

Snake Oil in Your Pomegranate Juice: Food Health Claims and the FTC

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Introduction

A COMPANY'S CLAIM that its food or food components provide health and wellness benefits is certainly not a novel idea. Hippocrates espoused, "[l]et food be thy medicine and medicine be thy food," well over two thousand years ago.¹ Fueled by various factors, including rapid advances in science and technology, increasing healthcare costs, and an aging population, it is now receiving renewed interest.² In fact, food masquerading as drugs is one of today's hottest trends.³ Whether it is oatmeal to lower cholesterol,⁴ yogurt to regulate digestion,⁵ or pomegranate juice to take care of your heart,⁶ so called "functional foods,"⁷ foods that provide a health benefit beyond basic nutrition are

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1. Patricia Fitzgerald, *Let Food be Thy Medicine: Top 10 Healing Foods of the Decade*, HUFFINGTON POST (Dec. 30, 2009), http://www.huffingtonpost.com/dr-patricia-fitzgerald/let-food-be-thy-medicine_b_406582.html.

2. INT'L FOOD INFO. COUNCIL FOUND., FUNCTIONAL FOODS (2011), available at <http://www.foodinsight.org/Content/3842/FinalFunctionalFoodsBackgrounder.pdf>.

3. Matthew Herper & Rebecca Ruiz, *Snake Oil in Your Snacks*, FORBES (June 7, 2010), <http://www.forbes.com/forbes/2010/0607/health-probiotics-vitamins-supplements-snake-oil-in-snacks.html>.

4. *How Oats Work*, QUAKER OATS.COM, <http://www.quakeroats.com/oats-do-more/for-your-heart/cholesterol/how-oats-work.aspx> (last visited Mar. 3, 2012).

5. Lauren Sandler, *Gut Instinct: What Health Benefits, Exactly, is Activia Yogurt Supposed to Offer?*, SLATE (July 3, 2008), http://www.slate.com/articles/news_and_politics/hey_wait_a_minute/2008/07/gut_instinct.html.

6. Brindusa Vanta, *Is Pomegranate Juice Good for Your Heart?*, LIVESTRONG.COM (Dec. 27, 2010), <http://www.livestrong.com/article/343553-is-pomegranate-juice-good-for-your-heart/>.

7. Although the term "functional foods" is not legally defined by the Food, Drug, and Cosmetic Act ("FDCA"), the term is informally defined for purposes of marketing as "foods or food components that provide a health benefit beyond basic nutrition." Gregory Connolly, *Functional Foods Provide More than Just Nutrition*, USA TODAY (Aug 3, 2011), <http://>

big business. With annual sales between \$20 and \$30 billion,⁸ functional foods comprise roughly five percent of the overall United States food market, and according to industry experts, functional food revenues are expected to soar.⁹ In order to capitalize on this trend of health-conscious consumerism, advertisers have begun aggressively touting their products' alleged health benefits.¹⁰

In response, the Federal Trade Commission ("FTC"), tasked with preventing fraudulent, deceptive, and unfair business practices, is cracking down on advertisers' dubious or exaggerated health-related claims. One brand in particular that has caught the attention of the FTC is POM Wonderful, a manufacturer of pomegranate juice and extract. Owned by California billionaires Stewart and Lynda Resnick,¹¹ POM Wonderful created a \$250 million market¹² for pomegranate juice in just under a decade.¹³ POM's eye-catching print advertisements, one of which featured its distinctively curvaceous POM Wonderful bottle with a noose around its neck, accompanied by the phrase "Cheat Death," claimed that the juice can "help prevent premature

/yourlife.usatoday.com/fitness-food/diet-nutrition/story/2011/08/Functional-foods-provide-more-than-just-nutrition/49791906/1.

8. PRICEWATERHOUSECOOPERS, LEVERAGING GROWTH IN THE EMERGING FUNCTIONAL FOODS INDUSTRY: TRENDS AND MARKET OPPORTUNITIES 5 (2009), available at <http://www.pwc.com/us/en/transaction-services/publications/assets/functional-foods.pdf>.

9. According to Jim Carroll, one of the world's leading global future trends and innovation experts, the sale of health and wellness oriented foods is expected to quadruple throughout the next five years. Jim Carroll, *The Big Food Industry Trend for 2012: Bold Goals, Big Bets*, JIM CARROLL BLOG (Nov. 11, 2011), <http://www.jimcarroll.com/2011/11/the-big-food-industry-trend-for-2012-bold-goals-big-bets/>.

10. One such company is Ferrero, maker of the chocolate-hazelnut spread Nutella. Ferrero was sued by two San Diego mothers for telling consumers that Nutella "is healthier than it actually is." NUTELLA CONSUMER CLASS ACTION SETTLEMENTS, <https://nutellaclassactionsettlement.com/Home.aspx> (last updated Sept. 5, 2012). Ferrero settled the lawsuit for a reported \$3 million. *Id.*

11. In addition to POM Wonderful, Mr. and Mrs. Resnick also own Fiji Water, Teleflora, Paramount Farming Company, and Paramount Citrus. The couple previously owned the Franklin Mint Company but sold it in 2006. Amanda Fortini, *Pomegranate Princess*, NEW YORKER, Mar. 31, 2008, at 92, available at http://www.newyorker.com/reporting/2008/03/31/080331fa_fact_fortini.

12. Opinion at 1, *In re POM Wonderful LLC*, No. 9344, (F.T.C. Jan. 10, 2013) [hereinafter *POM II*], available at <http://ftc.gov/os/adjpro/d9344/130116pomopinion.pdf>.

13. *Id.* Or, as Michael Hiltzik of the LA Times wrote, "[i]t has long been clear that the most wonderful thing about POM Wonderful pomegranate juice is the spectacular marketing skill that persuades consumers to fork over their hard-earned cash for a liquid that sells for five to six times the price of, oh, cranberry juice." Michael Hiltzik, *FTC Judge Calls Foul on POM Pomegranate Marketing*, L.A. TIMES (May 21, 2012), <http://articles.latimes.com/2012/may/21/news/la-mo-pom-20120521>.

aging, heart disease, stroke, Alzheimer's, even cancer. Eight ounces a day is all you need."¹⁴

The FTC took POM to task for their claims by filing an administrative complaint against POM Wonderful in September 2010.¹⁵ The FTC alleged that the company's advertising was deceptive and in violation of the Federal Trade Commission Act ("FTC Act").¹⁶ The FTC Act prohibits "any false advertisement" that is intended or likely to induce consumers to purchase food, drugs, devices, services, or cosmetics,¹⁷ and declares the dissemination of such a false advertisement an "unfair or deceptive act or practice."¹⁸

In May 2010, Chief Administrative Law Judge ("ALJ") D. Michael Chappell agreed with the FTC and found that nineteen of the forty-three challenged advertisements implicitly claimed that POM Juice, POMx Liquid, and POMx Pills (collectively "Challenged POM Products") could prevent, treat, cure, or mitigate heart disease, prostate cancer, and erectile dysfunction.¹⁹ Since the ALJ's decision was a partial victory for both POM and the FTC, both sides appealed, which necessitated a ruling from the FTC as a whole ("the Commission"). On January 16, 2013, the Commission affirmed the ALJ'S initial decision.²⁰ The Commission found that thirty-six of POM's forty-three claims were implied disease claims—claims that a product can diagnose, cure, mitigate, treat, or prevent disease²¹—seventeen more than the ALJ had found.²²

The POM case continues to be closely followed by the food industry because it addresses the broader question: What does a company need to do to adequately substantiate its product's health benefits?²³ The Commission, in its decision, imposed greater substantiation re-

14. Appendix to initial decision at 108, *In re POM Wonderful LLC*, No. 9344 (F.T.C. May 17, 2012) [hereinafter POM Appendix], available at <http://www.ftc.gov/os/adjpro/d9344/120521pomappendix.pdf>.

15. See Complaint, *In re POM Wonderful LLC*, No. 9344 (F.T.C. Sept. 24, 2010), [hereinafter POM Complaint], available at <http://www.ftc.gov/os/adjpro/d9344/100927admincmplt.pdf>.

16. *Id.*; 15 U.S.C. §§ 41–58 (2006).

17. *Id.* § 52(a)(1)–(2).

18. *Id.* § 52(b).

19. POM Appendix, *supra* note 14 at 84–85.

20. POM II, *supra* note 12 at 3.

21. POM Appendix, *supra* note 14 at 21–34.

22. See POM II, *supra* note 12 at 9.

23. Elaine Watson, *Will POM Wonderful Finally Clear Up Confusion Over What Evidence Is Needed to Support Ad Claims?*, FOOD NAVIGATOR-USA.COM (Dec. 7, 2012), <http://www.foodnavigator-usa.com/Regulation/Will-POM-Wonderful-case-finally-clear-up-confusion-over-what-evidence-is-needed-to-support-ad-claims>.

quirements than the historically flexible “competent and reliable scientific evidence” standard.²⁴ In order to meet the Commission’s standard, a product’s disease-related efficacy claim now requires double-blind, randomized well-controlled trials (“RCTs”).²⁵ Widely known as the gold standard of clinical trials,²⁶ RCTs are commonly used for drug testing.²⁷ Because of the expense associated with RCTs, critics of the Commission’s decision, such as the Alliance for Natural Health USA, accused the FTC of gagging food manufacturers from informing the public about their products’ health benefits, implicating the protections of the First Amendment.²⁸ According to Washington food industry attorney Mark Mansour,²⁹ the “FTC has drawn a very specific and an exacting line in the sand that will impose serious limitations and expensive, time-consuming, and unrealistic constraints on the ability of food manufacturers to communicate to consumers positive research developments about their products.”³⁰

This Comment explores the recent proliferation of food health claims. Part I outlines the current regulatory standard for food health claims and discusses why its inadequacies harm both consumers and businesses. Part II highlights the FTC’s recent efforts to regulate these claims through voluntary consent agreements and the resulting backlash from companies challenging the FTC’s legal authority to regulate in this manner. Part III discusses the key issues determined by *In the Matter of POM Wonderful*,³¹ and its likely implications on the food and supplement industry.

24. *POM II*, *supra* note 12 at 22.

25. *Id.*

26. Opinion at 108, *In re POM Wonderful LLC*, No. 9344 (F.T.C. May 17, 2012) [hereinafter *POM I*], available at, <http://www.ftc.gov/os/adjpro/d9344/120521pomdecision.pdf>.

27. *Id.* at 102–103.

28. The Alliance for Natural Health USA, *FTC Proceeds with Raw Power Grab on Health Claims—In Effect Thumbing Its Nose at Congress* (Jan. 22, 2013), <http://www.anh-usa.org/ftc-proceeds-with-raw-power-grab-on-health-claims/>. In the article, The Alliance for Natural Health USA calls for the passing of the Free Speech about Science Act, which would allow natural product companies, like POM, to cite peer-reviewed science in their advertising. *Id.*

29. For Mark Mansour’s professional profile, see *Mark Mansour*, AKIN GUMP, <http://www.akingump.com/en/lawyers-advisors/mark-mansour.html> (last visited Apr. 15, 2013).

30. Alicia Mundy, *FTC Bars Pom Juice’s Health Claims*, WALL ST. J. (Jan. 16, 2013), <http://online.wsj.com/article/SB10001424127887323468604578245740405648024.html>.

31. See *POM II supra* note 12; *POM I supra* note 26.

I. Food has Fallen Through the Regulatory Cracks

The FTC's truth-in-advertising law is comprised of two common-sense propositions: (1) advertising must be truthful and not misleading;³² and (2) before disseminating an ad, advertisers must be able to adequately substantiate all objective product claims.³³

Although these requirements seem relatively simple, their execution in practice leaves much to be desired. The combination of mismatched regulations,³⁴ arbitrary distinctions,³⁵ and unclear substantiation guidelines,³⁶ means litigation will continue to define the parameters of permissible health-related claims on a case-by-case basis.³⁷ Congress could fairly easily enact a law providing clear guidelines on the amount and type of evidence required to make a health claim in a manner that is understood by consumers and backed by good science.³⁸ This cat and mouse game between the food industry and government regulators is not in the best interest of either group, and least of all, the consumer; but without congressional intervention it will continue.³⁹

A. FTC Jurisdiction Over Food Advertising

In 1914, Congress passed the FTC Act, creating the FTC, a federal agency with jurisdiction over economic competition and consumer protection.⁴⁰ "Prior to 1938, any authority the FTC possessed to regulate food product claims was strictly implied" because the FTC did not have express statutory authority to regulate food advertising.⁴¹

32. These principles are articulated in the FTC's Policy Statements on Deception and Advertising Substantiation. See FTC Policy Statement on Deception (Oct. 14, 1983), reprinted in *In re Cliffdale Assocs., Inc.*, 103 F.T.C. 110 app. at 174 (1984) [hereinafter FTC Deception Statement], available at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>; FTC Policy Statement Regarding Advertising Substantiation, reprinted in *In re Thomas Med. Co.*, 104 F.T.C. 648 app. at 839 (1984) [hereinafter FTC Advertising Statement], available at <http://www.ftc.gov/bcp/guides/ad3subst.htm>.

33. See FTC Advertising Statement, *supra* note 32.

34. See *infra* Part I.B.

35. See *infra* Part I.C.

36. See *infra* Part I.D.

37. See Jann Bellamy, *POM: Not So Wonderful*, SCIENCE-BASED MED. (May 31, 2012), <http://www.sciencebasedmedicine.org/index.php/pom-not-so-wonderful/>.

38. *Id.*

39. *Id.*

40. See Federal Trade Commission Act, Pub. L. No. 63-203, § 1, 38 Stat. 717 (1914) (codified as amended at 15 U.S.C. §§ 41-58 (2006)) (establishing the FTC).

41. Chelsea M. Childs, Note, *Federal Regulation of the "Smart Choices Program": Subjecting Front-of-Package Nutrition Labeling Schemes to Concurrent Regulation by the FDA and the FTC*, 90 B.U. L. REV. 2403, 2410 (2010) (citing 15 U.S.C. §§ 41-77 (2006)).

In 1938, Congress passed the Wheeler-Lea Amendments, giving the FTC express jurisdiction over all food advertising.⁴² These amendments outlawed “deceptive acts or practices in commerce” and empowered the FTC to prevent such acts or practices.⁴³ The FTC Act now prohibits “any false advertisement” that is intended or likely to induce consumers to purchase food,⁴⁴ and declares the dissemination of such a false advertisement an “unfair or deceptive act or practice.”⁴⁵

As discussed in more detail below,⁴⁶ the FTC may enforce the FTC Act through rulemaking, which affects an entire industry,⁴⁷ or adjudication, which issues a case-specific decision with respect to an individual advertiser’s practices.⁴⁸ Section twelve of the FTC Act gives the FTC authority to institute administrative cease and desist order proceedings against persons whom the FTC believes are disseminating advertisements in violation of section twelve.⁴⁹ Thus, when the FTC believes that a claim is false or misleading, it typically orders the advertiser to cease and desist from making such claims.⁵⁰

After the FTC issues a cease and desist order, it usually “proceeds with the customary administrative hearing and [FTC] determination, followed by the opportunity for court appeal.”⁵¹ The administrative hearing focuses on whether the advertiser’s claim is deceptive.⁵² “A deceptive claim is one that ‘is false and misleading in itself’ or ‘lacks substantiation,’ and therefore violates the FTC Act.”⁵³ Whether a

42. Wheeler-Lea Amendments of 1938, Pub. L. 75-447, § 4, 52 Stat. 111, 114-17 (1938) (codified as amended at 15 U.S.C. § 45).

43. *Id.* § 3, 52 Stat. 111-12.

44. 15 U.S.C. § 52(a)(1)-(2).

45. *Id.* § 52(b).

46. *See infra* Part II.A.

47. *See* 15 U.S.C. § 57(a)(1)(B).

48. *See id.* § 45(b).

49. *Id.*

50. *Id.* In deciding whether to commence an action against an advertiser, the FTC considers several factors, including: (1) whether the FTC has jurisdiction over advertisements made about the product in question; (2) whether the advertising campaign is national in geographic scope; (3) whether the advertisement “represents a pattern of deception, rather than an individual dispute between a consumer and a business or a dispute between two competitors;” and (4) the extent to which the advertisement harmed consumer health, safety, or finances. FED. TRADE COMM’N, ADVERTISING PRACTICES: FREQUENTLY ASKED QUESTIONS, ANSWERS FOR SMALL BUSINESS 7 (2001), available at <http://business.ftc.gov/sites/default/files/pdf/bus35-advertising-faqs-guide-small-business.pdf> (responding to the question: “How does the FTC decide what cases to bring?”).

51. Childs, *supra* note 41, at 2409.

52. *Id.*

53. *Id.*

claim is deceptive requires the resolution of three factors.⁵⁴ First, the FTC considers whether the advertiser uses a “a representation, omission, or practice that is likely to mislead the consumer.”⁵⁵ The challenged claim may constitute an express claim such as “this product reduces the risk of heart disease,” an implied claim such as “pomegranate reduces the risk of heart disease; this product contains pomegranate,” or an omission.⁵⁶

Second, the FTC considers whether the representation is likely to mislead the reasonable consumer.⁵⁷ The FTC judges consumer reasonableness in light of the advertisement’s target audience.⁵⁸

Third, the representation must be material in that it is “likely to affect a consumer’s conduct or decision with regard to a product.”⁵⁹ A representation is presumed material when the advertiser makes an express claim, intends to make an implied claim, omits information that it knew or should have known a consumer requires, or makes a claim involving health or safety.⁶⁰

[T]he FTC will not consider an advertiser’s claim deceptive under two circumstances. First, despite literally false claims, an advertisement is “not legally deceptive if consumers understand that the claims are not meant to be taken literally, and therefore are not misled into forming false beliefs.” For example, “[t]he claim that ‘Exxon puts a tiger in your tank,’ though literally false, is not legally actionable.” Second, an advertisement is not deceptive if the advertiser has adequate substantiation for any claims regarding its products. “The FTC balances six factors in determining the appropriate level of substantiation required for an advertised product: (1) the nature of the product involved, (2) the type of claim, (3) the benefits of a truthful claim, (4) the cost of developing substantiation for the claim, (5) the consequences of a false claim, and (6) the amount of substantiation that reasonable experts in the field would agree on.”⁶¹

54. *Id.* (internal citations omitted).

55. FTC Deception Statement, *supra* note 32, at 175.

56. *See* Childs, *supra* note 41, at 2409. With respect to an implied claim, identifying the exact claim made by an advertiser is often difficult and controversial. *Id.* The FTC has the authority to “rely on its reasoned analysis to determine what claims, including implied ones, are conveyed in a challenged advertisement, so long as those claims are reasonably clear from the face of the advertisement.” *Id.* (citing *Kraft, Inc. v. FTC*, 970 F.2d 311, 319 (7th Cir. 1992)).

57. FTC Deception Statement, *supra* note 32, at 175.

58. *Id.*

59. *Id.*

60. *Id.*

61. *See* Childs, *supra* note 41, at 2410 (internal citations omitted).

When it comes to food advertising, however, the FTC must often seek the opinion of outside parties such as the Food and Drug Administration ("FDA") to complete its deceptive advertising analysis.⁶²

B. The FTC and FDA: Complementary Regulation

Pursuant to the regulatory scheme established by Congress through complementary statutes, the FTC and FDA operate under a Memorandum of Understanding⁶³ that governs the division of responsibilities between the two agencies over claims by food manufacturers.⁶⁴ The current understanding is that the FTC has jurisdiction over food advertising and the FDA has jurisdiction over food labeling.⁶⁵

In response to the Nutrition Labeling and Education Act of 1990 ("NLEA"),⁶⁶ which required FDA regulation of disease-prevention claims in food labeling,⁶⁷ the FTC issued the Enforcement Policy Statement on Food Advertising in 1994.⁶⁸ Although the NLEA applies only to food labeling, the FTC recognized the importance of the consistent treatment of health claims in both food advertising and label-

62. See, e.g., *infra* note 66.

63. Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, 36 Fed. Reg. 18,539, 18,539 (Sept. 16, 1971) (replacing and updating previous agreements between the FTC and FDA) [hereinafter FTC/FDA MoU]. The FTC/FDA MoU states the division as follows:

In order to facilitate the purposes of this agreement, it is specifically agreed that: With the exception of prescription drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of foods, drugs, devices, and cosmetics. In the absence of express agreement between the two agencies to the contrary, the Commission will exercise primary jurisdiction over all matters regulating the truth or falsity of advertising of foods, drugs, . . . devices, and cosmetics;

The Food and Drug Administration has primary responsibility for preventing misbranding of foods, drugs, devices, and cosmetics shipped in interstate commerce. . . . In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of foods, drugs, devices, and cosmetics.

Id.

64. The FDA's food labeling authority is embodied in Section 403(a) of the FDCA, which prohibits false or misleading advertising. Food, Drug and Cosmetic Act, Pub. L. No. 75-717, § 403(a), 52 Stat. 1040, 1047 (1938).

65. See generally FTC/FDA MoU, *supra* note 63.

66. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

67. *Id.* The NLEA amended Section 403 of the FDCA and requires nutrition information on virtually all food products, directs the FDA to standardize and limit the terms permitted on labels, and allows only FDA-approved nutrient content claims and health claims to appear on food labels. See *id.*

68. FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (June 1, 1994).

ing.⁶⁹ Thus, the FTC will generally look to the FDA's labeling regulations in evaluating health claims made in food advertising, acknowledging the FDA's specific scientific expertise.⁷⁰

Critics of this approach cite the fundamental differences that exist between the two agency's regulatory schemes.⁷¹ Congress has long recognized the division of roles between the two agencies—the FTC concentrates on the interests of commerce and economic needs, whereas the objective of the FDA is the “health of the people.”⁷² The sphere of regulation of food health claims, however, is one in which the traditional mandates of the two agencies are seemingly intertwined.⁷³

C. Health Claims: Terms of Art

There are several types of nutrition and health claims commonly associated with food products, including health claims, structure/function claims, and dietary guidance statements. Health claims suggest a link between consuming a food and reducing the risk of “a disease or a certain health-related condition.”⁷⁴ The statement “[d]iets

69. *Id.*

70. *Id.* Although similar, the regulation standards of the FTC and FDA are not identical:

While the Commission's approach to evaluation of unqualified health claims will generally parallel FDA's assessment of whether there is significant scientific agreement supporting the relevant diet-disease relationship, the Commission recognizes that there may be certain limited instances in which carefully qualified health claims may be permitted under section 5 although not yet authorized by the FDA, if the claims are expressly qualified to convey clearly and fully the extent of the scientific support.

Id. at 28,394.

71. Before the passage of the Wheeler-Lea Amendments of 1938, congressional members were divided amongst those who supported FTC jurisdiction over food advertising and those who believed that the FDA should have advertising jurisdiction. “Those supporting extending the FDA's jurisdiction over advertising argued that the FTC was concerned primarily with economic issues, such as trade and competition, and not the protection of consumer health, and that advertising regulation is a necessary corollary to labeling regulation.” Nicole Gerhart, *The FDA & the FTC: An Alphabet Soup Regulating the Misbranding of Food* 3 (Apr. 30, 2002) (unpublished course paper, Food and Drug Law, Winter 2001), <http://dash.harvard.edu/bitstream/handle/1/8965563/Gerhart.html?sequence=2>.

72. General Requirements for Health Claims for Dietary Supplements, 55 Fed. Reg. 395, 405 (1994) (internal quotations omitted).

73. *See infra* Part I.C.

74. Barbara O. Schneeman, U.S. Food & Drug Admin., *Guidance for Industry and FDA: Dear Manufacturer Letter Regarding Food Labeling* (Jan. 2007), <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Labeling/Nutrition/ucm053425.htm> [hereinafter *Dear Manufacturer Letter*] (citing 21 C.F.R. § 101.14 (2009)).

low in sodium may reduce the risk of high blood pressure” is an example of a health claim.⁷⁵ Structure/function claims are similar to health claims, but instead of describing a relationship between consumption of a certain food and a health condition or disease, they describe how consumption affects the normal structure or function of the human body.⁷⁶ For example, “calcium builds strong bones” is a structure/function claim because it cites a specific effect—bone strength—as the result of consuming a certain nutrient, calcium.⁷⁷ Dietary guidance statements, such as “[c]arrots are good for your health,” typically make broad, general health recommendations.⁷⁸

The distinction amongst claims is critical because the amount of substantiation required depends on whether a claim is characterized as a health claim, structure/function claim or dietary guidance statement. Neither structure/function claims nor dietary guidance statements require FDA review or authorization before manufacturers may use them in a label, as long as the statements are true and not misleading.⁷⁹ The same is not true for health claims.⁸⁰ Without increased substantiation, or prior FDA approval for labeling, a food product like yogurt can claim to “regulate digestion,” so long as it doesn’t claim to “treat chronic constipation.”⁸¹ Consumers are being flooded with unsubstantiated health claims, murkily disguised as structure/function claims.⁸²

D. Substantiation: Science Through Compliance

In its Enforcement Policy Statement on Food Advertising, the FTC announced that it would examine health claims on a case-by-case basis.⁸³ Unlike the FDA, there is no pre-clearance of advertising claims by the FTC, even if the advertisement is categorized as a health claim.⁸⁴ Instead, the FTC requires that an advertiser have a reasonable basis to substantiate its claim from the time the claim is first made.⁸⁵ The FTC’s substantiation standard is a flexible one, requiring that

75. *Id.*

76. *Id.* (citing 21 C.F.R. § 101.93).

77. *Id.*

78. *Id.*

79. *See* Dear Manufacturer Letter, *supra* note 74.

80. *Id.*

81. Herper & Ruiz, *supra* note 3.

82. *See id.*

83. FTC Enforcement Policy Statement on Food Advertising, 59 Fed. Reg. 28,388 (June 1, 1994).

84. Gerhart, *supra* note 71.

85. *Id.*

claims be supported by “competent and reliable scientific evidence.”⁸⁶ The FTC has interpreted this requirement to mean: “[T]ests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.”⁸⁷

The reason for this flexible standard is twofold: First, to ensure that consumers have access to information about emerging areas of science; and second, to maintain consumer confidence in the accuracy of information presented in advertising.⁸⁸ Thus, there is no fixed formula for the amount or type of study required, or for more specific parameters like sample size and study duration. This case-by-case regulatory standard is inadequate and bad for both consumers and companies.

Most consumers are not in a position to critically evaluate the differences in credibility between small-scale manufactured studies and large double-blind, placebo-controlled studies.⁸⁹ Advertisers are permitted to tout their products’ health-enhancing benefits based on individual, manufacturer-sponsored studies,⁹⁰ which increases the likelihood that consumers will be misled. Essentially, these companies get the best medical research outcome that money can buy,⁹¹ regardless of whether the underlying studies are flawed.⁹²

86. 59 Fed. Reg. at 28,388.

87. *Id.*

88. *See id.* at 28,396. (“[W]hile the Commission recognizes the desirability of educating consumers about the role of other factors that bear on the risk of disease and how such factors interact with diet, the Commission must evaluate whether the failure to disclose such qualifying information in a claim about the health effects of a food would mislead consumers.”).

89. David Vinjamuri, *POM Wonderful’s Deception is the Tip of the Iceberg*, FORBES (May 23, 2012), <http://www.forbes.com/sites/davidvinjamuri/2012/05/23/judge-finds-pom-wonderful-advertising-deceptive-but-thats-just-the-tip-of-the-iceberg/>.

90. *Id.*

91. For example, in its advertisements, POM claimed to have invested more than \$35 million in research to prove that pomegranate juice has health benefits. *POM I*, *supra* note 26, at 295.

92. For example, one POM study on the effects of drinking pomegranate juice on myocardial perfusion, or blood flow to the heart, was conducted by Dr. Dean Ornish, a Clinical Professor of Medicine at the University of California at San Francisco and the Founder and President of the Preventative Medicine Research Institute in Sausalito, California. The study was originally designed to last 12 months, however, the FTC charged that the study was cut short when the three-month data came in favorably and Dr. Ornish faced cost overruns. Dr. Frank Sacks, an expert witness for the FTC, stated that the shortened study period and failure to report the planned duration were inconsistent with widely ac-

Why are misled and increasingly skeptical consumers bad for business?

Faced with a barrage of sensational claims relating to everything from weight loss to impotence, we lose a measure of trust in all brands. This loss of goodwill effectively becomes a tax born by ethical brands as well as dodgy ones, as gaining consumer trust and loyalty becomes more difficult and more expensive for all.⁹³

While the FTC and FDA have the enforcement power to stop false and misleading claims, both agencies are subjected to continuous budget pressure, and in practice, only the most egregious offenders are addressed.⁹⁴ For this reason, the FTC is seeking voluntary compliance from offending businesses through consent orders.⁹⁵ The FTC's ability to regulate through these voluntary consent orders, however, is being challenged.⁹⁶

II. Voluntary Consent Orders: Regulation in the Twenty-First Century?

The litigation between the FTC and POM began in September 2010 when POM filed an action in the District Court for the District of Columbia, seeking a declaratory judgment against the FTC.⁹⁷ To give some background, in July 2010, the FTC entered into voluntary consent agreements with two companies, Nestlé Health Care Nutrition and Iovate Health Sciences USA, whose advertisements were deemed to overstate their products' effect on disease prevention and mitigation by the FTC.⁹⁸ Both agreements required the companies to root their future health claims in "competent and reliable scientific evidence . . . consist[ing] of at least two adequate and well controlled

cepted standards for conduct of clinical trials and undermine any confidence in the standings. In response, Dr. Ornish testified that the study was cut short only because the Resnicks did not provide the funding that they had previously committed to. *POM I*, *supra* note 26 at 268–69.

93. Vinjamuri, *supra* note 89.

94. *Id.*

95. "A company that signs a consent order need not admit that it violated the law, but it must agree to stop the disputed practices outlined in an accompanying complaint." *Consumer Protection: Law Enforcement*, FED. TRADE COMM'N (July 27, 2007), <http://www.ftc.gov/bcp/menus/resources/enforcement.shtm>.

96. See discussion *infra* Part II.B.

97. *POM Wonderful LLC v. FTC*, No. 10–1539 (RWR), 2012 WL 4475698 (D.D.C. Sept. 30, 2012).

98. *Id.*; see also *FTC v. Iovate Health Scis. USA, Inc.*, No. 10–cv–587 (W.D.N.Y. July 29, 2010), available at <http://www.ftc.gov/os/caselist/0723187/100729iovatestip.pdf>; Agreement Containing Consent Order, Nestlé HealthCare Nutrition, Inc., No. 092–3087, 2010 WL 2811203, at *10 (F.T.C. July 14, 2010).

human clinical studies of the product.”⁹⁹ The Nestlé agreement also provided that all disease-based representations be pre-approved by the FDA.¹⁰⁰

In its complaint, POM alleged that the FTC had enacted new and obligatory advertising standards, including heightened standards for scientific studies and prior FDA approval for all health claims, by publishing the Nestlé and Iovate consent orders and insisting the orders had the force of law.¹⁰¹ POM sought judgment that these purported new rules governing disease claims in food advertising exceeded the FTC’s statutory authority, violated POM’s First and Fifth Amendment rights, violated the rulemaking procedures of the FTC and the Administrative Procedures Act (“APA”),¹⁰² and were arbitrary and capricious.¹⁰³

A. Notice-and-Comment Rulemaking Versus Voluntary Consent Orders

The FTC promulgates broad policies in accordance with the administrative law concept of “rulemaking”. In *National Petroleum Refiners Association v. FTC*,¹⁰⁴ the District of Columbia Court of Appeals upheld the agency’s authority to make legislative rules, those that have the force of law through the informal procedures of section 553 of the APA. Notice-and-comment rulemaking (otherwise known as informal rulemaking) is a common rulemaking procedure under which a proposed agency rule is published in the *Federal Register* and is open to comment by the general public.¹⁰⁵

Section 553 provides that legislative rules should be made after publishing notice in the *Federal Register*, giving opportunity for written

99. See *Iovate*, No. 10-cv-587, at 7; *Nestlé*, No. 092-3087, at *4.

100. *Nestlé*, No. 092-3087, at *3.

101. Complaint for Declaratory Relief at 6, *POM Wonderful LLC v. FTC*, No. 10-01539, 2010 WL 3968871 (D.D.C. Sept. 13, 2010).

102. Administrative Procedure Act (APA) of 1946, 5 U.S.C. §§ 500-559 (2006).

103. *POM Wonderful LLC*, No. 10-1539 (RWR), 2012 WL 4475698, at *41.

104. 482 F.2d 672 (D.D.C. 1973).

105. 5 U.S.C. § 553. The APA, however, has carved out a number of exceptions to the procedural informal rulemaking requirements. For example, all rules pertaining to (1) “a military or foreign affairs function of the United States,” (2) “a matter relating to agency management or personnel,” or (3) a matter relating to “public property, loans, grants, benefits, or contracts” are wholly exempt. 5 U.S.C. § 553(a). The APA also provides an exception to the notice-and-comment rulemaking procedure for “interpretative rules, general statements of policy, and rules of agency organization, procedure, or practice.” *Id.* § 553(b)(A).

comments, and providing a statement of support for the rules.¹⁰⁶ The final rule must be published in the *Federal Register* not less than thirty days before the rule's effective date.¹⁰⁷ Many commentators feel that notice-and-comment rulemaking, is an effective and equitable mechanism.¹⁰⁸ Despite its general efficacy, business interest groups have regularly criticized the FTC's legislative rulemaking activities.¹⁰⁹

Consequently, the FTC also seeks compliance from offending companies through individual consent orders. Generally, the FTC begins investigating a company it believes is making dubious or exaggerated claims. For example, the FTC's consent agreement with Nestlé regarding the company's BOOST Kid Essentials drink.¹¹⁰ If the results of the investigation reveal unlawful conduct, the FTC may seek voluntary compliance by the offending company through a consent order in lieu of filing an administrative complaint.¹¹¹ Since the agreement is private, it may contain any measure agreed upon, regardless of what is considered common practice in the industry.

In effect, consent decrees allow the FTC to effectively (and extrajudiciously) regulate offending companies, while companies are spared the immediate costs and consequences of litigation. The practice, however, may have industry-wide impact, as the FTC is accused of using consent orders to leverage other companies, like POM, into greater compliance.¹¹²

B. *POM Wonderful, LLC v. FTC*

In its federal complaint, POM alleged that the FTC specifically advised POM that it was applying a new standard of review for deceptive advertising based on the Nestlé and Iovate consent orders.¹¹³ According to this new standard, advertisers were required to: (1) obtain prior FDA approval before making certain types of health claims, specifically disease claims; and (2) conduct two well-controlled clinical

106. Charles Koch & Beth Martin, *FTC Rulemaking Through Negotiation*, 61 N.C. L. REV. 275, 279 (1983).

107. 5 U.S.C. § 552(d)(1).

108. Koch & Martin, *supra* note 106, at 280.

109. *Id.*

110. *See, e.g.*, Agreement Containing Consent Order, Nestlé HealthCare Nutrition, Inc., No. 092-3087, 2010 WL 2811203 (F.T.C. July 14, 2010).

111. *See, e.g., id.*

112. *See infra* Part II.B.

113. Complaint for Declaratory Relief at 6, *POM Wonderful LLC v. FTC*, No. 10-01539, 2010 WL 3968871 (D.D.C. Sept. 13, 2010).

studies for non-disease claims.¹¹⁴ POM alleged that these new standards were “not merely interpret[ive of] present standards or rules,” but rather were directly contrary to “over twenty . . . years of FTC food advertising rules and regulations.”¹¹⁵

POM believed that the FTC violated the APA by implementing a new rule requiring RCTs without notice-and-comment rulemaking.¹¹⁶ POM also alleged that the FTC had never before “require[d] prior FDA approval” irrespective of whether the claims “are true or supported by competent, reliable scientific evidence[.]”¹¹⁷ According to POM, by requiring prior FDA approval regardless of whether the claims are true or supported by competent and reliable scientific evidence, the FTC was seeking to restrain non-deceptive speech, in violation of the First Amendment and the FTC’s statutory authority.¹¹⁸

Shortly after POM filed its action for declaratory relief, the FTC filed an administrative complaint against POM.¹¹⁹ In September 2012, the district court declined to exercise its discretionary jurisdiction under the Declaratory Judgment Act and dismissed POM’s suit due to the pending overlapping proceeding.¹²⁰

III. In the Matter of POM (Not So) Wonderful

Two weeks after POM filed its claim against the FTC in federal court, the FTC filed an administrative complaint against POM.¹²¹ The FTC alleged that POM engaged in deceptive acts and disseminated false advertising in violation of sections 5(a) and 12 of the FTC Act.¹²²

114. POM Wonderful LLC v. FTC, No. 10-1539 (RWR), 2012 WL 4475698, at *1 (D.D.C. Sept. 30, 2012).

115. *Id.*

116. *Id.*

117. *Id.*

118. *Id.* at *2.

119. *Id.*

120. POM Wonderful Sept. 30, 2012, *supra* note 114, at *2. In dismissing the suit, the court noted that “[g]enerally, in the interest of judicial efficiency, courts decline to hear declaratory judgment actions that would not fully resolve the parties’ claims. Here, if the court resolved the issues POM raised in its declaratory judgment action, the parties would still have to litigate whether POM’s health claims about its products were false, misleading, and unsubstantiated in violation of the FTC Act.” *Id.* The court further stated that the Commission hearing “is ‘perfectly capable’ of determining whether the proposed order exceeds the bounds of the FTC Act, violates the First and Fifth Amendments, and seeks to abrogate the FDA’s power.” *Id.* at *3 (citation omitted).

121. *See* POM Complaint, *supra* note 15.

122. *Id.* As previously discussed, Section 5(a) of the FTC Act provides that “unfair or deceptive acts or practices in or affecting commerce are hereby declared unlawful.” 15 U.S.C. § 45(a)(1) (2006). Section 12 of the FTC Act prohibits the dissemination of “any false advertisement” in order to induce the purchase of “food, drugs, devices, services, or

The FTC challenged forty-three POM advertisements and promotional pieces, including print advertisements, newsletters, website advertisements, and “public relations” promotional materials.¹²³ Specifically, the FTC alleged that POM’s ads represented that the daily consumption of the Challenged POM Products will “treat, prevent, or reduce the risk of heart disease . . . prostate cancer . . . [or] erectile dysfunction,” without having a reasonable basis to substantiate such claims.¹²⁴ Additionally, POM’s ads claimed “clinical studies, research, and/or trials prove that consuming the POM Products ‘prevents or reduces the risk of’ or ‘treats’ heart disease, prostate cancer or erectile dysfunction,” when in fact clinical studies, research, or trials did not so prove.¹²⁵ The FTC proposed that POM agree to pre-screening by the FDA of any claims that its products cure, prevent, treat, or reduce the risk of any disease to prevent future violations.¹²⁷ The FTC also demanded that POM refrain from making any other health-related claims about its products without “competent and reliable scientific evidence” from two RCTs.¹²⁸

In determining whether POM disseminated false or misleading advertisements, the ALJ and Commission used the following three-part inquiry: “(1) whether [POM] disseminated advertisements conveying the claims alleged in the Complaint; (2) whether those claims were false or misleading; and (3) whether those claims are material to prospective consumers.”¹²⁹

A. Step One: Identifying Claims and Interpreting Ad Meaning

The first step in evaluating the truthfulness and accuracy of advertising is identifying all express and implied claims that an ad conveys to consumers.¹³⁰ Although advertisers must ensure that whatever is expressly claimed in an ad is accurate, an advertiser is equally re-

cosmetics.” *Id.* § 52(a)(2). For the purposes of Section 12, “false advertisement” is defined as “an advertisement, other than labeling, which is misleading in a material respect.” *Id.* § 55(a).

123. *POM I*, *supra* note 26, at 207.

124. POM Complaint, *supra* note 15, at 16–19.

125. *Id.* at 16–17.

126. *Id.*

127. *Id.* at 22.

128. *Id.*

129. *POM I*, *supra* note 26, at 211.

130. FTC Deception Statement, *supra* note 32, at 175.

sponsible for the accuracy of claims suggested or implied.¹³¹ Thus, advertisers cannot suggest claims that they could not make directly, through, for example, the juxtaposition of phrases and images.

In their complaint, the FTC believed that POM's advertisements claimed daily consumption of Challenged POM Products "treats, prevents or reduces the risk of heart disease, prostate cancer, or erectile dysfunction."¹³² Claims that a product is effective without expressly or impliedly representing a level of support are called "efficacy claims."¹³³ According to the FTC, POM falsely represented that it possessed and relied upon a reasonable basis for substantiating its efficacy claims.¹³⁴ Consequently, the representations were false or misleading.¹³⁵

POM also represented that "clinical studies, research, and/or trials prove" that drinking POM Juice or taking POMx Pills or Liquid daily treats the diseases or prevents or reduces the risk of each of the diseases.¹³⁶ Such claims are referred to as "establishment claims"—expressly or clearly implied statements that the advertising claim is supported by scientific or medical studies.¹³⁷ Common examples of establishment claims include statements such as "tests prove," "studies show," or "doctors recommend."¹³⁸

The ALJ found that nineteen of the forty-three challenged ads and promotional materials conveyed health claims, but the Commission believed that the actual number was thirty-six.¹³⁹

Because none of the ads expressly stated that the Challenged POM Products "treat, prevent, or reduce the risk of heart disease, prostate cancer, or erectile dysfunction," the Commission relied on the ads' implicit messages. Declining to focus solely on the individual phrases or statements in the ads—many of which were humorous or irreverent like the "Cheat Death" slogan—the Commission considered the individual ads as a whole.¹⁴⁰ Assessing the "net impression" of

131. FED. TRADE COMM'N, BUREAU OF CONSUMER PROTECTION, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY (2001), available at <http://business.ftc.gov/sites/default/files/pdf/bus09-dietary-supplements-advertising-guide-industry.pdf>.

132. See POM Complaint, *supra* note 15, ¶¶ 9–10, 19.

133. POM II, *supra* note 12, at 7.

134. *Id.* at 18.

135. *Id.*

136. *Id.* (citing POM Complaint, *supra* note 15, ¶¶ 9–10, 12, 14, 16).

137. FTC Advertising Statement, *supra* note 32, at 194 ("Advertisements that claim a certain type or level of support are considered establishment claims.")

138. *Id.*

139. POM II, *supra* note 12, at 9.

140. *Id.* at 9–12.

the ads through words and images, both the ALJ and Commission found that certain ads made health claims indirectly through logical syllogism.¹⁴¹ For instance: “free radicals cause or contribute to heart disease; the POM Products contain antioxidants that neutralize free radicals; therefore, the POM Products are effective for heart disease.”¹⁴²

As to the establishment claims, the Commission found that POM’s textual representations (i.e., “eight ounces a day can reduce plaque by up to 30%!”) that specified scientific support (i.e., “[b]ased on a clinical study”) conveyed the existence of clinical proof for the disease claims made, regardless of the small print and qualified assertion.¹⁴³ Furthermore, the Commission noted that statements relating to the millions of dollars spent on medical research reinforced the impression that the research supporting the claims was established and not merely preliminary.¹⁴⁴

B. Step Two: False and Deceptive or Substantiated

Since thirty-six ads implied that the Challenged POM Products provided a disease benefit, the next question was whether POM could adequately substantiate its health claims. Because POM lacked adequate substantiation, its claims were deemed false (as to the establishment claims) and lacking a reasonable basis (as to the efficacy claims).¹⁴⁵

1. POM’s False Establishment Claims.

The FTC alleged, and the Commission agreed, that POM’s establishment claims were false.¹⁴⁶ The company did not possess a level of proof sufficient to satisfy the relevant scientific community of the claim’s truth, specifically that the Challenged POM Products treat, prevent, or reduce the risk of heart disease, prostate cancer, or erec-

141. *POM I*, *supra* note 26, at 225.

142. *Id.*

143. *POM II*, *supra* note 12, at 13. The Commission noted:

The specific percentage reduction of plaque in someone’s arteries cannot be ascertained by any means other than by scientific measurement, and the statement therefore implies that the claim of plaque reduction is scientifically established. The claim of scientific proof is bolstered by the asterisk that directs the reader to the quoted citation for the ‘clinical pilot study,’ which the Commission acknowledges is in small print.

Id.

144. *Id.* at 14.

145. *Id.* at 34, 38.

146. *Id.* at 12–14.

tile dysfunction.¹⁴⁷ In order to determine the standards that the relevant scientific and medical communities would demand, the Commission reviewed the testimony of the fourteen expert witnesses qualified in the fields of heart disease, prostate cancer, and erectile dysfunction who were called as witnesses by the FTC and POM before the ALJ.¹⁴⁸

Based on a review of the entire record, including 2000 exhibits and a 3300 page transcript, the Commission concluded that: (1) POM's establishment claims were not adequately substantiated; and (2) a higher level of substantiation would be necessary to support POM's establishment claims.¹⁴⁹ The ALJ determined that experts in the relevant fields would require "competent and reliable evidence [that] must include clinical studies although not necessarily RCTs" to support POM's claims.¹⁵⁰ In contrast, the Commission found that experts required RCTs to establish a causal relationship between food and the treatment, prevention, or reduction of the risk of heart disease, prostate cancer, or erectile dysfunction.¹⁵¹

2. POM's Efficacy Claims Lacked a Reasonable Basis.

The FTC alleged that POM lacked a "reasonable basis" for its efficacy claims.¹⁵² "[A]n objective claim about a product's performance or efficacy carries with it an express or implied representation that the advertiser had a reasonable basis of support for the claim."¹⁵³ In determining what constitutes a reasonable basis, the FTC generally considers the "Pfizer factors," factors relevant to the benefit and costs of substantiating a claim.¹⁵⁴

147. *Id.*

148. *Id.* at 22.

149. *POM II*, *supra* note 12, at 22.

150. *POM I*, *supra* note 26, at 253.

151. *POM II*, *supra* note 12, at 23. The Commission found "that RCTs are required to substantiate [POM's] disease claims because it is necessary to isolate the effect of consuming the Challenged POM Products on the incidence of the disease, and the expert testimony revealed that only RCTs can isolate that effect." *Id.*

152. *Id.* at 17.

153. *Id.* (citing *Thompson Med. Co.*, 104 F.T.C. 648.813 (1984)) "Consumers find these representations of support to be important in evaluating the reliability of the product claims. Therefore, injury is likely if the advertisement lacks support for the claims." *Id.*

154. *Id.* at 18; FTC Advertising Statement, *supra* note 32, at 840 (explaining that the "determination of what constitutes a reasonable basis depends . . . on a number of factors relevant to the benefits and costs of substantiating a particular claim . . . [including,] the type of claim, the product, the consequences of a false claim, the benefits of a truthful claim, the cost of developing substantiation for the claim, and the amount of substantiation experts in the field believe is reasonable").

The experts called by both the FTC and POM consistently testified that the degree of substantiation necessary for general nutritional and health benefits claims is different than the requisite level of substantiation for specific disease treatment and prevention claims.¹⁵⁵ Thus, according to one POM expert, “the standard of substantiation is different for a product that is directly associated as a treatment for erectile dysfunction and for a product that claims to have helpful benefits for or improves one’s erectile function.”¹⁵⁶

After the Commission found that the efficacy claims made by POM were related to disease treatment and prevention, it declined to determine the requisite level of substantiation for generalized nutritional and health claims involving food products.¹⁵⁷ POM argued that pomegranate juice’s categorization as a non-hazardous food¹⁵⁸ should exempt POM from the RCT requirement because such studies are impractical, impossible, unethical, and too costly.¹⁵⁹ This argument was rejected.¹⁶⁰ Focusing on the nature of the claims made—disease claims—rather than the nature of the product making the claim—all-natural pomegranate juice—the Commission determined that RCTs were required to substantiate POM’s efficacy claims.¹⁶¹

C. Step Three: POM’s Claims Were Material

A misleading claim in advertising only violates the FTC Act if the misleading information is a material factor in the consumer’s decision to purchase the product.¹⁶² A “material misrepresentation” is one that is likely to affect a consumer’s conduct with respect to the product or service.¹⁶³ “Express claims, claims significantly involving health or safety, and claims pertaining to the central characteristic of the prod-

155. *POM II*, *supra* note 12, at 20. Expert Dr. Stamper explained that if the claim does not imply a causal link, then evidence short of RCTs would support the claim. *Id.* Even if a product is safe and might create a benefit, like a fruit juice, he would still require an RCT to justify claims that POM was charged with making. *Id.*

156. *Id.*

157. *Id.* at 20–21.

158. The FDA maintains a list of substances that it identifies as “Generally Regarded As Safe” (“GRAS”). *POM I*, *supra* note 26, at 14. Before a substance can be GRAS identified, the FDA reviews the scientific literature and the traditional consumption of the substance. Both pomegranate juice and pomegranate extract are GRAS identified. *Id.*

159. *POM II*, *supra* note 12, at 24–25.

160. *Id.*

161. *Id.* at 22.

162. *In re Am. Home Prods. Corp.*, 98 F.T.C. 136, 368 (1981).

163. FTC Deception Statement, *supra* note 32, at 182.

uct,” are presumptively material.¹⁶⁴ Consequently, because the claims made by POM in the challenged advertisements were health-related claims, they were presumptively material.¹⁶⁵

POM argued that the claims were immaterial because they related to the health benefits of the Challenged POM Products, as opposed to claiming to prevent disease.¹⁶⁶ The ALJ and the Commission disagreed.¹⁶⁷ Noting that the focus of the ads was not the Challenged POM Products’ “taste, price, or other attributes, but rather their impact on heart disease, prostate cancer or ED(erecile dysfunction),” the Commission concluded that POM[’s] “products’ impact on health was such a strong selling point that they invested over \$35 million to develop supporting evidence that they could use in marketing.”¹⁶⁸ The evidence indicated that POM was aware that sales increased when the results of POM health studies were advertised.¹⁶⁹ The Commission determined that it was “no great leap’ to find that consumer purchasing decisions would likely be influenced by claims that the Challenged POM Products treat, prevent, or reduce the risk of these diseases.”¹⁷⁰

D. Cease and Desist Order

Having determined that POM violated the FTC Act in a serious, deliberate, and consistent manner, the Commission affirmed the ALJ’s cease and desist order.¹⁷¹ The Commission ordered that POM “must have at least two RCTs before making any representation regarding a product’s effectiveness in the diagnosis, treatment, or prevention of any disease.”¹⁷² The order applied to “any food, drug, or

164. *In re* Novartis Corp., 127 F.T.C. 580, 686 (1999) (citing FTC Deception Statement, *supra* note 32, at 182).

165. *POM II*, *supra* note 12, at 39.

166. *Id.*

167. *Id.* at 40.

168. *Id.*

169. According to one POM conducted consumer research study, forty-seven percent of the survey respondents that identified “health” as a reason for drinking pomegranate juice further chose POM because it “helps protect against prostate cancer.” *POM I*, *supra* note 26, at 293.

170. *POM II*, *supra* note 12, at 40 (internal citations omitted).

171. *Id.* at 49, 51.

172. *Id.* at 51. Commissioner Ohlhausen disagreed with the majority’s view that two RCTs are warranted, and would have required one RCT and regarded the study in view of other available scientific evidence. *Id.* at 51 n.36.

Requiring a second RCT is not reasonably related to the violations at issue in this case because a second study would not cure any particular statistical or methodological problems. . . . Repetition or replication of poorly designed studies does not make those studies sound. Moreover, although it might provide the Commission with some subjective comfort, requiring two RCTs does so at the expense of

dietary supplement” made by the manufacturer.¹⁷³ The Commission, however, declined to impose the FDA pre-clearance requirement.¹⁷⁴ Consequently, POM is permitted, with the appropriate substantiation, to advertise that their products treat, prevent, or reduce the risk of a disease without prior FDA approval.

Conclusion

In the Matter of POM Wonderful may have a significant and long-lasting impact on advertisers in the booming food and dietary supplement industry. Advertisers are paying close attention to this case as it winds its way back into federal court. With this decision, the FTC has taken the unprecedented step of holding food companies to standards that more closely resemble the standards applicable to pharmaceutical companies. Arguably, this step is in response to the evolving understanding amongst Americans of the relationship between food, diet, and health, in conjunction with the food industry’s desire to exploit this relationship.

What effect will this have on consumers? According to POM, who intends to appeal the decision, this “new legal standard would require food companies to conduct double-blind, placebo-controlled studies in order to talk about potential health benefits of fruits and vegetables.”¹⁷⁵ To POM, this represents a giant step backward in the campaign to get Americans to eat healthier.¹⁷⁶ This assumes, of course, that Americans only reach for healthy foods when those foods claim to treat, prevent, or reduce the risk of serious and potentially fatal dis-

limiting consumer access to potentially useful information. The product at issue is an admittedly safe food product – a type of fruit juice. To set an unnecessarily high bar for such a product is in tension with the balanced approach to substantiation set forth in the Commission’s own *Pfizer* factors and with our policy commitment to avoid imposing “unduly burdensome restrictions that might chill information useful to consumers in making purchasing decisions.” To set an especially high bar without an adequate rationale also raises First Amendment concerns. 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.” (internal citations omitted).

Id.

173. *Id.* at 50.

174. *Id.* at 52.

175. Diane Suchetka, *POM Wonderful Ordered to Stop Making Health Claims*, CLEVELAND.COM (Jan. 28, 2013), http://www.cleveland.com/healthfit/index.ssf/2013/01/pom_wonderful_ordered_to_stop.html.

176. *Id.*

eases. Apparently, merely being part of a healthy and well-balanced diet doesn't cut it anymore.

Congress could fairly easily enact a law that would provide clear guidelines on the amount and type of evidence required to substantiate a food health claim in a manner that is understood by consumers and backed by good science. By differentiating between food and drug manufacturers, such a law would encourage food companies to raise awareness of the correlation between overall health and a balanced diet. Without additional guidance from Congress, however, a federal court may ultimately decide whether substantiation is *only* possible with an RCT.

Although consumer and industry groups are clashing over how and if the government should regulate these claims, the need is clear. If case-by-case litigation continues to define the parameters of permissible claims, consumers will continue to be misled, and all brands will pay the price.

