ORAL ARGUMENT NOT YET SCHEDULED

DOCKET NO. 13-1060

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

POM WONDERFUL LLC, et al.,

Petitioners,

v.

FEDERAL TRADE COMMISSION,

Respondent.

On Petition for Review of a Final Order of the
U.S. Federal Trade Commission

BRIEF OF AMICI CURIAE ALLIANCE FOR NATURAL HEALTH-USA AND TECHFREEDOM SUPPORTING PETITIONERS' OPENING BRIEF

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Pursuant to D.C. Circuit Local Rules 29(b) and 26.1, ANH-USA is a Virginia nonprofit corporation founded in 1992. ANH-USA is a membership based organization of consumers (including patients), healthcare practitioners (including physicians, nurses, nurse practitioners, nutritionists, and dietitians), food and dietary supplement company members, and over 200,000 advocate members. Among ANH-USA board members and general membership are those who manufacture and sell dietary supplements and make claims in the market for those products. Those individuals and entities, which ANH-USA represents, are directly and adversely affected by the reduction in the ambit of truthful information that may be communicated as a result of the Federal Trade Commission's (FTC's) POM Wonderful decision.

TechFreedom is a nonprofit, nonpartisan public policy think tank. It encourages development of "simple rules for a complex world" across a wide range of information technology policy issues, including privacy, data security, and antitrust.

Neither ANH-USA nor TechFreedom has a parent corporation or issues stock. No publicly held corporation has a direct financial interest in the outcome of this litigation due to the ANH-USA's or TechFreedom's participation as amici curiae.

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rules 28(a)(1) and 26.1, counsel for *amici*, ANH-USA and TechFreedom, certify as follows:

Parties and Amici:

All parties, intervenors, and amici appearing in this court are listed in the Petitioners' Opening Brief.

Rulings Under Review:

References to the rulings at issue appear in the Brief for Appellant.

Related Cases:

This case has not previously been before this Court. Amici are unaware of any related cases within the meaning of Circuit Rule 28(a)(1)(C).

CERTIFICATE OF COMPLIANCE WITH RULE 32(a)

This brief complies with Fed. R. App. P. 32(a)(7)(B) because it contains 6,998 words, excluding the parts of the brief exempted by Fed. R. App. 32(a)(7)(B)(iii).

This brief complies with the requirements of Fed. R. App. P. 32(a)(5) and Fed. R. App. P. 32(a)(6) because this it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Times New Roman font.

By: */s/ Jonathan W. Emord*
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CERTIFICATE OF COUNSEL FOR SEPARATE BRIEF

Pursuant to Circuit Rule 29(d), counsel for amici certifies that a separate brief is necessary for other respective amici.

ANH-USA and TechFreedom's arguments contained herein are rooted in the First Amendment and the Administrative Procedure Act.

Counsel for amici Consumer Healthcare Products Association (CHPA) and the Council for Responsible Nutrition (CRN) informed ANH-USA and TechFreedom that CHPA' s and CRN's brief will address different issues than those contained in the ANH-USA's and TechFreedom's brief, and as such, that CHPA's and CRN's brief will not overlap with the brief filed by ANH-USA and TechFreedom. Therefore, ANH-USA and TechFreedom respectfully request leave to file a separate *amici curiae* brief.

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1. *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)

2. Dan Schiff, *FTC's Pending Claims Substantiation Changes Will Weigh on Small Firms*, The Tan Sheet at 9, Mar. 1, 2010

3. Andrew Shao, PhD and Douglas Mackay, ND, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, Natural Medicine Journal 2010; 2(12):10-18

4. Jeffrey Blumberg, et al., *Evidence-based criteria in the nutritional context*, Nutrition Reviews 2010; 68(8):478-484

5. Robert P. Heaney, MD, Connie M. Weaver, PhD, and Jeffrey Blumberg, PhD, *EBN (Evidence-Based Nutrition) Ver. 2.0*, Nutrition Today 2011; 46(1):22-26

6. Roger Clemens, *Dietary Guidelines May Produce Unintended Health Consequences*, Food, Medicine & Health (Feb. 2011)

7. Joanne Slavin, *Dissecting the Dietary Guidelines*, Food Technology (2011)

INTERESTS OF THE AMICI

ANH-USA is a Virginia nonprofit corporation founded in 1992. ANH-USA is a membership based organization of consumers (including patients), healthcare practitioners (including physicians, nurses, nurse practitioners, nutritionists, and dietitians), food and dietary supplement company members, and over 200,000 advocate members. ANH-USA promotes access to information on the benefits of foods and dietary supplements. By educating the public and ANH-USA members about those benefits and about healthy lifestyles, ANH-USA strives to enable consumers to make informed choices and take personal responsibility for their health. ANH-USA aims to encourage disease prevention, reduction of medical intervention, and reduction in the public cost of health care.

TechFreedom is a nonprofit, nonpartisan public policy think tank. It encourages development of "simple rules for a complex world" across a wide range of information technology policy issues, including privacy, data security, and antitrust.

ARGUMENT

For the first time in the FTC's history, through its sweeping order in the POM Wonderful case ("POM"), the agency has prohibited the regulated class from communicating a disease-related claim in commerce unless the claim is backed by

randomized clinical trials (RCTs) – which, given the cost of RCTs, ordinarily amounts to an outright prohibition on such claims. *See* Final Order, *In re POM Wonderful LLC, et al.*, FTC Docket No. 9344 (Jan. 10, 2013), at 2 ("Final Order"). Through multiple public pronouncements by FTC officials[1] and the POM Order, FTC intends its RCT requirement to be followed by the entire regulated class, thus establishing it as a general rule adopted without notice and comment in violation of the Federal Trade Commission Act (15 U.S.C. §§ 41-58) and the Administrative Procedure Act (5 U.S.C. § 553FTC's new rule excludes from the ambit of permitted commercial speech the great bulk of scientific information concerning the actual and potential role of nutrients in disease risk reduction, including science conveyed by POM in qualified claims. That rule replaces the "totality of scientific evidence" and conflicts with the generally accepted scientific view that it is the totality of science, not the presence or absence of RCTs, that determines the relative validity of a nutrient-disease claim. That rule suppresses truthful qualified claims based on science other than RCTs (*i.e.*, claims that include disclaimers that alert the public to the inconclusiveness of the evidence), thereby denying industry

[1] *See* Dan Schiff, *FTC's Pending Claims Substantiation Changes Will Weigh on Small Firms*, The Tan Sheet at 9, Mar. 1, 2010 (Exhibit 2); Remarks of David Vladeck, National Advertising Division Annual Conference, New York, NY (Oct. 5, 2009) at 3, *available at*, http://tinylink.net/57474; Remarks by David C. Vladeck, Council for Responsible Nutrition Annual Symposium for the Dietary Supplement Industry, Rancho Palos Verdes, CA (Oct. 22, 2009), *available at,* http://tinylink.net/93463; *see also infra* at 5-7.

and consumers access in commerce to the great bulk of emerging science on the disease-risk-reduction potential of nutrients. That new rule conflicts with the First Amendment determination of this Court in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999) ("*Pearson I*"), wherein the Court determined that the First Amendment required allowance of qualified claims based on the totality of the scientific evidence as a less speech-restrictive alternative to outright suppression.

In short, FTC's new rule suppresses the republication in consumer markets of nearly all nutrition science, which science is evident in the totality of scientific evidence (and not RCTs to the exclusion of other evidence). Because precious few RCTs exist concerning foods and food elements, most science of utility to consumers arises from a combination of the following: animal studies, observational studies, case-control studies, cohort studies, cross-sectional studies, ecological studies, research synthesis studies (including meta-analyses), *in vitro* studies, epidemiological studies, patient series (or practitioner case series). It is that universe of science concerning foods and food elements upon which consumers must depend to exercise informed choice in an imperfect world. The FTC's idealized conception of perfect information, backed by RCTs, has led the Commission to impose a requirement so burdensome that it will deny consumers the benefits of reasonably substantiated health claims in selecting healthier foods.

The POM Decision applies to all disease-related claims, including disease-risk-reduction claims, and conveys to the regulated class that all similarly situated regulatees are expected to abide by the rule, a point reiterated publicly by FTC agents. *See supra* note 1. The decision thus has an *in terrorem* effect, causing regulatees to avoid commercial speech protected by the First Amendment to ensure compliance with FTC's severely constrictive RCT requirement.

The POM Decision also violates the Administrative Procedure Act (APA) in four ways. First, FTC has promulgated the RCT requirement without explaining with reason why RCTs are necessary before any truthful disease-related claim may be made. For example, a claim predicated on science other than RCTs might be qualified with a disclaimer that alerts consumers to the fact that the supportive science is inconclusive, yet even that truthful qualified claim, held to be protected commercial speech in *Pearson I*, would not pass muster under the POM Decision. Second, FTC has promulgated the RCT requirement as a rule applicable to the entire regulated class, making that intent evident through the language of the decision and in public pronouncements (*see supra* note 1). The promulgation of a legislative rule applicable to the entire regulated class is prohibited unless adopted through notice and comment rulemaking. *See* 15 U.S.C. §§ 57b-3, 74; 5 U.S.C. §

553.[2] Third, FTC's RCT requirement is at odds with the standard for qualified claims adopted by its sister agency, the Food and Drug Administration. Under *Pearson I*, 164 F.3d 650 (D.C. Cir. 1999), the FDA is required to allow qualified health claims based on the totality of scientific evidence, not limited to claims backed by RCTs. Fourth, the FTC's RCT requirement conflicts with, and was adopted without addressing, serious scientific criticism of dependency on RCTs for validation of nutrient-disease claims because nutrients, unlike synthetic xenobiotic drugs, exist in a milieu within the body and, thus, cannot ordinarily be isolated in their effects, which effects must instead be assessed based on the totality of non-RCT information.[3]

I. THE RCT REQUIREMENT IS AN ILLEGITIMATE ATTEMPT TO PROMULGATE A LEGISLATIVE RULE APPLICABLE TO THE REGULATED CLASS

FTC agents have communicated publicly their intent that the RCT requirement (in the POM Final Order at ¶ 2) be a binding rule applicable to the

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[2] *See also* Federal Trade Commission, *Operating Manual Chapter 7: Rulemaking*, at 1, Section 7.1, *available at*, http://www.ftc.gov/foia/ch07rulemaking.pdf#page=4.

[3] *See* Andrew Shao, PhD and Douglas Mackay, ND, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, Natural Medicine Journal 2010; 2(12):10-18 (Exhibit 3); Jeffrey Blumberg, et al., *Evidence-based criteria in the nutritional context*, Nutrition Reviews 2010; 68(8):478-484 (Exhibit 4); Robert P. Heaney, MD, Connie M. Weaver, PhD, and Jeffrey Blumberg, PhD, *EBN (Evidence-Based Nutrition) Ver. 2.0*, Nutrition Today 2011; 46(1):22-26 (Exhibit 5).

regulated class.[4] In October 2009, then-acting Director of FTC's Bureau of Consumer Protection, David Vladeck, stated at an industry trade convention that the FTC "will be looking for more precise injunctive language in future orders that will provide clearer guidance to defendants and courts alike as to the amount and type of scientific evidence that will be required in future advertising."[5] Speaking on the Commission's behalf, Richard Cleland, Assistant Director of the Division of Advertising Practices, explained that the "FTC plans to promulgate the revised standard initially through consent orders and eventually revise its advertising guide for the supplement industry." *See* Dan Schiff, *FTC's Pending Claims Substantiation Changes Will Weigh on Small Firms*, The Tan Sheet at 9, Mar. 1, 2010 (Exhibit 2). Consistent with those statements, the FTC has compelled reliance on RCTs as a condition precedent for claims in consent orders. *See FTC v. Iovate Health Sciences*, No. 10-CV-587 (W.D.N.Y. 2010); *In re Nestle Healthcare Nutrition, Inc.*, FTC Docket No. C-4312 (Jan. 18, 2011); *In re The Dannon Company, Inc.*, FTC Docket No. C-4313 (Feb. 4, 2011). In March 2010, FTC agents stated publicly that a heightened standard in consent orders would

[4] S*ee* Remarks of David Vladeck, National Advertising Division Annual Conference, New York, NY (Oct. 5, 2009) at 3, *available at*, http://tinylink.net/57474; Remarks by David C. Vladeck, Council for Responsible Nutrition Annual Symposium for the Dietary Supplement Industry, Rancho Palos Verdes, CA (Oct. 22, 2009), *available at* http://tinylink.net/93463.

[5] *See* Remarks of D. Vladeck, CRN Annual Symposium, *supra* note 4.

hopefully "reduce the amount of enforcement that's necessary," an indication that FTC expects the RCT orders to be followed universally. *See* Schiff, *supra* note 1 (Exhibit 2). "The legal and regulatory effect of … consent orders is evidenced by the FTC's own description of its consent orders as 'regulatory activity.'" *Mulford v. Altria Group, Inc.*, 506 F.Supp. 2d 733, 762 (D.N.M. 2007) (stating further that "[t]he history of FTC involvement in cigarette advertising demonstrates that the FTC used consent orders such as these to regulate the cigarette industry, make general rules, and express FTC policies for the industry in lieu of formal rulemaking").

Those FTC orders have signaled the Commission's intent to bind the regulated class, a point unmistakable after the FTC's sweeping POM Order. *See Watson v. Philip Morris Companies, Inc.*, 420 F.3d 852, 859 (8th Cir. 2005) ("[b]ringing a single case against one cigarette company would have the effect of bringing the whole industry into compliance and would do so much more quickly than would a formal rulemaking process"); *Mulford,* 506 F.Supp.2d at 762; *see also Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 513 & n.7 (1992). Because patent exclusivity is often unavailable, the food and supplement market contains many similar products and claims. Competitors come to understand FTC's interpretation of the "competent and reliable" standard primarily through FTC orders and adjudications. Particularly when those Orders reveal a pattern of

identical decisions, the FTC effectively regulates the industry through enforcement in individual cases.

State courts have also acknowledged the coercive and rule-like nature of FTC orders. *See Azar v. Prudential Ins. Co. of America,* 68 P.3d 909, 929 (N.M. 2003); *see also Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 46, 53-54 (Ill. 2005) (holding that FTC informal regulatory activity, including consent orders, fell within Illinois Consumer Fraud Act's exemption provision that exempted actions or transactions "specifically authorized by laws administered by" a state or federal regulatory body).

The entire regulated class, like those food and drug industry members of the ANH-USA, cannot afford to disregard FTC's POM decision. The RCT requirement in POM (and a string of consent decrees) informs the industry that FTC believes RCTs necessary to substantiate every disease-related claim.[6] The FTC's Order unmistakably applied the RCTs requirement prospectively and to *all* claims concerning disease. *See* FTC Final Order, at 2 ¶ I; FTC Decision at 51. Although FTC stated that it had "not determined the level of substantiation that is

[6] When interpreting statutory or contractual text, Courts generally give a word or phrase the same meaning when it is repeated in other sections of that text. *See Sierra Club v. Seaboard Farms Inc.*, 387 F.3d 1167 (10th Cir. 2004); *Sorenson v. Sec'y of the Treasury*, 475 U.S. 851, 860 (1986). It is thus logical for industry to project FTC's interpretation of "competent and reliable" to all products that closely resemble the product subject to FTC enforcement.

required to support all health and nutritional claims," the agency noted that its reasoning should guide all regulatees: "while our reasoning may be informative about our likely approach to evaluate other health claims, our ruling in this case should address only the substantiation of claims regarding the efficacy of *particular foods to treat, prevent or reduce the risk of serious disease*." *See* FTC Decision at 36-37 (emphasis added). In other words, the FTC intended its decision to govern the regulated class, not just POM.

Thus in the immediate case, the POM Order censors prospective speech that may be true, but it also has a chilling effect on all similarly situated who sell essentially equivalent products (foods and supplements) with nutrient-disease claims. *See Multimedia Holdings Corp. v. Circuit Court of Florida, St. Johns County*, 544 U.S. 1301, 1304 (2005); *Virginia v. Am. Booksellers Ass'n, Inc*., 484 U.S. 383, 393 (1988); *Laird v. Tatum*, 408 U.S. 1, 12-13 (1972) (stating that "constitutional violations may arise from the deterrent, or 'chilling' effect of governmental regulations that fall short of a direct prohibition against the exercise of First Amendment rights"). That *in terrorem* effect therefore chills the speech of all regulatees. The FTC has enacted a new industry-wide rule equivalent to the FDA's prior restraint this Court condemned as unconstitutional in *Pearson I*. *See Pearson I*, 164 F.3d at 655-60.

II. FTC VIOLATED THE FIRST AMENDMENT WHEN IT ADOPTED A RULE THAT SUPPRESSES PROTECTED COMMERCIAL SPEECH

The FTC has historically assessed disease-related claims based on the totality of scientific evidence. *See, e.g.,* FTC Enforcement Policy Statement (May 1994) ("[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").[7] Now, through public statements, the POM decision and several consent orders, the FTC has imposed a severely restrictive speech rule that deems deceptive all disease-related claims when based on scientific evidence other than RCTs:

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[7] *Available at*, http://tinylink.net/29667. FTC has explained that "[t]he benefits of a flexible approach are especially significant when the information relates to consumer health" because "[a]dvertising and labeling can be extremely effective tools to educate consumers about diet-disease relationships, to increase their awareness of diseases, to inform them of different treatment options, and to empower them to manage their own health." *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 (Exhibit 1); *see also In re Pfizer Inc.*, 81 F.T.C. 23, 30 (1972); *F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1186 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009) ("Competent and reliable scientific evidence has been defined in various contexts … this definition is context specific and permits different variations o[f] 'competent and reliable scientific evidence' depending on what pertinent professionals would require for the particular claim made"); *Am. Home Products Corp. v. F.T.C.*, 695 F.2d 681, 716 (3d Cir. 1982) (FTC requires only a reasonable basis for representations which shall consist of competent and reliable scientific evidence).

> ***For purposes of this Part …, competent and reliable scientific evidence shall consist of at least two randomized and controlled human clinical trials (RCTs)*** of the Covered Products that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies. Such studies shall also yield statistically significant results, and shall be double-blinded unless Respondents can demonstrate that blinding cannot be effectively implemented given the nature of the intervention.

See Order, *In re POM Wonderful LLC, et al.*, FTC Docket No. 9344 (Jan. 10, 2013), at 2 (emphasis added) (hereinafter "Final Order").[8]

The requirement of RCTs as a condition precedent to the lawful publication of disease related claims violates the First Amendment because it deems deceptive, and thus unlawful, claims that are truthful based on the totality of scientific evidence and based on feasible claim qualification. FTC's sweeping order limits *all* disease-prevention claims, whether qualified or not, unless predicated on at

[8] In the POM Decision, the FTC has expanded its "fencing in" authority beyond constitutional limits. *See U. S. v. Reader's Digest Ass'n, Inc*., 464 F.Supp. 1037, 1051 (D.C. Del. 1978). First Amendment protections directly apply to FTC orders and limit the expansion of FTC advertising regulation. *See, e.g., Standard Oil C. of California v. F.T.C.*, 577 F.2d 653, 662 (9th Cir. 1978) ("First Amendment considerations dictate that the Commission exercise restraint in formulating remedial orders which may amount to a prior restraint on protected commercial speech"); *Sears, Roebuck and Co. v. F.T.C.*, 76 F2d 385, 399 n.31 (9th Cir. 1982); *Beneficial Corp. v. FTC*, 542 F.2d 611 (3d Cir. 1976); *F.T.C. v. Simeon Management Corp.*, 532 F.2d 708, 713 (1976) ("[a]lthough commercial advertising may be subject to regulation serving an important public interest, it is not beyond the protection of the First Amendment").

least two RCTs. *See* Final Order at 2. By limiting the science that might support a claim to only RCTs, the FTC categorically excludes constitutionally protected commercial speech that reveals the existence of an association between nutrients and disease (including claims supported by credible but inconclusive science) that can be rendered non-misleading through the addition of qualifying language. *See Pearson I*, 164 F.3d at 655-58.

In *Pearson I*, this Court held that so-called deficiencies in the scientific record must be proven incapable of being rendered non-misleading through the addition of mandated claim qualifications before the government may impose a prospective speech ban. *See Pearson I*, 164 F.3d at 658 (holding that "[i]t is clear … that when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a 'far less restrictive' means"); *see also Whitaker v. Thompson*, 248 F.Supp. 2d 1 (D.D.C. 2002); *Alliance for Natural Health U.S. v. Sebelius*, 714 F.Supp. 2d 48, 53 (D.D.C. 2010) ("*ANH I*"); *Alliance for Natural Health U.S. v. Sebelius*, 786 F.Supp. 2d 1, 8 (D.D.C. 2011) ("*ANH II*").

Whatever interest the government may have in protecting consumers from misleading claims does not overcome the First Amendment's preference for disclosure (e.g., by mandated claim qualification) over censorship when claim qualification serves as a less speech restrictive alternative. *See Whitaker*, 248

F.Supp. 2d at 10. Put simply, when "credible evidence supports a claim, that claim may not be absolutely prohibited." *See id.* (citing *Pearson I*, 164 F.3d at 659).

Qualified claims are indispensable to informed consumer choice. They give consumers truthful information that would otherwise be blocked by government censors. Properly qualified claims are truthful expressions and, therefore, protected ones. *See Pearson I*, 164 F.3d at 655-56. Moreover, unqualified disease prevention claims that are supported by credible but inconclusive scientific proof are not "false" for lack of more evidence. *See Pearson v. Shalala*, 130 F.Supp. 2d 105, 115 (D.D.C. 2001) ("*Pearson II*") ("[t]he mere absence of significant affirmative evidence in support of a particular claim … does not translate into negative evidence against it"). When supported by credible science those claims are, at worst, only "potentially misleading." *See Pearson I*, 164 F.3d at 655-56. *Pearson I* and its progeny explain that the credible but inconclusive science supporting such claims may well be correct, and that the onus is on the government to prove falsity before choosing suppression. *See Edenfield v. Fane*, 507 U.S. 761, 770 (1993) ("[i]t is well established that the party seeking to uphold a restriction on commercial speech carries the burden of justifying it"); *Thompson v. Western States Medical Center*, 535 U.S. 357, 373 (2002) (same); *Bolger v. Youngs Drug Products Corp.*, 463 US. 60, 71 n.20 (1983) (same).

The First Amendment thus protects qualified claims to provide consumers with accurate, beneficial, and potentially life-saving health information, even if that information does not reach the level of certainty that a government official thinks preferable. *See Pearson I*, 164 F.3d at 657-59; *ANH I*, 714 F.Supp. 2d at 53 ("[t]he [government's] rejection of disclaimers without a showing that they were insufficient to meet the government's goal of avoiding consumer confusion demonstrated a disregard for 'less restrictive' means of speech regulation that violated the First Amendment").

Emerging scientific information can be truthfully conveyed with claim qualifications, a point which *Pearson I* recognized as having First Amendment significance. There, the FDA argued, much as FTC contends in POM (*see* FTC Decision at 43-44, 51), that flaws in the scientific record justify suppression. *See Pearson I*, 164 F.3d at 657-58. The *Pearson I* decision specifically involved health claims supported by less-than-conclusive science and science other than RCTs. *Pearson I*, 164 F.3d at 658. Nutrition science, like science in general, is evolutionary; rarely, if ever, are scientific conclusions accepted by scientists as conclusive, even when in the form of RCTs. *See generally* Shao & Mackay, *supra* note 3 (Exhibit 3); Blumberg, et al., *supra* note 3 (Exhibit 4); Heaney, et al., *supra* note 3 (Exhibit 5).

The FDA in *Pearson I* was concerned that certain claims were unsupported because, for example, studies focused on foods generally rather than the specific components of foods. *See id.* (noting FDA's concern that "existing research had examined only the relationship between consumption of *foods* containing these components and risk of disease"). In response, the Court proposed the following remedy: "The evidence is inconclusive because existing studies have been performed with *foods* containing antioxidant vitamins, and the effect of those foods on reducing the risk of cancer may result from other components in those foods." *Id.* at 658 (emphasis original). *Pearson I* forecloses FTC's attempt to eschew qualifying language in favor of a prospective ban. Here the FTC's rule is functionally equivalent to the FDA's "Significant Scientific Agreement" (SSA) standard at issue in the *Pearson I* and its progeny. Both condemn commercial speech based on an assessment of scientific evidence, excluding the totality of science in favor of a select subset deemed dispositive by the government. By categorically censoring all disease-related claims unsupported by RCTs, whether or not such claims include truthful qualifiers, the FTC bans future commercial speech the same way FDA in *Pearson* banned speech failing the SSA standard. The majority of POM's claims that FTC found misleading were qualified by language revealing inconclusiveness and by the statement that the product was "not intended to diagnose, treat, prevent, or cure any disease." To the extent that FTC

thought those disclaimers were inadequate, the FTC had the burden of proving that no qualification would suffice before moving to a categorical prospective ban on all disease-related claims.

FTC Commissioner Ohlhausen agreed that the Commission trod beyond First Amendment limits:

> To set an unnecessarily high bar for such a[safe food] product is in tension with the balanced approach to substantiation . . .in the Commission's own Pfizer factors and with [its] policy commitment to avoid imposing "unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions. . . . . As the court in *Pearson* noted, "[t]he government insists that … the commercial speech doctrine does not embody a preference for disclosure over outright suppression. Our understanding of the doctrine is otherwise."

See Opinion of the Commission, *In re POM Wonderful, et al.*, FTC Docket No. 9344, at 51 n.36 (Jan. 10, 2013) (hereinafter "FTC Decision") (summarizing Ohlhausen's dissenting remarks).

III. FTC ARBITRARILY AND CAPRICIOUSLY DEMANDED RCTS WHEN MANY DISEASE CLAIMS GENERALLY ACCEPTED IN THE SCIENTIFIC COMMUNITY ARE BACKED BY SCIENCE OTHER THAN RCTS

RCTs are difficult, if not impossible, to obtain for most nutrients. *See* Jeffrey Blumberg, *et al.*, *Evidence-based criteria in the nutritional context*, Nutrition Reviews 2010; 68(8):478-484, at 480 (Exhibit 4). FTC's new rule

reflects an evidentiary threshold commonly reserved for drug products or evidence-based medicine (EBM).[9] "Several leading authorities . . . have raised concerns over what is perceived to be the misapplication of drug-based trials to assess nutrition questions, 'without taking into account the totality of the evidence or the complexities and nuances of nutrition.'" Shao, *supra* note 3. The difficulties applying clinical intervention studies in the nutrition context have led clinical researchers to conclude that "[r]ecommendations, whether they be public health-based or practitioner-patient-based, should be developed from the totality of the available evidence, not . . . a single study or study design." Shao, *supra* note 3, at 12.

A "health claim" characterizes the risk-reductive effect of a nutrient on disease, *e.g.*, the product "*may* (but might not) reduce your risk of heart disease."[10] Consumers are necessarily informed that the product may not perform at all because the risk-reductive effect only lessens chance or probability. Unlike drugs,

[9] *See* Andrew Shao, PhD and Douglas Mackay, ND, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, Natural Medicine Journal 2010; 2(12):10-18 (Exhibit 3); Jeffrey Blumberg, et al., *Evidence-based criteria in the nutritional context*, Nutrition Reviews 2010; 68(8):478-484 (Exhibit 4); Robert P. Heaney, MD, Connie M. Weaver, PhD, and Jeffrey Blumberg, PhD, *EBN (Evidence-Based Nutrition) Ver. 2.0*, Nutrition Today 2011; 46(1):22-26 (Exhibit 5).

[10] *See* FDA Guidance: FDA Labeling Guide (Appendix C: Health Claims), *available at*, http://tinylink.net/38346. For example, FDA permits the following claim concerning low sodium diets and blood pressure: "Diets low in sodium *may reduce the risk* of high blood pressure, a disease associated with many factors." *Id.*

which offer immediate and acute remedies for existing conditions, nutritional products lower the *risk* of disease over a lifetime. If the health claim later proves false, the consumer is still not harmed physically or exposed to heightened risk. If the claim proves true, a significant population avoids certain life-threatening diseases. Pragmatically speaking, health claims based on credible science (of any kind) should reach consumers because the potential benefits far outweigh risks.

Drugs and nutrients also differ substantially, a fact not addressed by the FTC. Those differences limit the effectiveness of clinical trials in the nutrition context:

> Drugs tend generally to have single, targeted effects; drugs are not homeostatically controlled by the body and can easily be contrasted with a true "placebo" group; drugs can act within a relatively short therapeutic window . . ., often with large effect sizes. [N]utrients tend to work in complex systems in concert with other nutrients and affect multiple cells and organs; nutrients are homeostatically controlled, and thus the body's baseline nutrient "status" affects the response to a nutrient intervention; a nutrient intervention group cannot be contrasted with a true placebo group (i.e., "zero" exposure group); and with . . . chronic disease prevention, nutrient effect sizes tend to be small and may take decades to manifest. Finally the very absence (or inadequacy) of a given nutrient produces disease, which is a fundamental difference compared to drugs.

Shao, *supra* note 3, at 11.

Dr. Blumberg, head of the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University concurs:

> [C]ertain features of [Evidence-Based Medicine] seem ill-suited to the nutrition context. Some of the differences between the evaluation of drugs and nutrients cited previously are as follows: (i) medical interventions are designed to cure a disease *not* produced by their absence, while nutrients prevent dysfunction that would result from inadequate intake; (ii) it is usually not plausible to summon clinical equipoise for basic nutrient effects, thus creating ethical impediments to many trials; (iii) drug effects are generally intended to be large and with limited scope of action, while nutrient effects are typically polyvalent in scope and, in effect size, are typically within the "noise" range of biological variability; (iv) drug effects tend to be monotonic, with response varying in proportion to dose, while nutrient effects are often of a sigmoid character, with useful response occurring only across a portion of the intake ranges; (v) drug effects can be tested against a nonexposed (placebo) contrast group, whereas it is impossible and/or unethical to attempt a zero intake group for nutrients; and (vi) therapeutic drugs are intended to be efficacious within a relatively short term while the impact of nutrients on the reduction of risk of chronic disease may require decades to demonstrate—a difference with significant implications for the feasibility of conducting pertinent [randomized clinical trials].

Blumberg, *supra* note 3, at 480. For example, where low intake is the hypothesis for causation, clinical trials would present "nearly insuperable ethical barriers because the investigative team has to be prepared to put subjects in harm's way" by, for instance, lowering levels of essential nutrients when the hypothesis is that increased levels will prevent the very onset of disease. *See* Heaney, et al, *supra* note 3, at 23; Blumberg, *supra* note 3, at 480.

The FTC now requires RCTs that yield "statistically significant results, [which] shall be double-blinded unless Respondents can demonstrate that blinding cannot be effectively implemented given the nature of the intervention." *See* FTC Final Order, at 2 (emphasis added). FTC's own experts testified that a suitable study must involve 10,000 to 30,000 participants at a staggering cost of about $600 million. *See* FTC Initial Decision, *In re POM Wonderful LLC, et al.*, FTC Docket No. 9344 (May 17, 2012), at 96, ¶ 650 (hereinafter "ALJ Decision"). Food products are rarely patentable and, therefore, recouping $600 million from profits is all but impossible. FTC's requirement for at least two RCTs, at a potential cost of perhaps $1.2 billion (assuming FTC's experts were correct,) effectively rids the market of vital health information through an impractical and unnecessarily high standard and related cost.

That RCT requirement not only fails from a practical perspective, it also conflicts with standards of sister agencies and disregards the totality of scientific evidence upon which the scientific community outside the government depends in evaluating the relative validity of a nutrient-disease association, which might include mechanistic studies, observational and epidemiological studies, animal models, in vitro studies, textbooks and literature, basic biochemistry, and other potentially favorable data. *See* Heaney, et al, *supra* note 3, at 22, 24 (noting that the field of nutrition has "seemingly swallowed [evidence-based medicine] whole

without either asking how well it might fit, or adapting it to the unique features of ... nutrition"). Most RCT studies focus on *treatment* effects. Because clinical trials are rarely, if ever, designed to demonstrate nutrient disease-*risk reduction*, an RCT requirement forecloses claims that can be supported by the totality of the scientific record without need for RCTs.

The FDA, for example, has never expressly required clinical studies in support of health claims. *See* FDA Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims (Jan. 2009).[11] The FDA did not subject itself to a clinical trial requirement when promulgating dietary guidelines which are intended to influence consumer purchasing decisions based on health consequences. *See* USDA Press Release, *USDA and HHS Announce New Dietary Guidelines to Help Americans Make Healthier Food Choices and Confront Obesity Epidemic* (Jan. 31, 2011).[12] The FTC's RCT standard thus

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[11] *Available at*, http://tinylink.net/59936. FDA explains that it "evaluate[s] the strength of the totality of scientific evidence by consider study types, methodological quality, quantity of evidence for and against the claim (taking into account the numbers of various types of studies and study sample sizes), relevance to the U.S. population or target subgroup, replication of study results supporting the proposed claim, and overall consistency of the evidence." *Id.* at Part III.A.

[12] *Available at*, http://tinyurl.com/4kpafy5. The Department of Agriculture's Dietary Guidelines have never been supported by multiple clinical trials. *See* Roger Clemens, *Dietary Guidelines May Produce Unintended Health Consequences*, Food, Medicine & Health (Exhibit 6); Joanne Slavin, *Dissecting the Dietary Guidelines*, Food Technology (2011) (Exhibit 7). The Guidelines are "based on evidence that consuming … foods within the context of an overall

conflicts with those of its sister agencies, a risk that did not escape Commissioner Ohlhausen in dissent.[13]

IV. FTC VIOLATES THE APA BECAUSE IT HAS ADOPTED A STANDARD OF GENERAL APPLICABILITY WITHOUT NOTICE AND COMMENT RULEMAKING AS REQUIRED BY THE FTCA AND THE APA

The APA defines a "rule" as "the whole or part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency." 5 U.S.C. § 551(4).

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healthy eating pattern is associated with a health benefit…" *See* Dietary Guidelines for Americans, 2010 (Jan. 31, 2011), at Ch. 4, *available at*, http://tinyurl.com/6k55bl6. Again, "making strict recommendations for optimal dietary practices is difficult to support with evidence-based nutrition science." Slavin, *supra*, at 40, 46 ("the scientific support for these recommendations is more historical than evidence-based"). "Intervention studies, where diets following the Dietary Guidelines are fed long-term to human volunteers, do not exist." *Id.* at 46 (noting that, "[g]enerally, adherence to the Dietary Guidelines is measured in epidemiological studies by determining a healthy eating index (HEI), a measurement of adherence to the diet recommendations of the Dietary Guidelines").

[13] Commissioner Ohlhausen was "concerned that the majority's interpretation of certain exhibits blurs … boundaries and creates an inconsistency between FTC advertising requirements and FDA food labeling and advertising requirements." *See* Ohlhausen Concurring Opinion, at MKO-3-4. Those risks are equally present when FTC adopts differing standards for health claims regulated principally by the FDA.

While the FTC is empowered to fashion and adjust substantive rules through case-by-case adjudication (*Securities & Exch. Comm'n v. Chenery Corp.*, 332 U.S. 194, 203 (1947)), the agency cannot avoid the heightened procedural safeguards of the APA's and Magnuson-Moss Act's rulemaking processes by relying on adjudicatory proceedings to promulgate industry-wide rules. *See NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1969). The distinction between an "adjudication" and "rulemaking" is often blurry, but this Court has explained that "agencies employ rulemaking procedures to resolve broad policy questions affecting many parties and turning on the issues of 'legislative fact.' Adjudicatory hearing procedures are used in individual cases where the outcome is dependent on the resolution of particular 'adjudicative facts.'" *Independent Bankers Ass'n of Georgia v. Board of Directors of Federal Reserve System*, 516 F.2d 1206, 1215 (D.C. Cir. 1975). Adjudicative facts concern the parties specifically or, facts that would "go to a jury." *Id.* at 1215 n.26. Legislative facts, by contrast, "are general facts which help the tribunal decide questions of law and policy and discretion." *Id.* There is thus a "recognized distinction … between proceedings for the purpose of promulgating policy-type rules or standards ... and proceedings designed to adjudicate disputed facts in particular cases. . ." *Id.* at 1215 n.25 (citing *U.S. v. Florida East Coast Ry. Co.*, 410 U.S. 224, 245 (1973)). Here the facts adjudicated and applied by the FTC were used to fashion a sweeping order, resolving broad

issues of law and policy concerning disease-prevention claims generally. The FTC therefore proceeded into territory properly left to rulemaking – where questions of science can be fully considered. Moreover, the result was in fact an industry-wide "rule" as defined by the APA.

"If a rule merely restates duties or reminds parties of those already contained in existing regulations, rather than spelling out new obligations, it may be considered interpretive and not subject to the requirements of APA § 553," but a legislative rule "does more than simply clarify or explain a regulatory term, or confirm a regulatory requirement, or maintain a consistent policy; it grants rights, imposes obligations, or produces other significant effects on private interests" and is subject to the APA's notice-and-comment procedures. *See Appalachian Power Co. v. E.P.A.,* 208 F.3d 1015, 1021 n.11 (D.C. Cir. 2000); *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 95 (D.C. Cir. 1997) (holding that an agency adopts a legislative rule when it creates a new "legal norm based on the agency's own authority"); *see also Stuttering Found. of America v. Springer*, 498 F.Supp. 2d 203, 211 (D.C. Cir. 2007) (explaining that the Court "does not defer to the agency's view that its regulations are a mere clarification of an existing rule pursuant to the APA; instead, the court conducts its own inquiry into whether the new rules work substantive changes in prior regulations"). The FTC's RCT rule is not interpretive or a general statement of policy because it substantially departs from the FTC's

previous substantiation standard and imposes new and costly obligations on advertisers, to wit, an obligation to conduct lengthy and costly RCTs as a condition precedent to communicating any disease related claims. *See U.S. Telecom Ass'n v. F.C.C.*, 400 F.3d 29, 35 (D.C. Cir. 2005) (explaining that "the Supreme Court has said that if an agency adopts 'a new position inconsistent with' an existing regulation, or effects 'a substantive change in the regulation,' notice and comment are required"); *Paralyzed Veterans of America v. D.C. Arena L.P.*, 117 F.3d 579, 586 (D.C. Cir. 1979) (allowing "an agency to make a fundamental change in its interpretation of a substantive regulation without notice and comment obviously would undermine" the APA rulemaking requirements). Although the FTC determined in past cases that, for certain limited claims, RCTs were required,[14] never before POM has FTC ruled that all prospective disease-related claims must be supported by RCTs. *See* FTC Decision at 36-37.

15 U.S.C. § 57a requires that FTC proceed through Magnuson-Moss rulemaking when promulgating rules defining practices which are unfair or deceptive. *See* 15 U.S.C. § 57a (requiring heightened procedural safeguards in

[14] *See e.g. F.T.C. v. Nat'l Urological Grp., Inc.*, 645 F. Supp. 2d 1167, 1202-03 (N.D. Ga. 2008), *aff'd*, 356 F. App'x 358 (11th Cir. 2009) (ordering permanent injunction after finding RTCs to be required for weight loss claims); *F.T.C. v. Sabal*, 32 F. Supp. 2d 1004, 1009-10 (N.D. Ill. 1998) (granting preliminary injunction after determining RCTs were required for claims concerning certain topical hair loss products).

FTC rulemaking proceedings); *see also* 5 U.S.C. § 553 (requiring federal agencies, with limited exceptions, to follow notice-and-comment rulemaking procedures when promulgating a new rule, regulation, or interpretation of a regulation). The FTC's RCT requirement is a rule defining what constitutes deceptive disease related advertising prospectively. Through POM, public statements, and other consent orders, the FTC spoke to industry in multiple regulatory and settings, and informed regulatees that the absence of RCTs for disease-related claims (even qualified health claims) renders a claim unsubstantiated and thus in violation of the FTCA. Because FTC binds the industry (*see supra* at 5-9), the APA required FTC to follow formal rulemaking before adopting the RCT requirement.

FTC therefore acted beyond legal authority when it promulgated a legislative rule without notice-and-comment rulemaking. *See Preminger v. Sec. of Veterans Affairs*, 632 F.3d 1345, 1350-51 (Fed. Cir. 2011) ("[a]n agency's failure to comply with notice-and-comment rulemaking procedures, when required, is grounds for invalidating a rule"); *Heartland Regl. Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009) ("[f]ailure to provide the required notice and to invite public comment . . . is a fundamental flaw that 'normally' requires vacatur of the rule"); *see also MCI v. Telecomms. Corp. v. AT&T*, 512 U.S. 218, 231 n.4 (1994) (agencies are "bound, not only by the ultimate purposes Congress has selected, but by the means it has deemed appropriate, and prescribed, for the pursuit of those

purposes"); *Tex. v. U.S.*, 497 F.3d 491, 501 (5th Cir. 2007) ("Regardless of how serious the problem and administrative agency seeks to address . . . it may not exercise its authority 'in a manner that is inconsistent with the administrative structure that Congress enacted into law.'") (quoting *FDA v. Brown Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000)).

That rulemaking process was essential, because experts, such as those quoted above, disagree with the FTC as to the quantity and quality of scientific information required to support health claims. Moreover, through the rulemaking process the FTC could have vetted the important constitutional issues with the aid of public participation. Although FTC received expert testimony from witnesses concerning the level of substantiation needed (experts who were compensated by FTC for their opinions), the FTC did not invite public participation from academics, scientists, and industry members. That input would have revealed the impracticality or unreasonableness of the blanket RCT requirement for nutritional products. After all, POM, having devoted more than $30 million researching the health benefits of food products traditionally known to provide substantial health benefits, ultimately failed the FTC's new requirement. How many food companies, if not POM, can afford to play by FTC's new rules?[15]

[15] Unlike drugs, medical devices, and other health products, foods and dietary supplements are rarely patentable. Companies like POM who devote

FTC experts testified that a suitable clinical study capable of supporting disease prevention claims about *un-patentable foods* would be expected to cost "in the range of $600 million." ALJ Decision at 96, ¶ 650 ("Dr. Eastham testified that studies of disease prevention should involve 10,000 to 30,000 men and that such studies are 'incredibly expensive' and in the range of $600 million").[16] If the FTC's experts are correct, then likely few, if any, food producer will ever be able to meet the FTC's substantiation standards. The FTC should have provided an economic impact assessment of the costs, and their practical consequences, for review by Congress, the Comptroller General, and the OMB. *See* 5 U.S.C.A. § 801; *see also* Exec. Order No. 12866, 50 FR 51735, Sec. 6(a)(3) (C)(ii) (Sept. 30, 1993) (requiring assessment of "the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation"). Those procedural safeguards are necessary to evaluate the prudence of a new administrative policy. *See* Exec. Order No. 12866, Sec. 1(a)(6) (Sept. 30, 1993) ("Each agency shall assess both the costs and the benefits of the intended

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substantial resources researching common food ingredients may be acting altruistically, as competitors benefit equally from the very RCTs now required under the FTC's new standard. FTC's rule has the perverse incentive of limiting scientific information from the market, while also diminishing any incentive to spend money on additional research. A public rulemaking may have helped FTC tailor its authority within constitutional limits and the practical reach of scientists.

[16] POM, in fact, had performed RCTs but with smaller sample sizes than the FTC deemed acceptable.

regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs"). The FTC must justify the imposition of such a heavy financial burden, even assuming that some form of an RCT standard might be adopted consistent with the First Amendment.

In POM's case, invalidation of the "rule" would compel the FTC to abandon its RCT requirement and to consider instead less speech-restrictive alternatives revealed in notice and comment rulemaking under 15 U.S.C. § 57a.

V. CONCLUSION

For the foregoing reasons, the Commission's decision imposing liability on POM advertising should be reversed and the FTC's Order vacated.

Respectfully submitted,

ALLIANCE FOR NATURAL HEALTH-USA
AND TECHFREEDOM

By: _____

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Dated: August 20, 2013

CERTIFICATE OF SERVICE

I hereby certify that on this 20th day of August, 2013, I electronically filed the foregoing "**BRIEF OF AMICI CURIAE ALLIANCE FOR NATURAL HEALTH-USA AND TECHFREEDOM SUPPORTING PETITIONERS' OPENING BRIEF**" with the Clerk of the Court using the CM/ECF system, thereby causing it to be served upon all counsel of record.

By: */s/ Jonathan W. Emord*

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