's Appeal Brief

CCAB, App. – Appendix to Complaint Counsel's Appeal Brief

CCARAB – Complaint Counsel's Answer to Respondents' Appeal Brief

CCCL – Complaint Counsel's Proposed Conclusions of Law

CCFF – Complaint Counsel's Proposed Findings of Fact

CCPTB – Complaint Counsel's Post-Trial Brief

CCPTRB – Complaint Counsel's Post-Trial Reply Brief

CX – Complaint Counsel Exhibit

ID – Initial Decision

IDF – Initial Decision Findings of Fact

RACCAB – Respondents' Answer to Complaint Counsel's Appeal Brief

RPTB – Respondents' Post-Trial Brief

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INTRODUCTION

Respondents' Answering Brief fails to present a persuasive rebuttal to the facts and arguments Complaint Counsel presented on appeal: the detailed facial analysis and other evidentiary indicia that the advertisements at issue make the challenged claims; an assessment that Respondents' science does not substantiate those claims; and the appropriateness of Part I as fencing-in relief. Instead, their brief does little more than rehash plainly erroneous arguments premised on two faulty assertions: 1) that their ads convey merely that the POM Products are natural antioxidant-rich foods that are good for prostate, heart, and erectile health; and 2) that any references in the ads to science are factually accurate and well qualified. Neither of those assertions can withstand scrutiny, and thus Respondents' remaining arguments disintegrate.

For the reasons stated herein and in Complaint Counsel's other briefs, the Commission should set aside the erroneous portions of the Initial Decision and Order, reject Respondents' appeal, and enter an injunction consistent with the Notice Order.

ARGUMENT

I. THE CHALLENGED ADS CONVEY THE ALLEGED DISEASE CLAIMS

Respondents argue that Complaint Counsel is taking the position that companies cannot present properly-qualified, verifiable scientific information about the health benefits of their products to the public. Not so. Complaint Counsel agrees that nonmisleading, properly-qualified, verifiable scientific information may be presented to the public. But that is not what Respondents have done. As detailed previously by Complaint Counsel, Respondents' ads did not provide a balanced, measured explanation of the science (CCARAB Section I.C; IDF¶¶579-84; ID at 220-34). Instead, Respondents embellished the research (as well as the POM Juice bottle) and deceived consumers concerned about serious health conditions, such as heart disease

and prostate cancer. (*E.g.*, IDF¶¶370, 451, 459-64, 540-41, 1320; CCFF Section V.C.2; CCAB Section III.A).

Respondents argue that it would be unprecedented to find that the challenged ads convey establishment claims. (RACCAB at 11-12). This argument flies in the face of one of the most distinctive and ubiquitous of Respondents' claims – that the POM Products are backed by millions of dollars in medical research. (*E.g.*, CCFF Section V.C.3; *see also* CCCL¶¶20-23 (examples of cases finding establishment claims based on the interplay of various imagery and words)). Respondents' protestation that they should not be liable for their claims because they did not expressly convey that their products are a medical treatment "substitute" is a red herring. (RACCAB at 12). Advertising a product to treat, prevent, or reduce the risk of disease is a medical benefit claim regardless of whether the product is offered as a treatment "substitute." Respondents cite nothing in the law to find otherwise.

Respondents argue that it is contrary to Commission guidance and would be bad policy to hold them liable for publicizing specific, accurate scientific statements in advertising. (RACCAB at 13). We agree that most of the challenged claims are specific (*e.g.*, disease establishment claims that promise a specific level of support) – indeed, that is our point. The flaw in Respondents' argument is that the claims are not accurate. As stated in the *FTC Policy Statement Regarding Advertising Substantiation*, "an ad may imply more substantiation than it expressly claims or may imply to consumers that the firm has a certain type of support; in such cases, the advertiser must possess the amount and type of substantiation the ad actually communicates to consumers." 104 F.T.C. 648, 839 (1984) (appended to *Thompson Med. Co.*). Regardless of whether a claim is general or specific, it is deceptive if it is not substantiated. The *Stouffer* and *Kraft* cases, cited by Respondents, are instructive. In *Stouffer*, the Commission

found that the company's Lean Cuisine ads carried a deceptive "low sodium" message, despite specific language that each entrée contains "less than 1 gram (1000 mg) of sodium." *Stouffer Foods Corp.*, 118 F.T.C. 746, 800-02, 811, 814 (1994). Similarly, as Respondents acknowledge (RACCAB at 13-14), in *Kraft*, the juxtaposition of specific, factually accurate statements still resulted in a misleading net impression that each slice of Kraft singles cheese contained the same amount of calcium as five ounces of milk. *Kraft, Inc. v. FTC*, 970 F.2d 311, 322 (7th Cir. 1992). Respondents' reliance on these two cases undercuts their argument that it would be "bad policy" for the Commission to prevent a company from disseminating accurate, detailed product information,[1] and underscores the importance of the net impression analysis. An ad may convey a deceptive message despite containing truthful statements.

The instant case is far removed from *Kraft* and *Stouffer*, however, because the deceptive net impressions conveyed by Respondents' ads were not even the product of accurate, verifiable statements.[2] Consequently, what would be "bad policy" would be to allow advertisers like

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[1] *Kraft* also undermines Respondents' argument that the First Amendment shields them from liability. As articulated in *Kraft* and other FTC cases, advertising that is deceptive under the FTC Act is actually, not potentially, misleading and thus not protected by the First Amendment. *Kraft*, 970 F.2d at 320-21; *Bristol-Myers Co.*, 738 F.2d 554, 562 (2d Cir. 1984); *Daniel Chapter One*, No. 9329, 2009 WL 5160000, at *20 (Dec. 24, 2009), *aff'd*, 405 F. App'x 505 (D.C. Cir. 2010); *Nat'l Urological Group*, 645 F. Supp. 2d 1167, 1185 (N.D. Ga. 2008), *aff'd*, 356 F. App'x. 358 (11th Cir. 2009); *see also* CCARAB at 27-30.

[2] For example, from 2004 through at least 2009, Respondents ran ads promoting a 30% reduction in arterial plaque purportedly shown by the small, unblinded Aviram CIMT/BP Study (2004) (*see, e.g.*, CCFF¶¶329-30, 336, 344, 408, 411, 415, 430-31, 435, 437, 443, 449, 454).. However, Respondents knew, as early as 2006, of the inconsistent and negative results of their large, well-designed RCT study (Davidson CIMT Study (2009)) that showed, at most, a 5% decrease in arterial plaque in some patients measured at an interim point in the study. (*See, e.g.*, CCFF¶420). Even if consumers had the necessary scientific expertise, they would not have been able to verify the accuracy or reliability of the Aviram study in relation to the Davidson study because Respondents delayed publication of the Davidson study for three years while they

(con't)

Respondents to oversell their products based on a skewed and selective presentation of the science. The outcome would be a race to the bottom – detrimental to competition as well as consumers – in which advertisers could make sweeping health and disease benefit claims based on exploratory science that neither has been confirmed nor borne out in well-designed, well-controlled trials.

Respondents also make the unsound argument that advertiser intent plays no role in the analysis. (RACCAB at 7-9). Their position is not surprising, given the robust record evidence of Respondents' intent to make the challenged claims. (*E.g.*, CCFF Section V.C). The ALJ found sufficient evidence "to conclude that Respondents disseminated advertisements containing the alleged claims, without regard to Respondents' intent." (ID at 216). Although the ALJ recognized that the law permitted him to consider advertiser intent in addition to conducting a facial analysis, he avoided doing so, noting that *advertiser intent alone*, absent a facial analysis and/or other extrinsic evidence, would not be a valid basis to determine ad meaning. (*Id.* at 217). Complaint Counsel never advocated finding ad meaning based *only* on advertiser intent. Given the ample evidence of intent here, the ALJ should have considered it as corroborating evidence of the net impression facial analysis, and the Commission should now review this evidence on appeal. (CCAB Section III.A.4).

Respondents' summary of their intent is telling, but incomplete. (RACCAB at 8). They claim they intended to promote what they now call "health-promoting qualities" (*i.e.*, treatment and prevention for heart disease, ED, and prostate cancer), as well as the scientific research evaluating those "qualities" and the specific purported "promising results" produced by the

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continued to market POM Juice and POMx to consumers for this purported cardiovascular benefit. (*See also* CCARAB at 30-31).

research. Their summaries skirt closer to the truth with each reiteration in their briefs. What they actually communicated to consumers was a message of "established" disease benefit qualities – not a soft, measured portrayal of product attributes, including the limited nature of the science supporting those attributes. Moreover, contrary to Respondents' assertion, consumers could not evaluate for themselves the purported product benefits touted in the ads. (CCARAB at 30-32). While Respondents criticize the FTC for arguing that their ads convey "silver bullet" treatment claims, the evidence squarely supports that this message is precisely what Respondents intended and communicated. Respondents chose to: 1) tell the public that POM Juice "is the magic elixir of our age and of all ages" (CCFF¶570); 2) liken the "medical research that has been conducted on POM [as] . . . more akin to research being done on pharmaceutical drugs" (CCFF¶1121); and 3) direct their message to consumers concerned about preventing or reducing their risk of illnesses, such as prostate cancer and heart disease (CCFF Section V.C.2). Having adopted that marketing approach, Respondents must be held to the level and type of evidence they told consumers they had.

II. THE MEDIA INTERVIEWS ARE ACTIONABLE UNDER THE FTC ACT

Respondents mischaracterize both the ALJ's ruling with respect to four challenged media interviews given by Lynda Resnick and Matthew Tupper, and Complaint Counsel's appeal with respect to those interviews. (RACCAB at 14-15). The ALJ found the media interviews were not "advertisements" within the scope of Section 12 of the FTC Act, citing a statement from *R.J. Reynolds Tobacco Co.*, 111 F.T.C. 539 (1988) (hereinafter "*RJR*"). (ID at 208-10). Contrary to Respondents' assertion, however, the ALJ did not address the "fundamental indicia of commercial speech," nor did he "reject[] . . . Complaint Counsel's characterization of the interviews as commercial speech[.]" (RACCAB at 14-15; ID at 210). The ALJ limited his

analysis to a statutory analysis under Section 12. Respondents incorrectly assert that "Complaint Counsel argues [on appeal that *RJR*] is irrelevant here because [it] was a Section 12 case and Complaint Counsel has sued Respondents under both Section 12 and Section 5." (RACCAB at 15). In fact, Complaint Counsel argued that the Commission in *RJR* did not define the term "advertisement" for purposes of Section 12, because, among other reasons, *RJR* was *not* a Section 12 case. (CCAB at 19). In addition, Complaint Counsel noted that Respondents are also being sued under Section 5 of the FTC Act, which is not limited to "advertisements," paid for or otherwise, an issue that the ALJ failed to consider. (CCAB at 20; 15 U.S.C. § 45(a)(1); ID at 207-10).[3]

The challenged media interviews are actionable under both Sections 5 and 12 of the FTC Act and make the challenged claims alleged in Complaint Counsel's Proposed Findings of Fact. (CCAB at 19-21). In their Answering Brief, Respondents do not dispute that the challenged interviews evidence *RJR*'s indicia of commercial speech, *i.e.*, they convey explicit messages promoting demand for the POM Products, refer to the POM brand and POM Juice by name, and make specific claims about the health effects associated with consuming POM Juice. (CCAB at 20-21; RACCAB at 14-16).[4] They also do not dispute Complaint Counsel's description of

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[3] The Commission has found non-paid media interviews solicited by respondents to violate Section 5. *Witkower Press, Inc.*, 57 F.T.C. 145, 160-69, 221-22 (1960).

[4] Respondents cite *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60 (1983), in which certain pamphlets were "conceded to be advertisements," insinuating that unless an advertisement is paid for it is unlikely to be commercial speech. (RACCAB at 14-15 n.11); *Bolger*, 463 U.S. at 66. The *Bolger* court, however, said it did not "mean to suggest that each of the [three] characteristics present in this case must necessarily be present in order for speech to be commercial." *Id.* at 67 n.14. The Commission considered *Bolger* when it found that being "paid-for advertising" was one of five possible characteristics of commercial speech and declined to say which characteristics are determinative. *RJR*, 111 F.T.C. at 544-46. *See also*

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Respondents' views about the value of public relations, including press interviews, or that promoting sales of the POM Products was Mrs. Resnick's and Mr. Tupper's primary motivation for their press appearances. (CCAB at 21; RACCAB at 14-16). Finally, they do not dispute that the media interviews make the claims alleged. (CCAB at 19; RACCAB at 14-16).

Instead, Respondents suggest the interviews do not constitute commercial speech because they are not "related solely to the economic interests of the speaker and the audience" but instead purportedly "covered a wide-range of matters." (RACCAB at 15-16 (citing *Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n*, 447 U.S. 557, 561 (1980))).[5] But the Supreme Court has rejected arguments that the commercial speech doctrine does not apply to communications made by corporations about their products to consumers when the communications also address non-commercial matters. *See, e.g., Bolger*, 463 U.S. at 66-68 (pamphlets promoting contraceptives that also "contain discussions of important public issues such as venereal disease and family planning" constitute commercial speech even though they did not readily fit into the category of commercial speech as the Court had previously defined it — as "merely . . . proposals to engage

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Washington Legal Found. v. Friedman, 13 F. Supp. 2d 51, 64-65 (D.D.C. 1998), *vacated in part on other grounds*, 202 F.3d 331 (D.C. Cir. 2000) (in determining whether seminar was an "advertisement" under *Bolger*, court looked to dictionary definition of the term "advertisement" – something that "call[s] public attention to, especially by emphasizing desirable qualities so as to arouse a desire to buy or patronize.").

[5] Respondents' assertion that the media interviews "covered a wide-range of matters unrelated to POM Products" (RACCAB at 16) is incorrect. The Matthew Tupper interview focused almost entirely on POM Products and the challenged health claims. (CX0473 (Exh. E-7)). The Lynda Resnick segment on Martha Stewart's show focused almost exclusively on the various uses of POM Products. (CX0473 (Compl. Ex. E-6)). Mrs. Resnick's interview on the CBS Morning show focused primarily on POM Products, but also promoted her book and Fiji water. (CX0472). Only Lynda Resnick's Newsweek interview covered a wide range of matters, but it was used expressly as a marketing tool when Respondents linked to it on the "Blog" page of the pomwonderful.com website. (CX1426_00032-35).

in commercial transactions"); *see also RJR*, 111 F.T.C. at 543, 546. "Advertisers should not be permitted to immunize false or misleading product information from government regulation simply by including references to public issues." *Bolger*, 463 U.S. at 68. When commercial speech and non-commercial speech are voluntarily combined, no special consideration is afforded the commercial speech. *Bd. of Trustees of the State Univ. v. Fox*, 492 U.S. 469, 473-74 (1989) ("'Tupperware parties' . . . [which] 'propose a commercial transaction' . . . [and] also touch on other subjects . . . such as how to be financially responsible and how to run an efficient home" constitute commercial speech because "[n]othing . . . prevents the speaker from conveying, or the audience from hearing, these noncommercial messages, and nothing in the nature of things requires them to be combined with commercial messages.").

As discussed in Complaint Counsel's Appeal Brief, the four challenged interviews fit comfortably within the indicia of commercial speech outlined in *RJR*.[6] Respondents express concern that finding such speech actionable might chill purveyors of goods and services from giving interviews. (RACCAB at 16). But increasingly, companies use non-traditional media (*e.g.*, unpaid promotional or PR efforts) to communicate their selling messages; the Commission is not powerless when such marketing is squarely false and deceptive. There is little likelihood of commercial speech being chilled by proper regulation. *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Counsel,* 425 U.S. 748, 771-72 (1976); CCARAB at 27-28. Accepting

[6] Respondents cite *Koch v. FTC*, 206 F.2d 311, 317 (6th Cir. 1953), in which the court said prohibiting the dissemination of "a book on 'The Chemistry of Immunity,' . . . widely distributed among physicians, which explains in detail his theory of heightening the natural immunity of the body against disease" would violate the First Amendment. (RACCAB at 16). The challenged media interviews are different in nature from the book in *Koch* and meet the requirements of commercial speech outlined in *RJR*. *See also* CCPTRB at 47-48.

Respondents' argument would give marketers free rein to lie and deceive consumers in interviews and other non-paid public appearances.[7]

III. RCTS ARE REQUIRED TO SUBSTANTIATE RESPONDENTS' DISEASE CLAIMS

A. Commission Law and Policies and the Evidence Support the Need for Well-Controlled Human Clinical Trials to Substantiate Respondents' Disease Claims

Much of Respondents' discussion of substantiation is devoted to a straw-man argument that the Commission is being asked to find that "any and all health claims about any and all products" must be substantiated with RCTs. (RACCAB at 24). This is not what Complaint Counsel seeks, and not what the proposed order requires. The policy statements and precedents that Respondents cite merely state the obvious – that the Commission and courts must look to the facts presented in each instance and determine the level of evidence necessary to substantiate the particular claims at issue. In this case, based on the law and evidence, the Commission is well within its authority to require RCTs to support Respondents' disease claims.

The Commission's Enforcement Policy Statement on Food Advertising ("Food Policy Statement"), which Respondents agree is "an important source for determining what the law on substantiation is" (RACCAB at 18), states that the central factor in determining "the specific

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[7] Since *Virginia Board of Pharmacy*, the Commission has challenged unpaid public appearances, *see FTC v. Gill*, 71 F. Supp. 2d 1030 (C.D. Cal. 1999) (granting summary judgment for the Commission based in part on representations made by defendants at public appearances before mortgage brokers and a bar association), and the Securities and Exchange Commission has challenged deceptive statements in media interviews, *see, e.g., SEC v. Weintraub*, No. 11-CV-21549, 2011 U.S. Dist. LEXIS 149999, at *4-7, 31 (S.D. Fla. Dec. 30, 2011) (summary judgment granted in matter involving allegations of materially false or misleading statements and omissions in press interviews); *SEC v. Uniprime Capital Acceptance, Inc.*, 2005 SEC LEXIS 2328, at *1-3 (SEC 2005) (Litigation Release No. 19371) (announcing consent judgment settling allegations of material misrepresentations and omissions in statements in Bloomberg News interview).

level of scientific support necessary to substantiate the claim . . . is an assessment of the amount of substantiation that experts in the field would consider to be adequate." (CX0002_0006). Similarly, the guidance document "Dietary Supplements: An Advertising Guide for Industry" ("Dietary Supplement Advertising Guide"), which Respondents also rely upon (RACCAB at 18), states that "[a] guiding principle for determining the amount and type of evidence that will be sufficient is what experts in the relevant area of study would generally consider to be adequate." (CX1014_0015). Ultimately, the inquiry is what experts in the field believe constitutes competent and reliable scientific evidence for the claims at issue.[8]

Respondents claim the Dietary Supplement Advertising Guide states that "health claims about dietary supplements also can be met through animal and in vitro studies." (RACCAB at 19). What the Dietary Supplement Advertising Guide actually says, however, is "as a general rule, well-controlled human clinical studies are the most reliable form of evidence." (CX1014_0015). Animal and *in vitro* study results "will be examined, particularly where they are widely considered to be acceptable substitutes for human research or where human research is infeasible." (CX1014_0015). Neither of those conditions exists here: Respondents' own experts acknowledge the weaknesses of relying on basic, non-human research for claims about a product's efficacy for human diseases (CCARAB at 12-13), and Respondents' own studies show

[8] Respondents also refer to an FTC staff comment to FDA and a letter from the Commission's Secretary denying a rulemaking petition (RACCAB at 19-20), but these documents reinforce that the claims at issue and the expert evidence drive the substantiation analysis. *See* Staff Comment (http://www.ftc.gov/os/2002/09/fdatextversion.pdf) at 17 ("How a claim is presented and qualified drives the standard."); D. Clark Letter to J. Emord, Nov. 30, 2000, (http://www.ftc.gov/os/2000/12/dietletter.htm) at 3 (substantiation doctrine is flexible "in the type and amount of evidence required depending on the nature of the claim and how it is presented and qualified"). Neither document suggests the Commission may not require RCTs where the claims and evidence warrant.

that human research, including well-controlled clinical trials, was not only feasible, it was a defining characteristic of their scientific research program. (CCAB at 34-35; CCARAB at 14). It was the unhelpful results of the studies, not their methodology, that was not to Respondents' liking.

Case law also supports Complaint Counsel's position that the Commission can, and in this matter should, require RCTs based on the claims and expert evidence presented. While the Courts of Appeal in *QT* and *Direct Marketing Concepts* correctly noted that the FTC Act does not require any specific level of science (such as RCTs) as a general rule for substantiating health-related claims, they affirmed the district court holdings that expert evidence established that RCTs were necessary to substantiate the specific claims made by the defendants. *See, e.g.*, *FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) (noting that "[p]lacebo-controlled, double-blind testing is not a legal requirement for consumer products" but upholding District Court finding that claims for an arthritis pain-treatment bracelet were false); *FTC v. Direct Mktg. Concepts, Inc.*, 641 F.3d 1, 11 (1st Cir. 2010) (Court "assume[d] for these purposes that a double-blind study is not necessarily required," but ultimately found "the FTC produced evidence establishing a rigorous standard of scientific reliability, and the record reveals that the Defendants fell well and unquestionably short of this standard."). Moreover, courts have accepted that human RCTs were needed to provide the "competent and reliable scientific evidence" required to advertise medical or disease claims, including that products treat or prevent: baldness, *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994); *FTC v. Sabal*, 32 F. Supp. 2d 1004 (N.D. Ill. 1998); pain, *FTC v. QT, Inc.*, 448 F. Supp. 2d 908 (N.D. Ill. 2006), *aff'd*, 512 F.3d 858 (7th Cir. 2008); cancer, *FTC v. Direct Mktg. Concepts, Inc.*, 569 F. Supp. 2d 285 (D. Mass. 2008), *aff'd*, 641 F.3d 1 (1st Cir. 2010); diabetes, *FTC v. Braswell*, CV 03-3700

DT, 2005 U.S. Dist. LEXIS 42976 (C.D. Cal. Sept. 26, 2005); and ED, *Nat'l Urological Group*, 645 F. Supp. 2d 1167, as well that products cause weight loss, *Schering Corp.*, 118 F.T.C. 1030 (1991) (Initial Decision); *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263 (S.D. Fla. 1999). (*See also* CCCL¶¶68-69).[9]

Substantial expert evidence in this case establishes that the challenged claims must be supported with RCTs. (CCAB at 21-36). Respondents argue that their experts testified RCTs are not necessary to advertise the "health benefits" of a food (RACCAB at 32, 34-35). But as Complaint Counsel has pointed out, the challenged claims are not simply that the POM Products provide vague "health benefits" but that they treat, prevent, or reduce the risk of heart disease, prostate cancer, or ED, and that scientific testing establishes these benefits. (CCAB at 8-32).[10] Nor did Respondents' experts or study authors testify that the evidence presented substantiated the specific claims at issue. (CCARAB at 11-15). The Commission should find that competent and reliable scientific evidence here must include RCTs, and that Respondents not only did not

[9] Respondents cite *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309 (2011), to argue that RCTs are not required to show a causal relationship between the POM Products and the advertised disease benefits. (RACCAB at 17). But *Matrixx,* a securities fraud case, does not address whether non-RCT data can establish a health benefit for a product. The issue there was whether there was a material failure to disclose to shareholders adverse event reports for an over-the-counter drug. In finding that less than statistically significant data should not deter disclosure of adverse event reports, the Court noted that such data are not always available because adverse events may be subtle or rare, and ethical considerations may prohibit conducting RCTs designed to prove an adverse effect is caused by a product. 131 S. Ct. at 1321. The case says nothing about the type of evidence needed to support efficacy claims. (*See also* CCPTRB at 19-20).

[10] Respondents argue that RCTs are not necessary because Complaint Counsel's experts have sometimes accepted non-RCT evidence, *e.g.*, in public health or dietary recommendations. (RACCAB at 35-37). Complaint Counsel has already explained that these arguments are irrelevant and inapplicable to the facts here. (CCAB at 27 & n.19; CCARAB at 14 n.13).

have such evidence to support the challenged claims, but conducted RCTs that failed to show the claimed benefits.[11]

B. Requiring Respondents to Have Adequate Substantiation for the Challenged Claims Is Not Unconstitutional

Respondents' Constitutional arguments are equally unavailing. It is not a Due Process violation to hold Respondents to longstanding Commission legal precedent and policy on substantiation. Respondents themselves cite approvingly the Food Policy Statement, which they acknowledge is "[n]ow nearly two decades old" and "a critical part of the law on the substantiation of health claims about food products," as well as the 2001 Dietary Supplement Advertising Guide. (RACCAB at 18-19). So it can be no surprise to Respondents that the Commission "imposes a rigorous substantiation standard" on their claims and would "likely . . . reach the same conclusion as FDA as to whether an unqualified claim about the relationship between a nutrient or substance in a food and a disease or health-related condition is adequately supported by the scientific evidence." (CX0002_0006-07).[12] Moreover, the Dietary Supplement Advertising Guide includes clear examples and warnings against the very conduct Respondents engaged in: 1) using vague qualifying words in advertisements to cover for insufficient evidence ("Vague qualifying terms – for example, that the product 'may' have the claimed benefit or

[11] Ironically, after conducting RCTs and telling consumers that the POM Products' claims were backed by rigorous human studies (CCARAB at 14), Respondents now portray as extreme and unattainable the RCT-level substantiation experts require to support the disease claims at issue.

[12] The evidence shows that Respondents internally acknowledged that their scientific evidence would not meet FDA's standards for treat, prevent, or reduce the risk of disease claims. (CCARAB at 4). By their own reckoning, nearly two decades of Commission policy under the Food Policy Statement should have put them on notice that their claims and supporting science would also be problematic under the FTC Act. (RACCAB at 18-19).

'helps' achieve the claimed benefit – are unlikely to be adequate."); 2) selective presentation of scientific evidence ("[A]dvertisers should not make qualified claims where the studies they rely on are contrary to a stronger body of evidence. In such instance, even a qualified claim could mislead consumers"; "[advertisers] should not focus only on research that supports the effect, while discounting research that does not."); and 3) overstating the significance of the science ("Advertising . . . should not suggest greater scientific certainty than actually exists. . . . [A]dvertisers must make consumers aware of any significant limitations or inconsistencies in the scientific literature."). (CX1014_0012, 0019, 0021; *see* CCPTB at 24, 26, CCAB at 11, 15, CCARAB at 10 (Respondents' use of vague qualifiers); CCARAB at 15-27 (Respondents' selective characterization of science)).[13] Moreover, as Complaint Counsel has pointed out above, numerous cases, dating back years, have looked to RCTs to substantiate disease and other medical benefit claims for a variety of products.[14]

Respondents would have the Commission believe this case raises novel issues, but it involves the application of well-established Commission precedent on substantiation. The two basic legal principles that: 1) advertisers must have the level of science they tell consumers they

[13] The Dietary Supplement Advertising Guide also refers back to, and follows the principles in, the Food Policy Statement. Thus, Respondents had long-standing policy guidance to follow in marketing both food (POM Juice) and supplements (POM_x). *See Nat'l Urological Group*, 645 F. Supp. 2d at 1186-87 (holding that Commission's substantiation standards, as described in Dietary Supplement Advertising Guide, were not unconstitutionally vague and gave "people of ordinary intelligence a reasonable opportunity to understand what evidence is required to substantiate their health-related claims").

[14] Respondents attempt to distinguish these cases, contending that their products do not have side effects, unlike the products at issue in *some* prior cases. The possibility of side effects does not drive the substantiation analysis, however; the advertiser's claims do. Moreover, the POM Products are not free of safety concerns. (CCAB at 33 n.28).

have (here, well-conducted human clinical trials); and 2) claims regarding health, which are difficult for consumers to evaluate on their own, require a high level of substantiation, are squarely applicable here. *Removatron Int'l Corp.*, 111 F.T.C. 206, 296-97, 306 n.20 (1988), *aff'd*, 884 F.2d 1489 (1st Cir. 1989); *Thompson Med. Co.*, 104 F.T.C. 648, 814, 822-23 (1984), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986).[15] In this case, most of the advertisements included establishment claims and very strong efficacy claims about serious medical conditions; thus, as Complaint Counsel's experts in the relevant fields have testified, rigorous evidence in the form of RCTs is needed as a basis for these claims. (CCAB at 24). This is not a new legal proposition. "Defendants would not be required to have a gold-standard study to substantiate [their product] if they did not make such a strong, medical claim. The choice belonged to Defendants." *QT, Inc.*, 448 F. Supp. 2d at 962. Respondents here had notice of the appropriate substantiation requirements, and are being held to the same standard as other advertisers who have made disease or other medical claims over the years. (CCCL¶68).[16] As Respondents can point to no change in the governing substantiation requirements, their Due Process argument fails.[17]

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[15] "The 'placebo' effect of consumer expectations when taking a purported remedy makes it difficult for consumers to verify product effectiveness for themselves." *Daniel Chapter One*, No. 9329, 2009 FTC LEXIS 157, at *230 (Aug. 5, 2009) (Initial Decision) (citing *Pantron I*, 33 F.3d at 1090 n.1; *Removatron*, 111 F.T.C. at 306 n.20; *Thompson Med.*, 104 F.T.C. at 822-23).

[16] Respondents exempt their own products from these precedents and policy statements, arguing that despite making claims as serious and strong as in prior cases, it is unfair to hold them to the same competent and reliable scientific evidence standard because they sell "foods." But focusing on the type of product over all other factors, including the claims at issue, is inconsistent with the law. (CCAB at 32-36).

[17] Respondents' reliance on *FCC v. Fox Television Stations, Inc.*, 132 S. Ct. 2307 (2012) (RACCAB at 24-26) is misplaced. In *Fox*, the FCC expressly reversed its stated policy on *(con't)*

Respondents also argue that requiring their advertising for the POM Products to be true and substantiated under the FTC Act violates the First Amendment because their claims are "literally true" and only "potentially misleading." (RACCAB at 29-31). Again, Respondents simply assume away the flaw in their argument: their ads were not true "literally" or "figuratively" and thus fall outside the First Amendment. And for that reason the Commission has already rejected this position, which implies that the FTC Act itself is unconstitutional. (CCARAB at 27-33). Moreover, Complaint Counsel does not seek to "completely bar Respondents from engaging in commercial expression about their studies." (RACCAB at 31). We have no interest in interfering with truthful, nonmisleading discussions of science and that is not the issue here. Rather, Respondents' advertising misrepresented that their studies show that the POM Products are effective for specific serious human diseases, and as Complaint Counsel has explained, such misrepresentations do not receive Constitutional protection. (CCARAB at 15-21).

IV. PART I OF THE NOTICE ORDER IS LAWFUL AND NECESSARY FENCING-IN

A. Part I Is Lawful Relief

Respondents do not question the Commission's broad remedial authority,[18] but instead erroneously argue that Part I of the Notice Order would impose enforcement responsibilities on the FDA and would result in the Commission overstepping its bounds to enforce FDA's statutes.

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indecency, and applied the new policy to broadcasts that occurred before the reversal. *Fox*, 132 S. Ct. at 2318. By contrast, as discussed above, the FTC's interpretation of its substantiation policy and law has been in place for many years, and the case law and guidance gave Respondents notice that RCTs were needed to support medical or disease claims.

[18] (*See* CCCL¶¶99-100).

In reality, Part I of the Notice Order imposes no obligations on the FDA; it does place an obligation on Respondents that is well within the Commission's fencing-in authority.[19] If Respondents want to advertise the POM Products to treat, prevent, or reduce the risk of a disease condition, they must first obtain FDA approval for that intended use through the avenues established by Congress in the Federal Food, Drug, and Cosmetic Act. For example, in an enforcement action, if the FTC establishes that an advertisement disseminated by Respondents conveys an unqualified claim that POM Juice treats or prevents prostate cancer, Respondents will have violated Part I of the Notice Order unless they demonstrate that FDA has approved that claim for use on the POM Juice label. (CCAB at 45).

However, if Respondents make a *qualified* health claim that accurately characterizes the limited scientific evidence supporting the relationship between a POM Product and reduction of disease risk, and does not misrepresent that the product has been shown to reduce the risk of disease, that claim would fall under Part III of the Notice Order. Part III of the Notice Order applies to future health claims for the Covered Products *other than* the unqualified disease efficacy claims covered by Part I. No FDA pre-approval is necessary for carefully *qualified* claims that convey a net impression other than that the product is effective for the treatment, prevention, or reduction of risk of disease.

The Notice Order incorporates the construct established by the Commission in its Food Policy Statement, which Respondents now embrace as "providing consistent enforcement principles that serve to facilitate long range planning for food advertisers." (RACCAB at 18

[19] Courts have affirmed Commission orders requiring fencing-in remedies in diverse factual scenarios. (CCARAB at 38).

n.12). Complaint Counsel agrees.[20] Part I of the Order makes clear that the Commission's approach to unqualified health claims parallels FDA's assessment. It also prevents Respondents from taking an end run (as the record here proves they did) around the petition process established under the NLEA and FDA regulations, which is a significant factor in assessing the adequacy of substantiation for *unqualified* health claims. (CX0002_0007, 0013) ("Food marketers should not expect to circumvent FDA's petition process for health claims simply by limiting the assertion of unapproved or unreviewed claims to advertising.").

Consistent with the Food Policy Statement, if Respondents make a carefully qualified claim under Part III of the Notice Order, FDA pre-approval will not be necessary. (*See* CX0002_0007 ("*[T]here may be certain limited instances in which carefully qualified health claims* may be permitted under Section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support. . . . In the absence of adequate qualification, the Commission will find such claims deceptive.") (emphasis added)). Thus, the Notice Order simply implements the principles the Food Policy Statement sets forth, which Respondents themselves acknowledge is a critical part of the law.[21]

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[20] Respondents attack Complaint Counsel's argument that the Notice Order harmonizes the Commission's approach to advertising and substantiation with the FDA's approach by claiming that Complaint Counsel misused selective quotations from the Food Policy Statement However, it is Respondents who have misrepresented the Food Policy Statement. *Compare* CCAB at 37-39 *with* RACCAB at 38-40.

[21] Respondents incorrectly cite *Bristol-Myers* and *Thompson Med. Co. v. FTC*, 791 F.2d 189 (D.C. Cir. 1986), for the proposition that it is improper for the FTC to harmonize with FDA. (RACCAB at 40). They wrongly assert that the Second Circuit rejected the Commission's position that FDA standards should apply to certain claims, citing *Bristol-Myers*, 738 F.2d at 559. However, it was Bristol-Myers that argued that the types of tests FDA accepted to prove safety, as opposed to the Commission order's more stringent two "well-controlled clinical studies" requirement, should be considered adequate to prove comparative safety establishment *(con't)*

Respondents' briefs make clear that without the Notice Order, they will refuse to acquiesce to the regulatory framework in the Commission's Food Policy Statement.

Contrary to Respondents' assertions, FDA pre-approval is not a novel remedy. The Commission has banned baldness treatment claims unless those claims were FDA-approved. *See Synchronal*, 117 F.T.C. 724 (1994) (consent order).[22] The Commission has also prohibited the sale of HIV test kits that are not FDA-approved. *See, e.g.*, *FTC v. Seville Mktg., Ltd.*, No. 04-cv-01181-RSL (W.D. Wash. May 24, 2005) (Amended Stipulated Judgment);[23] *FTC v. Medimax, Inc.*, No. 99-1485-CV-ORL-99A (M.D. Fla. Mar. 23, 2000) (Stipulated Final Order);[24] *FTC v. Sovo Tec Diagnostics, Inc.*, No. 00-CV-3468 (N.D. Cal. Sept. 20, 2000) (Stipulated Final Order).[25] Equally important, the Commission has already imposed Part I of the Notice Order in four consent orders. (CCAB at 39). Respondents dismiss the significance of these settlements (RACCAB at 38 n.19), but do not cite any case law or statute stating the FTC lacks authority to require FDA pre-approval as substantiation for future disease treatment claims, if such a remedy

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claims. *Bristol-Myers*, 738 F.2d at 557-59. The Second Circuit sided with the Commission, noting that FDA's regulatory scheme was designed to address whether an OTC drug is safe and effective, not whether it was safer or more effective than other drugs. *Id.* at 559. Comparative claims like those in *Bristol-Myers* would be subject to Part III of the Order here, not Part I. In *Thompson Medical*, the D.C. Circuit echoed the Second Circuit and was untroubled by the FTC's voluntary deference to FDA where the Commission believed it appropriate. 791 F.2d at 192-93.

[22] In another case involving an alleged baldness treatment, the Commission banned any representation that does not comply with applicable FDA rules or regulations. *FTC v. Sabal*, No. 98-cv-170 (N.D. Ill. Nov. 12, 1998) (Stipulated Order) (a*vailable at* http://www.ftc.gov/os/1998/11/sabkestip.htm).

[23] *Available at* http://www.ftc.gov/os/caselist/seville/050524amendstipx040047.pdf.

[24] *Available at* http://www.ftc.gov/os/2000/03/medimaxconsent.htm.

[25] *Available at* http://www.ftc.gov/os/2000/09/sovotecconsent.htm.

is reasonably related to the violations of the FTC Act. At a minimum, the Commission may look to its prior consent orders containing provisions similar to Part I as a guide in crafting an appropriate remedy here. *See, e.g., Realcomp II, Ltd.*, 2009 F.T.C. LEXIS 250, at *128 (Oct. 30, 2009) (stating the chosen remedy was "consistent with relief accepted in settlement of recent similar cases"); *N. Tex. Specialty Physicians*, 140 F.T.C. 715, 753 (2005) (noting the "wealth of guidance available" from FTC policy statements and "ten past Commission consents"), *aff'd in part*, 528 F.3d 346 (5th Cir. 2008).

B. Part I Is Necessary Fencing-In

Respondents' answering brief demonstrates why Part I is necessary. Respondents tell only part of the story, admitting they chose not to seek FDA approval in part because they "genuinely believed that the science behind their health claims was more than sufficient." (RACCAB at 41). As the record shows, Respondents knew their science was unlikely to meet FDA's standards, but Respondents have been more concerned with "hitting [their own] standard" for substantiation than what the scientific and regulatory communities require. (S. Resnick, Tr. 1655-56; s*ee also* CCFF Sections VI.E and VI.F). Throughout the litigation, Respondents held tight to their own standard, despite evidence that their science was inadequate. (CCAB at 41-43; CCARAB at 39-40). Even now, they submit that they have reliable evidence that the POM Products improve prostate health, "including inhibiting the recurrence of prostate cancer." (RACCAB at 2).[26] Only an order containing the bright-line substantiation standard of Part I will ensure compliance. As Complaint Counsel noted in its Appeal Brief, companies have attempted

[26] Respondents are well aware that FDA considers "prevent[ing] the recurrence of [prostate] cancer" to be "a drug use and a serious clinical claim," one requiring an Investigational New Drug application for POMx. (CCFF¶693).

to exploit the lack of perceived clarity in the "competent and reliable scientific evidence" standard in Commission Orders to re-litigate its meaning at every turn. (CCAB at 41 n.34). Respondents who previously have shown a willingness to game the system are likely to do the same.

Finally, Respondents argue that Part I of the Notice Order is unwarranted because of the possible consequences of requiring FDA pre-approval.[27] The respondents in *FTC v. National Lead*, 352 U.S. 419 (1957), made similar arguments, which the Supreme Court dismissed, stating:

> Respondents pose hypothetical situations which they say may rise up to plague them. However, "we think it would not be good judicial administration," as our late Brother Jackson said in *International Salt Co.* v. *United States*, 332 U.S. 392, 401 (1947), to strike the contested paragraph of the order to meet such conjectures. The Commission has reserved jurisdiction to meet just such contingencies. As actual situations arise they can be presented to the Commission in evidentiary form rather than as fantasies. And, we might add, if there is a burden that cannot be made lighter after application to the Commission, then respondents must remember that those caught violating the Act must expect some fencing in.

352 U.S. at 430.

Here, Respondents were aware of the regulatory landscape, made a conscious decision not to comply, and disseminated false and unsubstantiated disease treatment and prevention claims. The FDA cited Respondents for their claims and the ALJ found that they violated the FTC Act. Plainly speaking, Respondents played the game and lost. Is Part I of the Notice Order for similar future claims reasonably related to Respondents' violations? The unequivocal answer

[27] Although Respondents complain about the time and expense of seeking FDA pre-approval, they have already commenced the process by filing two INDs for the POM_x dietary supplement. (RPTB at 30).

is "yes." The Commission should enter the Proposed Notice Order attached to Complaint Counsel's Appeal Brief.

CONCLUSION

For the reasons above, and for the reasons set forth in Complaint Counsel's other briefs, the Commission should deny Respondents' appeal, grant Complaint Counsel's appeal, and enter the proposed order in Complaint Counsel's June 18, 2012 Appeal Brief.

Respectfully Submitted,

Date: July 27, 2012

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CERTIFICATE OF SERVICE

I hereby certify that on July 27, 2012, I filed the foregoing document electronically using the FTC's E-Filing System and delivered 12 copies to:

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I also certify that on July 27, 2012, I delivered via electronic mail and hand delivery a copy of the foregoing document to:

The Honorable D. Michael Chappell
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I further certify that on July 27, 2012, I delivered via electronic mail a copy of the foregoing to:

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