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No. 13-1060

United States Court of Appeals for the District of Columbia Circuit

POM WONDERFUL, LLC, ET AL

Petitioner

v.

FEDERAL TRADE COMMISSION

Respondent

ON APPEAL FROM THE FEDERAL TRADE COMMISSION
CASE NO. 9344

FINAL BRIEF FOR PETITIONERS POM WONDERFUL, LLC, ROLL GLOBAL, STEWART A. RESNICK, AND LYNDA RAE RESNICK

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and Amici.

Petitioners in this action are POM Wonderful, LLC, Roll Global, LLC, Stewart A. Resnick, Lynda Rae Resnick, and Matthew Tupper. Mr. Tupper is represented by separate counsel, and has filed a separate brief. Respondent is the United States Federal Trade Commission.

Amici filing on behalf of Petitioners in this matter include the Consumer Healthcare Products Association, the Council for Responsible Nutrition, the Alliance for Natural Health-USA, and Tech Freedom.

B. Rulings Under Review.

The Rulings under review in this matter are the FTC's Final Order and Opinion *In the Matter of POM Wonderful, LLC, et al.*, FTC Docket No. 9344, which are reported at 2013-1 Trade Cases P 78220, 2013 WL 268926 (Jan. 16, 2013), and contained in the Joint Appendix at JA578.

C. Related Cases.

Petitioners certify that this case has not previously been before this Court and that there are no related cases pursuant to Circuit Rule 28.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure and Circuit Rule 26.1, Petitioners make the following disclosures:

Petitioners POM Wonderful, LLC, and Roll Global, LLC, are both limited liability companies organized under Delaware law that are wholly owned by the Stewart and Lynda Resnick Revocable Trust. Stewart and Lynda Resnick are the sole trustees and beneficiaries of the Resnick Trust, and are the sole owners of POM Wonderful and Roll Global.

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GLOSSARY

ALJ: Administrative Law Judge

FDA: Food and Drug Administration

FTC: Federal Trade Commission

NIH: National Institutes of Health

POM: Pom Wonderful, LLC

RCT: Randomized and Controlled Human Clinical Trial

Roll: Roll Global, LLC

The Commission: The Federal Trade Commission

STATEMENT OF JURISDICTION

Petitioners challenge a Final Order entered by the Federal Trade Commission on January 10, 2013. JA578 (FTC Order 6). That Order directs Petitioners to cease and desist from engaging in alleged violations of the FTC Act. *Id.* at JA579-82. This Court has jurisdiction to review such orders under 15 U.S.C. § 45(c).

On June 21, 2013, this Court granted Petitioners' motion for an extension of time, and issued a revised briefing schedule making Petitioners' opening brief due on August 14, 2013. *POM Wonderful LLC, et al v. FTC*, No. 13-1060 (D.C. Cir. June 21, 2013).

ISSUES PRESENTED FOR REVIEW

1. Whether the Federal Trade Commission's Order violates the First Amendment to the United States Constitution by prohibiting constitutionally protected speech that is at most potentially, rather than actually, misleading without demonstrating that the prohibition directly advances a substantial government interest?

2. Whether the Commission's Order is impermissibly overbroad?

STATEMENT OF THE CASE

Petitioners incorporate and join in the Statement of the Case set forth in the brief of Petitioner Tupper, which summarizes the factual and procedural history of this matter, including the evidence presented at trial, as well as the decisions of the ALJ and the FTC.

SUMMARY OF THE ARGUMENT

The Commission's Order violates the First Amendment. The Order bans constitutionally protected statements about healthy foods. Part I, *infra*. Because that prohibition seeks to prevent *potentially* misleading speech rather than *actually* misleading speech, it is subject to constitutional scrutiny. Part II, *infra*. The Commission did not assert that its Order could survive First Amendment scrutiny, and it cannot for two reasons: (i) it does not directly advance the government's

asserted interest in preventing consumer confusion (Part III.A, *infra*); and (ii) it is broader than necessary to achieve that interest (Part III.B, *infra*).

I. The Commission's Order bans constitutionally protected speech. POM's advertisements advance accurate, truthful, and carefully qualified claims about the health benefits of consuming pomegranate juice. Those claims are based on the best science that is reasonably available. Although there are claims in POM's ads that are not based on statistically significant, randomized, and placebo-controlled human clinical trials ("RCTs"), the fact is that there will never be statistically significant RCTs to substantiate most of the health benefits of foods and nutrients because of overwhelming scientific, economic, and ethical barriers to conducting such studies on food products.

POM's ads are an important part of a larger ongoing public discussion about the health benefits of antioxidants. As such, they directly implicate the principle that a "consumer's concern for . . . commercial speech often may be far keener than his concern for urgent political dialogue." *Bates v. State Bar of Ariz.*, 433 U.S. 350, 364 (1977).

The Commission's Order, however, withdraws from consumers a significant source of truthful information: speech that is supported by competent and reliable scientific evidence other than statistically significant RCTs. The public will not be better informed if advertisers are unable to communicate accurately the results of

animal or *in vitro* testing, or the results of human clinical trials that fall percentage points short of the government's definition of statistical significance. The Commission's rush to ban speech that has been commonplace in food, beverage, and dietary supplement advertising for years can have only one effect: to prohibit a significant number of ubiquitous, truthful statements about a range of healthy products that each of us sees every day.

II. The Commission rested its prohibition on the theory that POM's ads are "not protected by the First Amendment" because they are actually misleading. JA625 (FTC Op. 41). That claim is meritless.

A. The Order is subject to First Amendment scrutiny because it bans speech that is at worst potentially, rather than actually, misleading. The fact that a subject is complicated and has the potential to confuse consumers does not give the government license to deem speech "inherently misleading" and ban it on that basis. *See Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999). The Commission may regulate such speech, but any such regulation must satisfy First Amendment scrutiny.

The Commission read many of POM's ads to imply that consuming POM's products will treat, prevent, or reduce the risk of a disease. For First Amendment purposes, that type of implied claim is at most "potentially" misleading. Even if some consumers inferred that POM products are causally linked to specific health

benefits, the Commission did not doubt that many others will not infer that claim and thus will not be misled. Also, the Commission did not find that the POM products fail to produce the positive health effects that the Commission inferred were claimed by the advertisements. Instead, it concluded that because POM did not substantiate its claims with RCTs, it lacked sufficient proof to justify its claims.

POM's advertisements cannot be labeled "actually misleading" on the theory that RCTs have not yet proven with scientific certainty that POM's products are causally linked to health benefits. The advertisements make no claims about RCTs, and every mention of science in the ads is heavily qualified with words like "preliminary" or "initial." The scientific community distinguishes those kinds of qualified claims (which do not require RCTs to be properly substantiated) from absolute or unqualified claims, such as those advanced on behalf of potentially toxic prescription drugs that are proposed as new treatments for serious diseases (which do). In any event, the Commission did not find, or even assert, that *consumers* would be misled into reading POM's qualified advertisements to imply that POM's claims were backed by statistically significant RCTs.

Of note, the Commission did not produce the proof it has regularly used in past cases to establish that consumers interpret advertisements as the Commission alleges: extrinsic evidence documenting the effects of advertising, such as consumer surveys. Traditionally, that evidence has ensured that the Commission's

regulatory impulses are based upon the actual effect of advertising on consumers, rather than an aggressive policy agenda. Here, however, the Commission asserted that the burden was on POM to produce evidence that would disprove the Commission's assertion that the advertising would mislead consumers. That the Commission has absolved itself in prior cases from producing such evidence cannot rescue the Order: the First Amendment does not permit the government to presume that protected speech is misleading and require the speaker to produce the evidence invalidating that assumption.

III. Assuming that POM's advertising was potentially misleading, under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 566 (1980), the Order can be upheld only if (1) the prohibition seeks to further a substantial interest, and its rule both (2) directly advances that interest and (3) is not broader than necessary to achieve that interest. This Court need not remand the case because the Commission did not even attempt to argue that its Order could withstand First Amendment scrutiny, if it applied. *See* JA627 (FTC Op. 43-45).

A. The Commission's Order does not directly advance a legitimate governmental interest. Importantly, the FTC's asserted interest in this case was to prevent consumer confusion, *not* to protect public health. The Commission asserted (albeit with no evidentiary support) that POM's advertisements could

mislead some consumers to "pay a higher price for POM products," because they are "buying what is considered to be a premium fruit juice." *Id.* at JA621-22 & n.30.

The Court can assume that preventing confusion in the marketplace is an important governmental interest. But the Commission failed to produce "substantial evidence" that its regulation "directly advances" its asserted interest. *See R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1222 (D.C. Cir. 2012). It is the government's burden to justify "its attempt to restrict commercial speech, and its burden is not light." *Id.* at 1218. Consumers will not be better informed if the Commission suppresses advertising that accurately reports the results of *in vitro* or animal studies, or if they are permitted to learn about a clinical trial involving human subjects only if that study satisfies the government's definition of statistical significance.

Further, the aim of the Order is to deprive consumers of information. The Commission "agree[d] that many of the facts in [Petitioners'] ads are verifiable," but it nonetheless held that the advertisements receive no First Amendment protection because POM allegedly failed to include additional details, such as the fact that other studies called into question the studies POM highlighted. *See* JA627 (FTC Op. 43). But the First Amendment does not allow the government to command a speaker to include all details and all sides of a debate on a matter of

public concern simply to avoid the possibility of creating misleading "implications." The Order pursues the forbidden objective of "prohibit[ing] certain kinds of speech on the premise that consumers need government to protect them from accurate information." *Spirit Airlines, Inc. v. U.S. Dept. of Transp.*, 687 F.3d 403, 415 (D.C. Cir. 2012), *cert. denied*, 133 S.Ct. 1723 (2013). The Supreme Court has repeatedly rejected that sort of paternalism. *See, e.g.*, *Bates*, 433 U.S. at 375 ("[W]e view as dubious any justification that is based on the benefits of public ignorance."). So, too, has this Court. *See Pearson*, 164 F.3d at 655.

If anything, the Order augments consumer confusion by creating different standards of proof that turn entirely on the identity of the speaker. It prohibits advertisers from making claims to promote their products based on competent and reliable scientific evidence other than RCTs. By contrast, regulatory agencies remain free to rely on such evidence as the basis for promoting, regulating, or even prohibiting products in the marketplace. For similar reasons, the Commission's rule also amounts to prohibited viewpoint discrimination: it bans speech only when the speaker asserts that its food products improve health; contrary claims of opponents and the government calling into question the benefits of POM products are freely permitted even if they are based on the same scientific basis.

B. The Commission's newfound RCT requirement also fails the third *Central Hudson* requirement because it is broader than necessary to achieve the

government's interest. Courts have consistently rejected the claim that the law requires RCTs. To determine whether advertising is misleading, the Commission has long applied its "competent and reliable scientific evidence standard," *In re Novartis Corp.*, 127 F.T.C. 580, 725 (1999), which it has interpreted through its traditional "*Pfizer* factors." *In re Pfizer*, 81 F.T.C. 23 (1972). Among other things, that standard accounts for the type of product being advertised, as well as the nature of the advertiser's claim.[1] For certain kinds of claims – such as an unqualified claim that a drug has been proven to be an effective treatment of heart disease or prostate cancer – an RCT might be required. Here, however, the Commission as a practical matter deemed irrelevant critical *Pfizer* factors – such as the type of product at issue, and the complete infeasibility of an RCT standard.

At no point has the Commission explained why it could not achieve its interest in preventing consumer confusion by faithfully adhering to its competent and reliable scientific evidence standard. Nor could it, for even if the Commission's Order stands, that same standard will continue to govern the

[1] Under *Pfizer*, the appropriate level of substantiation for health claims advanced on behalf of a product depends on a multi-factor analysis. *Pfizer*, 81 F.T.C. at 30. Specifically, the Commission and courts have traditionally examined (1) the type of claim advanced, including whether such claim is absolute or qualified; (2) the type of product being advertised, including whether the product is safe or has potential health risks; (3) the benefit of a truthful claim to consumers; (4) the ease of developing substantiation for the claim in question; (5) the consequences of a false claim; and (6) the amount of substantiation that experts in the relevant field would consider reasonable. *Id*.

substantiation of similar claims by the FDA, or those that happen to be advanced outside of the advertising context. At a minimum, the FTC had narrower remedies available, such as requiring claim qualification under *Pearson*, to protect consumers short of prohibiting categories of speech outright. The First Amendment compels the Commission at least to consider, if not to adopt, such remedies.

IV. If this Court were nonetheless to affirm the Commission's finding of liability, it should vacate the Commission's remedy requiring that all health claims in POM's advertising be supported by two RCTs. Such a broad "fencing in" remedy is inappropriate where far less intrusive remedies were available to prevent consumer deception, and where the Commission applied its newfound liability standard – the RCT requirement – for the first time in this case.

V. Petitioners also incorporate and join in the arguments of Petitioner Tupper that the Order violates the First Amendment and Administrative Procedure Act.

The Court accordingly should vacate the Commission's Order in its entirety.

STANDING

Petitioners have standing to appeal from the FTC's Cease and Desist Order because each has suffered concrete injuries in the form of significant obligations and liabilities imposed under the terms of the Order, which violate the First

Amendment to the Constitution of the United States and the Administrative Procedure Act. The relief requested herein would plainly and directly redress the identified injuries.

ARGUMENT

I. POM's Advertising Is Accurate Speech That Is Protected By The First Amendment

A. Petitioners' Advertisements Are Truthful And Accurate.

The POM products at issue are 100% pomegranate juice and (in the case of POMx pills) 100% pomegranate extract. These products are completely safe. JA93-94 (ALJ Op. ¶¶77-94).[2] Humans have safely consumed pomegranates for centuries, and certain societies have long believed that the fruit possesses health-promoting or healing qualities. They are also indisputably rich in antioxidants. For the last several decades, scientists have studied the health effects of consuming pomegranate and pomegranate derivatives. To date, more than seventy such studies have been published in peer-reviewed journals. *Id.* at JA99 (¶130). Petitioners have funded significant scientific research into the health effects of pomegranates and antioxidants. *Id.* at JA97-99 (¶¶124-32). The Commission itself acknowledged these studies, and did not dispute their central findings that

[2] Citations to the ALJ's Opinion with paragraph references identify the ALJ's specific fact findings. Citations without paragraph references refer to the "Analysis" section of the ALJ's Opinion.

pomegranate juice generally helps promote better heart, prostate, and erectile health. *See* JA603 (FTC Op. 19).

Petitioners have sought truthfully to inform consumers about this research, including at the point most likely to reach them: in POM product advertisements. JA98 (ALJ Op. ¶113). Petitioners' advertisements accurately state simple facts: pomegranate juice is high in antioxidants, antioxidants combat free radicals, and free radicals increase the risk of certain diseases. *See, e.g.*, JA666 (Fig. 5) (stating that POM has "more naturally occurring antioxidants than any other drink," that "antioxidants fight hard against free radicals," and that free radicals "can cause heart disease, premature aging, Alzheimer's, even cancer"). Other advertisements accurately report the results of scientific studies, such as one that notes that an "initial" study has shown "hopeful results for prostate health" in pomegranate juice's prolongation of "PSA doubling times." *See, e.g.*, JA727 (Fig. 24).

Many of these statements are heavily qualified. For example, an advertisement for POMx pills called "The Only Antioxidant Supplement Rated X," states that: (1) "[e]merging science suggests that antioxidants are critically important to maintaining good health because they protect you from free radicals, which can damage your body"; (2) taking POMx pomegranate extract "will help protect you from free radicals and keep you at your healthy best" because of the antioxidants it contains; (3) a "preliminary study on erectile function" showed that

"men who consumed POM Juice reported a 50% greater likelihood of improved erections as compared to placebo"; (4) an "initial" study showed "hopeful results for prostate health" due to "statistically significant prolongation of PSA doubling times"; and (5) a "preliminary study" showed "promising results for heart health." JA763 (Fig. 33).

POM's advertisements reflect accurate statements about existing science, which is limited by real-world scientific limitations. The vastly more rigorous studies that the Commission deemed to be required – statistically significant RCTs – are almost unheard of in the context of food products. JA182 (ALJ Op. ¶701). Indeed, the Commission understood that its RCT requirement would as a practical matter be the death knell for the ability to make many statements about the effects of healthy foods. *See* JA621 (FTC Op. 37). That is because, as the ALJ found, RCTs will rarely be available to test the health benefits of food products due to design limitations, ethical limitations, and economic infeasibility.

Concerning design, it is often impossible to construct an RCT for a fruit or other whole food that is appropriately "controlled" because it is difficult, if not impossible, to "blind" a fruit. *See* JA182 (ALJ Op. ¶703) (noting that it is "difficult to do double-blind, randomized, placebo-controlled trials [for a fruit or food] because the subjects know what they are consuming"). Unlike an experimental drug, fruits and fruit juices are widely available for human

consumption, so participants in control groups can easily thwart the study's control by consuming the "controlled" fruit or juice. *Id.* at JA179 (¶¶678-79) (citing Dr. Ornish). Moreover, designing such a test to isolate the antioxidants in POM Products could prove impossible because of the need to "control for other naturally occurring, dietary antioxidants, anti-inflammatory, and anticancer agents as well as lifestyle activities . . . , genetic predisposition, racial and ethnic factors . . . and other factors that might have an effect on" the disease in question. *Id.* at JA177 (¶664) (citing Dr. Miller). The Commission's experts supported these conclusions. *See id.* at JA173 (¶634) (citing FTC Expert Dr. Stampfer for the proposition that RCT study designs are simply not "available" for nutrients or food groups); *id.* at JA174 (¶641) (citing FTC Expert Dr. Sacks for the proposition that for foods, "the blinding of patients is not possible"). So did Petitioners' experts. *Id.* at JA177 (¶664) (citing Dr. Miller); *id.* at JA178 (¶673) (citing Dr. Heber); *id.* at JA179 (¶679) (citing Dr. Ornish); *id.* at JA180 (¶686) (citing Dr. Goldstein).

Further complicating the design limitations described above, there are ethical barriers to creating the conditions necessary to conduct an appropriate RCT of a nutrient found in foods. If individuals are suffering from a serious health condition, it often will be inappropriate to direct them *not* to take pharmaceutical drugs and only to consume the food being tested. As explained by the Commission's expert, Dr. Stampfer, it is "usually not plausible to summon clinical

equipoise for basic nutrient effects, thus creating ethical impediments to many trials." JA173 (ALJ Op. ¶636). It is also impossible to create a "zero intake group for nutrients" in an ethical manner – doctors cannot, for example, ethically deprive a control group of patients of all Vitamin C for a decade to determine whether Vitamin C helps prevent cancer. *Id.*; *see also id.* at JA174 (¶642) (citing Dr. Sacks for the proposition that "ethical considerations" preclude testing the effect of sodium reduction on humans in the form of RCTs).

The science underlying POM's advertisements also reflects the economic infeasibility of requiring the vastly more extensive RCT process for food products. Due to the limitations described above regarding control factors, an RCT on a product like POM's that would satisfy the standards set forth by the Commission "would take decades and thousands of patients." *Id.* at JA177 (¶664) (citing Dr. Miller). One of the Commission's experts testified that any such trial should involve at least 10,000 subjects, and would be "incredibly expensive" – somewhere in the range of $600 million. *Id.* at JA175 (¶650) (citing Dr. Eastham). Another admitted that clinical recommendations that have not been substantiated by RCTs are "common" because of the costs associated with them. *Id.* (¶647). Critically, unlike drug manufacturers, who hold patents on their products that allow them to exclude competitor products and can therefore make substantial capital investments, foods are subject to far less potent protections, which make the

investment of hundreds of millions of dollars in scientific studies economically unviable. *Id.* at JA182 (¶705) ("No manufacturer would spend billions of dollars to test a fruit. . . ."); *id.* (¶704) (in the "nutritional context, RCTs are extremely expensive and often not feasible because of the costs of conducting them"); *see also id.* at JA327 (summarizing barriers to conducting food RCTs). That is why the Commission's own expert concluded that, in the nutritional context, "a hypothesis about disease causation can, rarely, if ever, be directly tested in humans using the RCT design." *Id.* at JA172 (¶632) (citing testimony of Dr. Stampfer).

The Commission's only substantive answer to the recognized limitations on scientific studies for healthy foods like pomegranates was to state that the difficulties with conducting successful RCTs are inherent in the nature of proving the scientific basis of a causal claim. According to the Commission, a food producer or product manufacturer should simply avoid making any causal claims. JA609 (FTC Op. 25). The Commission's position is cold comfort when, as this case perfectly illustrates, the Commission reads more modest claims to assert by implication that statements are based on RCTs. *See* JA770-71 (Concurring Statement of Commissioner Ohlhausen, at 3-4) (arguing that the Commission's implied claims analysis means that "the mere mention of 'health' or healthy functioning can imply a disease-related efficacy . . . and that the mere mention of scientific evidence can imply a related establishment claim"). But in any event, the

Commission's position is precisely the First Amendment flaw in the Order: it prohibits speakers like POM from engaging in speech disfavored by the government unless they can satisfy an unduly rigorous government-imposed standard of proof.[3]

B. The First Amendment Protects Petitioners' Speech.

Advertising is commercial speech protected by the First Amendment. *See Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). The free flow of information empowers consumers to make better decisions about goods and services, and improves not just the efficiency of the market, but also public knowledge, safety, and health. Thus, the government may regulate commercial speech only as a "last resort," after proving that its regulation is necessary and not broader than necessary to cure the alleged deception. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002).

The First Amendment's protection of commercial speech is at its apex with respect to the subject of POM's advertisements: the health benefits of antioxidants. The value of commercial speech "has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011). The subjects addressed by POM's

[3] The Commission's bald assertion that studies can be designed in smaller settings to contain costs, *id.*, cited no record evidence and directly contradicted the testimony of the FTC's own experts. *See* JA175 (ALJ Op. ¶¶647, 650) (summarizing testimony of FTC experts).

advertisements have given rise to widespread public interest and debate. In what ways do antioxidants promote good health, and in what ways can they assist in the prevention or treatment of certain diseases? Which antioxidant supplements are beneficial for human consumption, and are certain antioxidant-rich foods and diets better or worse than others? These questions have been the topics of dozens of scientific studies, to the tune of tens of millions of dollars; they have been debated extensively in scientific, medical, and trade publications; and they have been featured on television, radio, and in newspapers.[4] They have also prompted a variety of legislative and regulatory actions.[5] POM's advertisements thus directly implicate the principle that a "consumer's concern for . . . commercial speech often

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[4] *See* The Organic Center, *Elevating Antioxidant Intakes* (Aug. 2010) (JA978), *available at* https://www.organic-center.org/reportfiles/AntioxFinal.pdf; Academy of Nutrition and Dietetics, *What Are Antioxidants?* (JA1304), *available at* http://www.eatright.org/public/content.aspx?id=6792 (last visited Aug. 9, 2013); Stanford Medicine Cancer Institute, *Nutrition to Reduce Cancer Risk* (JA1308), *available at* http://cancer.stanford.edu/information/nutritionAndCancer/reduce Risk/ (last visited Aug. 9, 2013); Joanna Slavin, *Dissecting the Dietary Guidelines*, 65 Food Tech. 40 (Mar. 2011); Robert Heaney et al., *EBN (Evidence Based Nutrition) Ver. 2.0*, 46 Nutrition Today 22-26 (Jan./Feb. 2011); Andrew Shao & Douglas Mackay, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, 2 Natural Med. J. 12 (Dec. 1, 2010); J. Blumberg et al., *Evidence-Based Criteria in the Nutritional Context*, 68 Nutrition Reviews 478 (Aug. 2010); Robert P. Heaney, *Nutrition, Chronic Disease, and the Problem of Proof*, 84 Am. J. Clin. Nutrition 471 (2006).

[5] *See, e.g.*, Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994); "Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk," 21 C.F.R. § 119.1 (2004).

may be far keener than his concern for urgent political dialogue." *Bates*, 433 U.S. at 364.

The public will be better served if the government encourages, rather than thwarts, the dissemination of information regarding the health benefits of food that is substantiated by non-RCT science. *See* JA171 (ALJ Op. ¶¶620-21); JA1245 (Tr. 1608-09 (Sacks)); JA1255 (Tr. 1978-79 (Heber)); JA1272 (Tr. 2270-71 (Burnett)); JA1277 (Tr. 2327-28 (Ornish)); JA1284 (Tr. 2599 (Goldstein)). As the Commission's own expert testified, "it may be appropriate to use evidence short of an RCT for crafting public health recommendations regarding nutrient guidelines even when causality cannot be established, because everyone eats and the public should be given advice based on the best evidence available." JA326 (ALJ Op. 247) (quoting Dr. Stampfer). Insisting on silence "in the absence of conclusive RCT evidence, increases the risk of forgoing benefits to the public that might have been achieved with little risk and little cost." *Id.*; *see also FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008) (noting that requiring expensive RCTs could require "vendors to bear such heavy costs [and] may keep useful products off the market (this has been a problem for drugs that are subject to the FDA's testing protocols) and prevent vendors from making truthful statements that will help consumers locate products that will do them good").

The Commission's RCT requirement thus prohibits a wide swath of constitutionally protected speech. Specifically, the fact that a causal link has not been proven to an exacting level of certainty does not mean that nothing may be said about the weight of the existing evidence. For example, a promising animal or *in vitro* study may offer hope that a food could contribute to a reduction of risk of a disease. At no point did *any* of the Commission's experts testify that the results of such tests should not be accurately communicated to consumers – indeed, they admitted the contrary. *See* JA326 (ALJ Op. 247).

The Commission also ignored the substantial evidence that tests short of statistically significant RCTs can still substantiate true and beneficial claims about a product's potential to prevent or treat serious diseases. *See id.* at JA171 (¶¶619-20) (finding that statistical significance "is an arbitrary convention in the context of studying a whole food" and that results short of 95% probability "can still evidence a clinically meaningful benefit that is scientifically supportable"); *see also* JA1245 (Tr. 1608-09 (Sacks)); JA1255 (Tr. 1978-79 (Heber)); JA1272 (Tr. 2270-71 (Burnett)); JA1277 (Tr. 2327-28 (Ornish)); JA1284 (Tr. 2599 (Goldstein)). As the Commission's own expert put it, "there are situations where you would determine causality in the absence of a randomized trial." JA1192 (Stampfer Dep. at 73). Consider, for example, the Forest/Padma-Nathan study in this case, which was an RCT showing that men who consumed pomegranate juice reported significantly

improved erectile function vis-à-vis men who consumed a placebo, but only demonstrated that result to a 94% probability, rather than the Commission's 95% standard for RCTs. *See* JA255 (ALJ Op. ¶¶1224-26). Experts would consider such an RCT adequate support for a claim that there is "very strong evidence" to indicate a causal relationship between the product in question and the prevention of a disease. JA1255 (Tr. 1978-79 (Heber)). Not only did the Commission reject that conclusion, JA609 (FTC Op. 25), its Order would prevent advertisers from making any claim about the results of such a study given its view that "the mere mention of scientific evidence can imply a related establishment claim." JA771 (Concurring Statement of Commissioner Ohlhausen, at 4).

The Commission's own experts also conceded that less rigorous tests than statistically significant RCTs are appropriate to substantiate qualified claims like those set forth in the POM advertisements. Not all claims that a product can treat, prevent, or reduce the risk of a serious disease are equal: some are qualified, others are unqualified; some are implied, others are express; and some recommend the replacement of existing medical therapies, while others do not. The testimony from both sides "was consistent" that RCTs are not required to substantiate the truth of qualified claims that a product may generally help to promote heart, prostate, or erectile health. *See* JA603-04 (FTC Op. 19-20). Specifically, Dr. Stampfer testified that a claim that uses the word "indicates" to describe the results

of a study would be sufficient to qualify an otherwise causal claim and remove the need for an RCT. JA1219 (Tr. 816-17). Stampfer also explained that using words such as "may" instead of "will" to describe the relationship between a product and the prevention of certain diseases would be sufficient to avoid making a causal claim. *See id.* at JA1217. The FTC's other expert witnesses explained that they had personally made product and medical treatment recommendations based on evidence short of RCTs where they thought they had advanced equivocal or non-causal claims. *See* JA1228-29 (Tr. 1150-57 (Melman)) (testifying that he had recommended a product he designed called hMaxi-k as a "fountain of youth" to treat erectile dysfunction in the absence of RCTs); JA1235-36 (Tr. 1331-32 (Eastham)) (conceding that he performed more than 200 radical prostatectomies per year before RCTs had established the benefits of the procedure); JA1242-43 (Tr. 1561-62 (Sacks)) (admitting he recommended sodium reductions and intake of Omega-6 to promote heart health benefits in the absence of RCTs). Not only did the FTC not dispute this testimony, but it tacitly acknowledged and embraced it. *See* JA604 (FTC Op. 20) (quoting with approval one of Petitioners' expert witnesses to explain the distinction between "an unqualified claim that the product has been shown to" prevent or treat a disease and a "qualified claim that [a product] may be effective" where there is no suggestion that the product alone can "absolutely prevent the disease") (quoting JA1136 (Miller Expert Report)).

Thus, the Commission's Order will extinguish a significant source of truthful and accurate information about widely consumed healthy food products. The importance of this case for the protections of the First Amendment is accordingly undeniable, given that similar statements are commonplace in food advertising throughout the marketplace.

II. Although The FTC Purported To Find POM's Advertising "Actually Misleading," In Fact The Commission's Claim Is That The Advertising Was "Potentially Misleading"

The actual statements made in each of the POM advertisements are true; the Commission does not argue otherwise. As the ALJ found, none of POM's advertisements expressly claims that consuming POM products will treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. JA165 (ALJ Op. ¶586). The Commission did not find that POM misreported the results of its studies. Nor has the Commission challenged POM's expert testimony that POM Products "generally promote good health," including heart, prostate, and erectile health. JA603 (FTC Op. 19).

There is no merit to the Commission's assertion that POM's advertisements nonetheless receive *no* First Amendment protection because they are "actually" misleading. *Id.* at JA626 (FTC Op. 42) ("Once the Commission has determined that [Petitioners'] ads are actually misleading, no further analysis is necessary because misleading commercial speech is not protected by the First

Amendment."). In reality, the FTC's theory is that POM's advertisements are "potentially" misleading.

The Order rests on two separate levels of "potentiality." First, the Commission surmised – without any evidence at all – that some consumers may infer claims that POM products prevent, treat, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction. But the Commission did not doubt that many consumers will not find that implication – rather, they will accurately read the advertisements as straightforward and qualified summaries of existing science, which POM recognizes is encouraging but uncertain. Importantly, the FTC admitted that the weight of expert testimony in the case supported the veracity of general and qualified health claims. *See supra* at 11.

Second, the Commission did not even assert that the claims it implied were actually false – *i.e.*, that the POM products do not produce the health effects that the Commission believed were implied by the advertisements. The Commission instead found that those claims *may* not be true. It reasoned that the claims could only confidently be made if based on RCTs.

Several examples illustrate the point the advertisements cannot fairly be read as actually false. The Commission held – contrary to the findings of the ALJ – that the advertisement in Figure 14 impliedly conveyed that POM's products have been scientifically established, through statistically significant RCTs, to be effective in

treating prostate cancer. JA643-44 (FTC Op. A6, A7). Headlined "One small pill for mankind," the ad begins by quoting a *New York Times* article verbatim for the following proposition: "Findings from a *small* study *suggest* that pomegranate juice *may one day* prove an effective weapon against prostate cancer." JA690 (Fig. 14) (emphasis added). The ad also notes that an "*initial* UCLA medical study on POM Wonderful 100% Pomegranate Juice showed *hopeful* results for men with prostate cancer." *Id.* (emphasis added). The latter claim is footnoted with the disclaimer that "[t]hese statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease." *Id*.

The Commission deemed the advertisement actually misleading because the science cited by POM is not an RCT and does not establish "clinical proof that the Challenged POM Products treat, prevent or reduce the risk of prostate cancer." JA616 (FTC Op. 32). But that, of course, is not what Figure 14 claims. Nor is the advertisement misleading in mentioning the millions of dollars spent on studies, or in describing POM products as "incredibly powerful," with "astonishing levels of antioxidants." JA644 (FTC Op. A7). All of those statements are true. Yet the Commission failed to explain how the combination of those true statements with

appropriately qualified and accurate descriptions of studies somehow caused the advertisement to become actually misleading.[6]

The Commission also found the advertisement in Figure 12 actually misleading. It depicts a bottle of POM Wonderful reclining on what appears to be a therapist's couch and states:

> Heart therapy. Seek professional help for your heart. Drink POM Wonderful Pomegranate Juice. It helps guard your body against free radicals, unstable molecules that *emerging* science *suggests* aggressively destroy and weaken healthy cells in your body and contribute to disease. POM Wonderful Pomegranate Juice is supported by $20 million of initial scientific research from leading universities, which has uncovered encouraging results in prostate and cardiovascular health. Keep your heart healthy and drink 8 ounces a day.

JA686 (Fig. 12) (emphasis added).

None of those statements is false. But the Commission overruled the ALJ and found the advertisement actually misleading because it supposedly "conveyed to at least a significant minority of reasonable consumers that [heart disease] efficacy claims have been scientifically established." JA643 (FTC Op. A6). *But see* JA772 (Concurring Statement of Commissioner Ohlhausen, at 5) (concluding that Figure 12 did not convey any efficacy or establishment claim to even a

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[6] The FTC's interpretation of Figure 14 is utterly indefensible given the ALJ's factual findings based on the same study cited in the ad, which the Commission did not refute, that "POM Products have shown an effect on prostate cancer with little or minimal toxicity," and "can potentially be used to prevent or delay clinical recurrence of prostate cancer." JA245 (ALJ Op. ¶¶1138, 1142).

minority of consumers). Of course, the advertisement makes no such claim. The very most that could be said is that it has the potential to mislead.

The FTC's flawed approach was not confined to Figures 12 and 14. The Commission repeatedly conflated potentially misleading speech with actually misleading speech as it overruled the ALJ's findings throughout its opinion. The Commission was obliged to apply the protections of the First Amendment to all of the advertisements that were based upon accurate and verifiable information that did not actually mislead any consumer. At the very minimum, that includes all of the advertisements approved by the ALJ. *Compare* JA640-651 (FTC Op. A3-A14) *with* JA771-74 (Concurring Statement of Commissioner Ohlhausen, at 4-7) (rejecting, in line with the findings of the ALJ, the majority's construction of Figures 4, 6, 10, 12, 13, 14, 17, 18, 19, 20, 23, 24, 25, 28, 29, 30, 31, 32, 33, 36, 37, and 39 as actually misleading).

It cannot seriously be maintained that the First Amendment offers no protection to commercial speech that accurately quotes a newspaper article and truthfully recites the results of a scientific study. *See* JA772 (Concurring Statement of Commissioner Ohlhausen, at 5) (arguing that "the record does not support a finding that these exhibits convey to a significant minority of reasonable consumers that . . . [POM products treat] prostate cancer or that such claim is clinically proven" and that, at most, the "exhibits contain conflicting elements and

heavily qualified descriptions of studies, thus suggesting the need for extrinsic evidence to determine what consumers take away"). Because "[t]he facts stated [in advertisements such as Figures 14 and 12] are true and verifiable," and there "is no contention that any potential [customer] or person was actually misled or deceived by" them, the advertisements should at most be treated as potentially misleading under the First Amendment. *Peel v. Att'y Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100-01 (1990).

The Commission cannot avoid that conclusion with its assertion that most of Petitioners' advertisements – including Figures 12 and 14 – *further* imply to consumers that the health benefits of POM products have been clinically established through statistically significant RCTs. *See* JA598, 604-05 (FTC Op. 14, 20-21). As discussed *supra* at 20-21, it was common ground among the experts that qualified claims need not be substantiated by RCTs. The Commission instead pointed to evidence that the "scientific and medical communities" expect RCTs to substantiate *unqualified* causal claims of clinical proof – *e.g.*, the bald assertion that a product treats a disease. JA604-05 (FTC Op. 20-21). But not even the Commission asserted that POM's advertisements imply that claim. Scientists and doctors easily distinguish between qualified nutrient or food claims like the ones in POM's ads and definitive claims of causation advanced on behalf of

potentially toxic drugs for serious diseases. The former need not be substantiated by RCTs.

Further, even if a *scientist* would require RCTs, that does not support the Commission's conclusion that the advertisements would mislead a *consumer* into believing that POM's claims were supported by RCTs. Under the Commission's own precedent, when "ads contain express or implied statements regarding the amount of support the advertiser has for the product claim . . . the advertiser must possess the amount and type of substantiation the ad *actually communicates to consumers*." JA605 (FTC Op. 21) (quoting *FTC* Policy Statement Regarding Advertising Substantiation, 104 F.T.C. 648, 839 (1984) (internal quotation marks omitted) (emphasis added), *aff'd*, 791 F.2d 189 (D.C. Cir. 1986)). But POM's ads did not actually communicate to consumers that its health claims have been substantiated by RCTs. Most consumers have never heard of RCTs. And most of POM's advertisements are like Figures 12 and 14 – they describe the supporting science in highly qualified language and identify the preliminary nature of studies. So even if consumers did perceive the disease causation claims implied by the Commission, they would not have expected those claims to be backed up by statistically significant, randomized, double-blinded, and placebo-controlled clinical trials using human subjects. Thus, even the supposed implied claim about

scientific proof was at most potentially, rather than actually, misleading to consumers.

In previous cases, the Commission has balanced its mandate to regulate misleading advertising with the requirements of the First Amendment by relying upon extrinsic evidence that documents the effects of advertising, such as consumer surveys. *See, e.g.*, *Kraft, Inc. v. FTC*, 970 F.2d 311, 318-20 (7th Cir. 1992). Although such surveys are not required as a matter of law, they help ensure that the Commission's regulatory impulse is grounded in actual consumer deception in the marketplace rather than theoretical objections apparent only to the agency. *See id.* at 318-19; *see also id.* at 319-20 (noting that implied claims range "from the obvious to the barely discernible" and that the "Commission does not have license to go on a fishing expedition to pin liability on advertisers for barely imaginable claims. . . ."). Here the Commission did the reverse: it required POM to produce extrinsic evidence that its advertisements would not mislead consumers. JA626-27 (FTC Op. 42-43). But the First Amendment does not permit the government to impose such a burden – a speaker may not be forced to disprove the need for a restriction that the government has already decided it favors. *See Peel*, 496 U.S. at 109-11.

Compounding this problem, the Commission made fundamental errors of claim interpretation. The Commission correctly acknowledged that existing

precedent allows it to imply claims without the support of extrinsic evidence such as consumer surveys when the claims are "reasonably clear," "clear and conspicuous," or "apparent." JA591-92 (FTC Op. 7-8). But that cannot be the case here, where four Commissioners disagreed sharply with both the ALJ and Commissioner Ohlhausen on the interpretation of virtually identical advertising material. That disagreement belies any argument that the implied claims here were "clear and conspicuous."

The Commission also blurred the categories of treatment, prevention, and reduction of risk of serious diseases. In the specific context of nutrition-related health claims, the Commission has previously recognized a broad range of health benefits that can be validly promoted without consumer deception because of consumers' general understanding of the role of nutrition in health. Indeed, as the Commission itself acknowledged, JA593 (FTC Op. 9), consumers understand nutrition-related claims to be general health benefit claims that suggest consumers could improve their chances of avoiding disease by eating nutritious foods, and not claims that the food products would eliminate the possibility of diseases. This is consistent with the Commission's long-standing position, which it adopted in its 1994 Enforcement Policy Statement on Food Advertising, that food advertisers are not required to include in advertisements "all potentially relevant information about the specific diet-related disease, or affirmatively to disclose that the risk of

the disease depends on many factors." 59 Fed. Reg. 28388, 28396 (June 1, 1994) (hereinafter "Policy Statement"). Consumers understand that nutrition is only one of many factors affecting their health. Until this case, the Commission's Enforcement Policy Statement made clear that it was permissible for advertisers to describe potential health effects of foods without engaging in an exhaustive discussion of every conceivably related aspect of nutrition and health.

The Commission in this case utterly failed, however, to differentiate among "treatment, prevention, or reduction of risk" not only for purposes of claim interpretation but, critically, when deciding what level of substantiation would be appropriate for this wide range of health benefit claims. Instead, the Commission lumped all such claims together, supposedly because they related to "serious diseases," and determined that RCTs were required to substantiate all of them. *See* JA606, 610, 619 (FTC Op. 22, 26, 35). The Commission's approach in this case resulted in an over-inclusive collection of supposed claims and imposition of an undifferentiated and arbitrary level of required substantiation for claims that it has previously recognized were entirely valid. This result is unlawful and cannot be reconciled with the First Amendment.

The Commission is left then with its assertion that in its expert opinion the advertisements make implied claims that it deems to be actually false. But the First Amendment's protections apply unless speech is inherently misleading "or

where the record indicates that a particular form or method of advertising *has in fact* been deceptive." *In re R.M.J.*, 455 U.S. 191, 202 (1982) (emphasis added); *see id.* at 203; *Peel*, 496 U.S. at 105-06 (plurality opinion). Entire categories of commercial speech, such as the category of "causal claims" targeted by the Commission's decision below, cannot be declared to be "inherently misleading" on a government agency's say-so. The Supreme Court has categorized speech as "inherently misleading" only where evidence in the record has proven it to be, or where the content of the speech is self-evidently misleading on its face. *See, e.g.*, *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 457 (1978) (holding that in-person solicitation by lawyers of accident victims was inherently misleading because of a demonstrated potential for exertion of pressure, as contrasted with public advertisements, which provide "an opportunity for comparison and reflection"); *Friedman v. Rogers*, 440 U.S. 1, 13-14 (1979) (finding trade name advertising by optometrists to be inherently misleading because the practice was shown in Texas to have been subject to abuse). The fact that a particular type of advertising carries with it a heightened potential to confuse and mislead laypersons has never been sufficient to deem it inherently misleading. *See Bates*, 433 U.S. at 383 (rejecting attorney advertising as inherently misleading even though "the public lacks sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in

legal advertising"). Indeed, even advertising that raises significant dangers of misleading consumers cannot be prohibited "if the information also may be presented in a way that is not deceptive." *R.M.J.*, 455 U.S. at 203.

This Court's decision in *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999), is instructive. There, this Court considered the FDA's refusal to permit the maker of a folic acid dietary supplement to claim on its product label that ".8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form." *Pearson v. Shalala*, 130 F. Supp. 2d 105, 108 (D.D.C. 2001) ("*Pearson II*"). The FDA prohibited the proposed label not because it found it to be false or actually misleading, but rather because it determined that there was insufficient scientific agreement to substantiate the claim that the dietary supplement in question was more effective than other forms of folic acid. The FDA also declined to permit the supplement maker to submit the claim with corrective disclaimers, reasoning that consumers would be confused by such disclaimers and that a "prophylactic approach" that would leave no doubt regarding "significant scientific agreement" regarding the health benefits of a supplement was superior public policy. *Pearson*, 164 F.3d at 653.

This Court held that the FDA's decision to ban the claim violated the First Amendment's preference for greater disclosure over "outright suppression."

Pearson, 164 F.3d at 657 (citations omitted). Specifically, *Pearson* rejected the FDA's claim that the lack of scientific agreement was sufficient to deem the claim "inherently misleading." As this Court explained, the FDA's

> argument runs along the following lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any judgment *at the point of sale*. It would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. . . . We reject it.

Pearson, 164 F.3d at 655.

The Commission's approach here is indistinguishable from the FDA's approach in *Pearson*. Like the FDA's "prophylactic" approach, the Commission decided that all of Petitioners' advertisements advance establishment and efficacy claims that lack "adequate substantiation evidence" in the form of statistically significant RCTs. JA625 (FTC Op. 41). As in *Pearson*, the Commission here acknowledged that "many of the facts in Respondents' ads are verifiable," JA627 (FTC Op. 43), yet found that the failure to discuss all of the scientific doubts surrounding those facts rendered the ads too confusing for consumers to "verify independently." *Id.* But *Pearson* makes clear that commercial speech cannot be banned as "inherently misleading" simply because the complexity of a scientific

claim might confuse consumers.[7] Speech is not inherently misleading unless there is either "*no* evidence [that] supports" a claim, or the "evidence in support of the claim is *qualitatively* weaker than evidence against the claim – for example, where the claim rests on only one or two old studies." *Pearson*, 164 F.3d at 659-60; *id.* at 659 n.10; *see also Whitaker v. Thompson*, 248 F. Supp. 2d 1, 10 (D.D.C. 2002). The FTC made no such showing here. *See* JA625-27 (FTC Op. 41-43).

The Commission also attempted to distinguish *Pearson* based upon that case's discussion of corrective disclaimers. The FDA in *Pearson* rejected the supplement makers' proposal to use corrective disclaimers in lieu of banning the claims outright. 164 F.3d at 658-59. This Court, however, held that the absence of "significant scientific agreement" on the folic acid claim did not justify banning it given that some credible evidence supported it – at most, the agency should have required a disclaimer that "[t]he evidence in support of this claim is inconclusive." *Id.* The Commission found *Pearson*'s preference for disclaimers over prohibition inapplicable because, in its view, Petitioners failed to make the same kind of disclaimers. But *Pearson* discussed disclaimers as part of its *Central Hudson* analysis, which was relevant only because it had already rejected the FDA's

[7] *See also Alliance for Natural Health U.S. v. Sebelius*, 786 F. Supp. 2d 1, 15 (D.D.C. 2011) ("In contrast to unsupported claims, health claims that are supported by some credible evidence, and which are therefore only potentially misleading, are protected commercial speech and are subject to" *Central Hudson*); *Pearson II*, 130 F. Supp. 2d at 118 (holding that the absence of scientific consensus does not make a claim "inherently misleading").

contention that speech lacking significant scientific agreement is "inherently misleading." 164 F.3d at 655, 658-59. Here, however, the Commission did not even purport to apply *Central Hudson*. *See* JA626 (FTC Op. 42).

Moreover, under *Central Hudson* it was not Petitioners' burden to include "disclaimers such as those described in *Pearson*." JA628 (FTC Op. 44). It is the government's burden to justify prohibitions on commercial speech. An agency may not "place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive." *FTC v. Brown & Williamson Tobacco Corp.*, 778 F.2d 35, 43 (D.C. Cir. 1985) (internal quotation marks and citation omitted). Here, the Commission acknowledged that many of Petitioners' advertisements contained disclaimers. *See, e.g.*, JA681 (Fig. 10) ("These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, cure or prevent any disease."); *id.* at JA688 (Fig. 13) (same); *id.* at JA690 (Fig 14) (same); *id.* at JA704 (Fig. 18) (same and providing qualifying information on studies cited in the ad); *id.* at JA707 (Fig. 19) (same); *id.* at JA727 (Fig. 24) (same); *id.* at JA729 (Fig. 25) (same); *id.* at JA750 (Fig. 28) (same); *id.* at JA753 (Fig. 29) (same); *id.* at JA755 (Fig. 30) (same); *id.* at JA757 (Fig. 31) (same); *id.* at JA760 (Fig. 32) (same); *id.* at JA763 (Fig. 33) (same). Yet, rather than directing Petitioners to correct or strengthen those disclaimers, the Commission simply declared the advertisements

to be misleading and banned them. The only way to justify so radical a remedy would be to show that no available disclaimer could correct the misleading nature of the claims at issue. *See Pearson*, 164 F.3d at 659; *Whitaker*, 248 F. Supp. 2d at 10-11. The Commission made no such showing.

III. The Order Violates The First Amendment

The Commission's decision to impose liability on broad categories of speech by producers of health foods violates the First Amendment. The government may prohibit speech that is actually or inherently misleading. *See Thompson*, 535 U.S. at 367 (actually misleading commercial speech is "not protected by the First Amendment"); *R.M.J.*, 455 U.S. at 203; *Va. Pharmacy*, 425 U.S. at 764. But the Constitution does not permit the Commission to ban potentially misleading advertising at will. *See Central Hudson*, 447 U.S. at 566. Truthful and accurate statements, even if potentially misleading, receive First Amendment protection. *See R.M.J.*, 455 U.S. at 202-03; *Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio*, 471 U.S. 626, 645 (1985) (noting that statements that are "easily verifiable and completely accurate" cannot be considered inherently misleading); *Peel*, 496 U.S. at 100 (plurality opinion) (noting that "true and verifiable" statements on at attorney's letterhead could not be considered inherently misleading); *see id.* at 111-12 (Marshall, J., concurring in the judgment); *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 145-46 (1994).

The government has the burden to prove that its regulation of potentially misleading speech directly advances a substantial governmental interest and that the regulation is not broader than necessary to achieve that interest. *See id.*; *Thompson*, 535 U.S. at 367; *Ibanez*, 512 U.S. at 144-46; *Peel*, 496 U.S. at 109-11 (plurality opinion); *R.M.J.*, 455 U.S. at 203. This Court need not remand the case for further consideration because the Commission did not even attempt to claim that its Order could withstand First Amendment scrutiny, if it applied. *See* JA627-29 (FTC Op. 43-45). For the reasons that follow, it cannot.

A. The Commission's RCT Substantiation Standard Does Not Directly Further An Important Governmental Interest.

Under the law of this Circuit, it was the Commission's burden to produce "substantial evidence" that its proposed regulation of commercial speech "directly advances" an important government interest. *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1222 (D.C. Cir. 2012). The Commission was obliged to identify that interest with specificity and to prove that its prohibition of speech would effectively promote that interest, but at no point during this litigation has it even attempted to do so.

In attempting to justify its Order, the Commission has never relied on any public health or safety justification. The ALJ found that pomegranates "have been safely consumed as nutritious food by humans for thousands of years," pomegranate juice and POMx are "safe for human consumption if consumed

within the nutritional range," "pomegranate juice has no adverse side effects," and both pomegranate juice and pomegranate extract have been identified by the FDA as products that are "generally regarded as safe." JA93 (ALJ Op. ¶¶77-82). The Commission did not overrule these findings, and it conceded that Petitioners "did not advertise or market the POM Products as an alternative to medical treatment." JA325, 327-28 (ALJ Op. 246, 248-49); *see also* JA604 (FTC Op. 20).

The governmental interest asserted by the Commission is instead that POM's advertisements might influence consumers to "pay a higher price for POM products," because they might believe they are "buying what is considered to be a premium fruit juice." JA621-22 (FTC Op. 37-38 & n.30). Indeed, the Commission's only justification for replacing its traditional "competent and reliable scientific evidence standard" with an RCT requirement appears to be its conclusory assertion that "[c]onsumers pay a higher price for POM products at least in part because of their ostensible health benefits," and a "major purpose of the [FTC] Act is to prevent consumers from economic injuries." *Id.*

The Court can assume that preventing consumers from suffering economic injuries in the marketplace is an important governmental interest. *But cf. Pearson*, 164 F.3d at 656 ("We are rather dubious that this simplistic view of human nature or market behavior is sound."); *Whitaker*, 248 F. Supp. 2d at 16 (describing any such harm as "severely limited" because "[a]t worst, any deception resulting from

Plaintiffs' health claim will result in consumers spending money on a product that they might not otherwise have purchased"). But to satisfy First Amendment scrutiny, the Commission must prove that the Order will "directly advance[]" that interest, *Central Hudson*, 447 U.S. at 566, by providing "substantial evidence" that the restriction will advance its asserted interest, and its burden in this respect "is not light." *R.J. Reynolds*, 696 F.3d at 1218, 1222. The Order cannot satisfy that standard.

The Commission's Order does not directly advance a substantial government interest because it withholds accurate information from consumers on the ground that they would not properly evaluate it in the full context of the available science. The RCT standard is based on the paternalistic theory that consumers are unwilling or unable to collect enough information to discern the truth of the claims in POM's advertisements. As applied to POM's ads, the Commission "agree[d] that many of the facts in Respondents' ads are verifiable," but it nonetheless found the advertisements to be actually misleading because they failed to include additional details, such as the fact that certain studies cited in POM's ads had not been accepted for publication in certain journals, or the fact that other studies called into question the studies POM highlighted. *See* JA627 (FTC Op. 43).

The Commission's objective is thus to "prohibit[] certain kinds of speech on the premise that consumers need government to protect them from accurate

information." *Spirit Airlines*, 687 F.3d at 415. But the First Amendment does not permit the government to advance an interest by providing that consumers must be kept in the dark to prevent them from making poor decisions. "It is precisely this kind of choice, between the dangers of suppressing information, and the dangers of its misuse if it is freely available, that the First Amendment makes for us." *Va. Pharmacy*, 425 U.S. at 770. "[T]he general rule is that the speaker and the audience, not the government, assess the value of the information presented." *Edenfield v. Fane*, 507 U.S. 761, 767 (1993); s*ee also Bates*, 433 U.S. at 375 ("[W]e view as dubious any justification that is based on the benefits of public ignorance."). The government may not ban speech simply because a speaker's failure to include all details and all sides of a debate on a matter of public concern might create misleading implications. *See id.*; *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (plurality) ("The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good."); *see also Peel*, 496 U.S. at 108-09; *Bates*, 433 U.S. at 375; *Spirit Airlines*, 687 F.3d at 415; *Pearson*, 164 F.3d at 650.

Furthermore, the Order is fatally under-inclusive. *See Rubin v. Coors Brewing Co.*, 514 U.S. 476, 489 (1995); *City of Ladue v. Gilleo*, 512 U.S. 43, 50-52 (1994); *Metro Lights, L.L.C. v. City of Los Angeles*, 551 F.3d 898, 904-05 (9th Cir. 2009). The marketplace is replete with health and nutritional

recommendations made on the basis of science that does not rise to the level of RCTs. Only some of those claims are disease claims; many others assert generalized health benefits of food products or dietary supplements. *See, e.g.*, JA1304 (Academy of Nutrition & Dietetics, *What Are Antioxidants?*, *available at* http://www.eatright.org/public/content.aspx?id=6792 (last visited Aug. 9, 2013)) (noting that free radicals "attack healthy cells," making them "more susceptible to cardiovascular disease and certain types of cancers," and that "[a]ntioxidants . . . help protect healthy cells from damage caused by free radicals"); JA1308 (Stanford Medicine Cancer Institute, *Nutrition to Reduce Cancer Risk, available at* http://cancer.stanford.edu/information/nutritionAndCancer/reduceRisk/ (last visited Aug. 9, 2013)) (noting that "[a]ntioxidants . . . protect the body from the damaging effects of free radicals (by-products of the body's normal chemical processes)," and that "[f]ree radicals attack healthy cells, which changes their DNA, allowing tumors to grow. . . .").

Similar claims are at the heart of health and nutritional recommendations that the government itself has advanced. The Supreme Court recently recognized that neither medical professionals nor the federal government "limit the data they consider to the results of randomized clinical trials or to statistically significant evidence." *Matrixx Initiatives, Inc. v. Siracusano*, 131 S. Ct. 1309, 1320 (2011) (internal quotation marks and citation omitted). The Court's conclusion in *Matrixx*

was based substantially on the position advocated by the Solicitor General on behalf of the federal government.[8] As the *Matrixx* Court noted, the FDA does not demand statistically significant RCTs before it bans the introduction of drugs based on feared health risks. *See id.* What is more, the government's FDA-approved dietary recommendations urge Americans to eat more fruits and vegetables not because there is statistically significant proof that such foods improve individual health, but rather because promising scientific studies suggest that nutrients found in those foods have the potential to promote health and prevent or reduce the risk of certain diseases. *See* Andrew Shao & Douglas Mackay, *A Commentary on the Nutrient-Chronic Disease Relationship and the New Paradigm of Evidence-Based Nutrition*, 2 Natural Med. J. 12, 13-14 (Dec. 1, 2010). Similarly, the NIH Office of Dietary Supplements recommends that Americans consume foods rich in Vitamin E, despite the fact that no RCTs have validated its purported benefits, by making the following claims:

> Antioxidants protect cells from the damaging effects of free radicals, which are molecules that contain an unshared electron. Free radicals damage cells and might contribute to the development of cardiovascular disease and cancer. Unshared electrons are highly

[8] *See also* 131 S. Ct. at 1319 ("Matrixx's argument rests on the premise that statistical significance is the only reliable indication of causation. This premise is flawed: As the SEC points out, 'medical researchers . . . consider multiple factors in assessing causation.'" (citing Br. for U.S. as *Amicus Curiae*, at 12)); *id.* ("A lack of statistically significant data does not mean that medical experts have no reliable basis for inferring a causal link between a drug and adverse events.").

> energetic and react rapidly with oxygen to form reactive oxygen species (ROS)[, . . .] and antioxidants might protect cells from the damaging effects of ROS. . . . Vitamin E is a fat-soluble antioxidant that stops the production of ROS formed when fat undergoes oxidation. Scientists are investigating whether, by limiting free-radical production and possibly through other mechanisms, vitamin E might help prevent or delay the chronic diseases associated with free radicals.

JA845 (Office of Dietary Supplements, National Institutes of Health, *Dietary Supplement Fact Sheet: Vitamin E, available at* http://ods.od.nih.gov/factsheets/VitaminE-HealthProfessional/ (last reviewed June 5, 2013)); *see also* JA832 (Office of Dietary Supplements, National Institutes of Health, *Dietary Supplement Fact Sheet: Vitamin C, available at* http://ods.od.nih.gov/factsheets/VitaminC-HealthProfessional/ (last reviewed June 5, 2013)) (recommending Vitamin C intake notwithstanding lack of clear scientific proof, in the form of RCTs, for its disease prevention and treatment benefits).

The fact that the Commission has never imposed an RCT requirement on dietary supplements is telling. The concerns regarding dietary supplements' potential toxicity and efficacy in relation to cost were sufficiently serious that Congress created a separate FDA regime that enhanced regulations above and beyond those that apply to conventional food products. See *Alliance for Natural Health U.S. v. Sebelius*, 775 F. Supp. 2d 114, 128-29 (D.D.C. 2011). Yet, notwithstanding these concerns, the Commission has opposed efforts to tighten the FDA's regulatory standards on dietary supplements because a "more rigid

standard" by which to judge health claims would be unnecessary and possibly counterproductive. *See* JA778 (Letter from Donald S. Clark to Jonathan W. Emord, Denying Petition for Rulemaking (Nov. 30, 2000), *available at* http://www.ftc.gov/os/2000/12/dietletter.htm). This history eliminates any credibility the Commission might have in arguing that only an RCT standard can prevent consumers from deception.

The FTC's new substantiation standard, because it applies only to advertisers, would leave consumers equally vulnerable to being misled by non-RCT health and disease claims advanced by the government, the media, and those in the scientific and medical communities. As a result, the Commission's RCT standard prohibits advertisers from making claims that promote their products based on competent and reliable scientific evidence, but leaves regulatory agencies free to make such claims as the basis for decisions to regulate or prohibit products at will. Other private speakers, moreover, remain free to criticize or question the health benefits of POM's products on the basis of evidence short of RCTs under the Commission's rule. The RCT standard, therefore, will increase consumer confusion by creating different measures of proof for claims that are identical but for the identity of the speaker. At most, the rule would be ineffective in providing consumers with more accurate information on which to make purchasing decisions. And, under *Central Hudson*, "a commercial speech regulation 'may not be

sustained if it provides only ineffective or remote support for the government's purpose.'" *44 Liquormart*, 517 U.S. at 505 (quoting *Central Hudson*, 447 U.S. at 564).

For related reasons, the operation of the Commission's RCT standard amounts to prohibited viewpoint discrimination. The rule prohibits a category of speech (claims based on competent and reliable scientific evidence, but not RCTs) only when it is uttered by those who assert that food products improve health. Given the ongoing discussion regarding the health benefits of various foods containing antioxidants, the RCT rule will inevitably mute one side of that debate. Even in the context of commercial speech, the First Amendment does not permit the government to silence only that speech with which it happens to disagree. *See Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664 (2011) (holding that "[c]ommercial speech is no exception" to the First Amendment's prohibition of viewpoint-based discrimination); *see generally Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1989).

What is more, the Commission has not provided "substantial evidence" that an RCT requirement will "directly advance" its goal to give consumers access to better or more accurate information. *R.J. Reynolds*, 696 F.3d at 1222. The Commission rejected the ALJ's findings regarding the lack of any real injury to consumers, JA621 (FTC Op. 37), and claimed that it had no need to consider actual

evidence regarding consumers' perceptions of POM's advertisements, *id.* at JA598-601. In fact, consumers plainly will not be better informed if advertisers cannot inform them about the results of *in vitro* or animal studies, or if they can only learn about a clinical trial involving human subjects if that study satisfies the government's definition of statistical significance.

Nor did the Commission offer any evidence to support its assertion regarding the price of POM's products. The fact that POM was regarded as a "premium juice" does not prove that it was POM's health claims that gave it that status. Other features of POM's product may be sufficient to sustain its "premium" status, even absent those health claims. And it is as equally plausible to presume that POM's price is driven primarily by its production costs, and that POM's advertising caused consumers to switch from other equivalently priced juice products, as it is to presume the price relationships asserted by the Commission. It is the Commission's burden to identify the justifications for its standard clearly and to provide evidence that support them – the government cannot satisfy its burden "by mere speculation or conjecture." *Rubin*, 514 U.S. at 487 (internal quotation marks and citation omitted).

B. The RCT Requirement Restricts More Speech Than Is Necessary To Further A Legitimate Government Interest.

The Commission's RCT standard restricts an enormous amount of constitutionally protected speech: accurate statements about healthy foods that are

supported by competent and reliable scientific evidence but not RCTs. It thus flies in the face of the principle that "any restrictions imposed on deceptive commercial speech can be no 'broader than reasonably necessary to prevent the deception.'" *Brown & Williamson*, 778 F.2d at 43 (quoting *R.M.J.*, 455 U.S. at 203).

The best evidence of the Order's impermissible reach is the government's own policies. As discussed *supra*, the government regularly provides the public with guidance about healthy eating habits and the benefits of particular foods and nutrients in the absence of RCTs. There is no basis to hold private speakers to a more rigorous standard. And even if there were, surely there can be no justification for holding concededly safe food advertisements to a more stringent standard than the one used by the FDA to evaluate drugs.

Indeed, the Commission's prior precedent demonstrates that the agency could achieve its asserted interests through more modest measures that survive constitutional scrutiny. Neither the FTC Act, nor any interpretation of it by any court, has previously held that only an RCT can substantiate a claim that a product –particularly a healthy food – can prevent, treat, or reduce the risk of a disease. *See FTC v. QT, Inc.*, 512 F.3d 858, 861 (7th Cir. 2008). The Seventh Circuit has explained that the FTC Act

> forbids false and misleading statements, and a statement that is plausible but has not been tested in the most reliable way cannot be condemned out of hand. The burden is on the Commission to prove that the statements are false. (This is one way in which the Federal

> Trade Commission Act differs from the Food and Drug Act.) Think about the seller of an adhesive bandage treated with a disinfectant such as iodine. The seller does not need to conduct tests before asserting that this product reduces the risk of infection from cuts. The bandage keeps foreign materials out of the cuts and kills some bacteria. It may be debatable *how much* the risk of infection falls, but the direction of the effect would be known, and the claim could not be condemned as false. Placebo-controlled, double-blind testing is not a legal requirement for consumer products.

QT, 512 F.3d at 861. Other courts have adopted similar reasoning. *See SEC v. Morgan Keegan & Co.*, 678 F.3d 1233, 1247 (11th Cir. 2012) (noting that "statistically significant data are not always available and that medical researchers and the FDA routinely rely on other evidence to establish an inference of causation"); *FTC v. Direct Mktg. Concepts, Inc.*, 624 F.3d 1, 9 (1st Cir. 2010) (declining to adopt the Commission's claim that RCTs were required for substantiation and explaining that "there may be other scientific evidence that could be sufficient, and we may assume . . . that a double-blind study is not necessarily required").

In the past, the FTC has consistently held advertisements that advance health or disease claims to the "competent and reliable scientific evidence" standard. *See In re Novartis Corp.*, 127 F.T.C. 580, 725 (1999).[9] It has interpreted that standard

[9] *See, e.g.*, Policy Statement, 59 Fed. Reg. at 28389 (explaining that, to make a health claim about a food product, an advertiser must have "competent and reliable scientific evidence sufficient to support the claim"); JA802-03 (Fed. Trade Comm'n, Bureau of Consumer Protection, *Dietary Supplements: An Advertising*

by applying a set of flexible factors, described in *In re Pfizer Inc.*, 81 F.T.C. 23 (1972), which collectively balance the protection of consumers from the harms of misleading advertising, on the one hand, with the need to provide consumers with information that can help them find products that they need or want, on the other. This approach "allows advertisers to provide truthful information to consumers" while preserving "consumer confidence by curbing unsubstantiated, false, and misleading claims." JA819 (Dietary Supplements at 25).

Nowhere in its opinion did the Commission explain why consumers will be better informed and more prone to making wise purchasing decisions if advertisers are held to an RCT standard for disease claims. The Commission acknowledged in this case "that less rigorous evidence may be sufficient to support some claims regarding health or nutritional benefits of food." JA604 (FTC Op. 20). And it has previously held that qualified claims require less robust scientific substantiation than unqualified claims. *See* Policy Statement, 59 Fed. Reg. at 28388 ("Unqualified as used in this discussion of substantiation refers to health claims that do not include specific disclosures concerning the extent of supporting scientific evidence."). But if the Commission demands an RCT every time it theorizes – without extrinsic evidence – that some minority of consumers might misinterpret a health claim to be a disease claim, or a qualified claim to be

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Guide for Industry 8-9 (2001), *available at* http://www.ftc.gov/bcp/edu/pubs/business/adv/bus09.shtm [hereinafter "Dietary Supplements"]) (same).

unqualified, then large numbers of consumers who would not misinterpret those claims will be denied access to helpful and truthful information. The obvious solution to this problem, which the Commission failed to consider, is to demand "more disclosure, rather than less." *Bates*, 433 U.S. at 376. The Commission's reflexive preference for prohibition is fundamentally at odds with the First Amendment. *See Pearson*, 164 F.3d at 657.

Finally, it is the government's burden to consider whether potentially misleading speech can be cured by any remedy short of prohibition. *See Brown & Williamson*, 778 F.2d at 43. The Commission cannot require RCTs to substantiate even concededly causal disease claims if there are disclaimers that could prevent consumers from being misled. *Pearson*, 164 F.3d at 159. The Commission failed to explain why POM's disclaimers failed in that regard, and perhaps more importantly, it utterly failed to show why simply requiring advertisers to include a standard "non-RCT" disclaimer would fail to prevent consumer confusion. Such an alternative would effectively address the Commission's asserted interest without impinging upon constitutionally protected speech.

IV. At The Very Least, The FTC's Fencing In Remedy Must Be Vacated

Even if this Court were to affirm the Commission's finding of liability, it nonetheless should vacate the Commission's remedy requiring that all health claims in POM's advertising be supported by two RCTs. The Order directs

Petitioners not to "make *any* representation in *any* manner, expressly or by implication . . . that [its] product is effective in the diagnosis, cure, mitigation, treatment, or prevention of *any* disease" unless such representation is both "non-misleading" *and* supported by at least two statistically significant RCTs. JA578 (FTC Order 5) (emphasis added). That broad mandate goes well beyond the purportedly misleading claims that the FTC challenged in its complaint. It prohibits not only speech that the Commission found to be actually misleading, but also prophylactically bans speech based entirely on its potential to mislead.

"If the First Amendment means anything, it means that regulating speech must be a last – not first – resort." *Thompson*, 535 U.S. at 367. Thus, even though the government's interest in regulating misleading speech is substantial, "any restrictions imposed on deceptive commercial speech can be no 'broader than reasonably necessary to prevent the deception.'" *Brown & Williamson*, 778 F.2d at 43; *see also 44 Liquormart*, 517 U.S. at 507 (a regulation on commercial speech must "satisfy the requirement that its restriction on speech be no more extensive than necessary"). Given that commercial speech restrictions must be "no broader than necessary," absolute prohibitions on speech are exceedingly difficult to justify. *See 44 Liquormart*, 517 U.S. at 500; *Rubin v. Coors*, 514 U.S. 476 (1995); *Pearson II*, 130 F. Supp. 2d at 118 ("[T]he agency must shoulder a very heavy burden if it seeks to totally ban a particular health claim.").

The Commission made no effort to justify banning all thirty-six purportedly offensive advertisements as a measure of first resort. Nowhere did the Commission explain what alternatives it had considered to prohibition, nor did it explain why requiring corrections, alterations, or disclaimers would not have sufficed to prevent the implied claims that the Commission found offensive. Petitioners do not challenge the Commission's authority to fashion broad prospective orders, *see* JA635-36 (FTC Op. 51-52), but even so, the Commission lacks authority to "'place an absolute prohibition on . . . potentially misleading information . . . if the information also may be presented in a way that is not deceptive.'" *Brown & Williamson*, 778 F.2d at 43 (quoting *R.M.J.*, 455 U.S. at 203). At minimum, the Commission was obliged to show that readily-available less restrictive alternatives were insufficient to prevent consumer deception before jumping to impose a draconian prohibition.

What is more, even if the Commission were correct that all of Petitioners' advertisements were actually misleading, the order goes too far. For a period of twenty years, the Commission has forbidden Petitioners from making "*any* representation in *any manner*, expressly or by implication, including through the use of a product name, endorsement, depiction, illustration, trademark, or trade name, that such product is effective in the diagnosis, cure, mitigation, treatment, or prevention of *any* disease," unless such a representation is *both* "non-misleading"

and is supported by *two* statistically significant RCTs "that are randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies." JA578 (FTC Order 5) (emphasis added). Such a broad "fencing in" remedy is inappropriate where the Commission applied its newfound liability standard – the RCT requirement – for the first time in this case. Petitioners could not have deliberately or flagrantly violated a standard that did not yet exist. *See Sears, Roebuck & Co. v. FTC*, 676 F.2d 385, 394-96 (9th Cir. 1982) (explaining that egregious or deliberate conduct is necessary to justify broad fencing-in orders). Moreover, if all representations about diseases except those substantiated by RCTs were self-evidently misleading, the Commission's order could simply have required that representations be "non-misleading." The fact that the Commission considers its RCT standard to be an additional requirement is telling.[10]

[10] The Commission relies extensively on the Seventh Circuit's decision in *Kraft, Inc. v. F.T.C.*, 970 F.2d 311, 325-26 (7th Cir. 1992). But the FTC's order in *Kraft* prohibited only the specific advertisements as they were then "currently designed" before the Commission; it permitted Kraft to advance similar claims so long as they were based on "reliable scientific evidence"; and it even allowed for Kraft to use the same advertisements so long as they included "prominent, unambiguous disclosures." *Kraft*, 970 F.2d at 325-36. In this case, the language of the FTC's Order applies to any claims relating to any diseases; the substantiation standard is significantly higher and, as is likely impossible to meet; and the FTC's Order mentions no possibility of corrective disclosures in the absence of statistically significant RCTs. *See* JA578 (FTC Order 5).

At no point did the Commission justify its decision to impose its drastic remedy on Roll products as a whole. The Commission's Order covers not only POM's pomegranate products, but also other Roll products, such as Fiji Water and Wonderful pistachios. The Commission's purported justification for this expansive remedy was that Petitioners have "explored" testing to see whether those products, like POM juice, might actually deliver health benefits to consumers. JA634 (FTC Op. 50). Whatever the merits of that view, it cannot justify banning Roll from saying anything about the health benefits of its other products until it has the support of statistically significant RCTs. It cannot be doubted that far narrower, yet equally effective, remedies were readily available to the Commission.

Finally, the FTC failed to establish that *all* claims related to the prevention, treatment, or reduction of risk of a disease are actually or inherently misleading in the absence of two statistically significant RCTs. It offends the First Amendment to hold that all claims that even mention the prevention, treatment, or reduction of risk of disease are inherently misleading if they are not supported by that level of substantiation. *See Pearson II*, 130 F. Supp. 2d at 115 ("The mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it."). And while the FTC has authority to "close all roads to the prohibited goal," *FTC v. Ruberoid Co.*, 343 U.S. 470, 473

(1952), the remedy it has chosen here closes off speech that is truthful, accurate, and constitutionally protected.

V. The Commission's Order Violates The First Amendment And The Administrative Procedure Act, And The Commission's Remedy Is Unlawful, For The Reasons Set Forth In The Brief Of Petitioner Tupper.

Petitioners incorporate and join in the arguments set forth in the brief of Petitioner Tupper that the Order violates the First Amendment and Administrative Procedure Act.

CONCLUSION

For the reasons contained herein, Petitioners respectfully submit that this Court should vacate the FTC's Order in its entirety.

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7) of the Federal Rules of Appellate Procedure and this Court's Circuit Rule 32(a), I hereby certify that the foregoing brief contains 13,328 words, excluding the exempted parts of the brief, as determined by the word counting feature of Microsoft Word 2010. The only modifications from the initial brief are citation changes and typographical corrections.

/s/ Thomas C. Goldstein
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CERTIFICATE OF SERVICE

Pursuant to this Court's Circuit Rule 25(c), I hereby certify that on this 25th day of March, 2014, I electronically filed the foregoing Brief for Appellee with the Court by using the CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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