Stopping Deceptive Health Claims: The Need for a Private Right of Action under Federal Law

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I. INTRODUCTION

Consumers are currently facing a torrent of new health claims as they shop for food and dietary supplements (hereinafter referred to as "nutritional products") in grocery stores, pharmacies, health food stores and on the Internet.[1] Some of these products make claims that they support immunity, improve memory,[2] and even cure cancer.[3] Such claims appear to correspond to a growing consumer demand for foods and supplements that improve or maintain

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[1] *See, e.g.*, Editors, *Snake Oil in the Supermarket*, SCIENTIFIC AMERICAN (Aug. 1, 2010), http://www.scientificamerican.com/article/snake-oil-in-the-supermarket/ (stating that "[f]rom cereals that boost immunity to yogurts that regulate digestion and juices that keep heart disease at bay, grocery stores in the U.S. are brimming with packaged foods and beverages that claim to improve health"); *see also* Caitlin Y. Kandil, *What Food Labels Really Mean*, U.S. NEWS & WORLD REPORT HEALTH (Aug. 22, 2012), http://health.usnews.com/health-news/articles/2012/08/22/what-food-labels-really-mean (stating that you can "[w]alk into any supermarket, and you'll find rows of packaged foods boasting how healthy they are").

[2] *See* Michael Taylor, *How the FDA Is Picking its Food Label Battles*, THE ATLANTIC (July 19, 2010), http://www.theatlantic.com/health/print/2010/07/how-the-fda-is-picking-its-food-label-battles/59927/.

[3] *See* David C. Vladeck, Director, Fed. Trade Comm'n Bureau of Consumer Protection, Remarks at the Annual Symposium for the Dietary Supplement Industry: Priorities for Dietary Supplement Advertising Enforcement 4 (Oct. 22, 2009), http://www.thenhf.com/pdf/VladedckCRNRemarks.pdf.

health and wellness.[4] A 2004 survey of U.S. consumers found that purchasing decisions in the food and dietary supplement markets "are guided almost entirely by product labeling claims."[5] Among the most persuasive of these are "claims that consumption may confer health benefits."[6]

Claims about health benefits are more persuasive to consumers when they appear to be authoritative. The problem with seemingly authoritative claims, however, is that most of them are neither based on rigorous clinical studies nor vetted by any government agency.[7] Some lack

[4] In the food arena, these products have been referred to as functional foods, i.e., foods that have a "potentially positive effect on health beyond basic nutrition." Katherine Zeratsky, *Nutrition and Healthy Eating: What are Functional Foods?*, MAYO CLINIC (Apr. 11, 2015), http://www.mayoclinic.org/healthy-living/nutrition-and-healthy-eating/expert-answers/functional-foods/faq-20057816. *See also infra* notes 37-44 and accompanying text.

[5] Leah A. Satine, *Is My Yogurt Lying? Developing and Applying a Framework for Determining Whether Wellness Claims on Probiotic Yogurts Mislead*, 63 FOOD & DRUG L.J. 537, 537 (2008).

[6] *Id.* at 538. The Academy of Nutrition and Dietetics links the growing demand for these nutritional products to rising health-care costs and scientific research supporting a connection between a good diet and a lower incidence of chronic disease. *See* Consumers Union of U.S. Inc., *'Functional Food' is Hot, but its Claims of Health Benefits Rely on Flimsy Data*, WASH. POST (June 18, 2012), http://www.washingtonpost.com/national/health-science/functional-food-is-hot-but-its-claims-of-health-benefits-rely-on-flimsy-data/2012/06/18/gJQAWmxflV_story.html.

[7] *See* Matthew Herper & Rebecca Ruiz, *Snake Oil in Your Snacks*, FORBES (May 20, 2010), http://www.forbes.com/forbes/2010/0607/health-probiotics-vitamins-supplements-snake-oil-in-snacks.html; *see also* Rahi Azizi, *"Supplementing" the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act*, 98 CAL. L. REV. 439, 440 (2010) ("'Nutraceutical' products—functional foods taken to enhance health, like vitamins or herbal and botanical products intended for ingestion—often carry labels that claim ambiguous benefits, but fail to demonstrate any measurable degree of efficacy.").

any evidence of effectiveness;[8] others go beyond what is permitted by law.[9] Although this problem has been recognized for some while,[10] it is compounded by the vigorous marketing of new product lines, such as probiotics, claiming a wide variety of health benefits.[11] The growing market for these new products,[12] coupled with lack of reliable studies of their efficacy,[13] create additional challenges for consumers and regulators.[14]

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[8] *See* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, DIETARY SUPPLEMENTS: COMPANIES MAY BE DIFFICULT TO LOCATE IN AN EMERGENCY (Oct. 2012), https://oig.hhs.gov/oei/reports/oei-01-11-00211.pdf. *See also* Herper & Ruiz, *supra* note 7; *see also* Azizi, *supra* note 7.

[9] Vladeck, *supra* note 3, at 2 (stating that "[s]ome marketers of dietary supplements make disease treatment and prevention claims that far exceed the bounds of the structure/function claims that are permitted under the Dietary Supplement Health and Education Act (DSHEA)"). *See also* OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, DIETARY SUPPLEMENTS: STRUCTURE/FUNCTION CLAIMS FAIL TO MEET FEDERAL REQUIREMENTS (Oct. 2012), https://oig.hhs.gov/oei/reports/oei-01-11-00210.pdf [hereinafter STRUCTURE/FUNCTION CLAIMS FAIL]; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-10-662T, HERBAL DIETARY SUPPLEMENTS: EXAMPLES OF DECEPTIVE OR QUESTIONABLE MARKETING PRACTICES AND POTENTIALLY DANGEROUS ADVICE (May 26, 2010), http://www.gao.gov/new.items/d10662t.pdf (testimony of Gregory D. Kutz, Managing Dir., Forensic Audits and Special Investigations, U.S. Gov't Accountability Office) [hereinafter Testimony of Gregory D. Kutz].

[10] *See, e.g.*, Norman J. Temple, *The Marketing of Dietary Supplements in North America: The Emperor is (Almost) Naked*, 16 J. ALTERNATIVE & COMPLEMENTARY MED. 803 (2010).

[11] Probiotics are products with live microorganisms that can confer a health benefit. *See* JOINT FOOD AND AGRICULTURE ORG. OF THE U.N./WORLD HEALTH ORG. EXPERT CONSULTATION, REPORT: HEALTH AND NUTRITIONAL PROPERTIES OF PROBIOTICS IN FOOD INCLUDING POWDER MILK WITH LIVE LACTIC ACID BACTERIA (Oct. 1-4, 2001), ftp://ftp.fao.org/es/esn/food/probio_report_en.pdf.

[12] *See* Nandhini Rajagopal, *The North American Probiotics Market*, NATURAL PRODUCTS INSIDER (Oct. 3, 2012), http://www.naturalproductsinsider.com/articles/2012/10/the-north-american-probiotics-market.aspx. *See also* Vijaya K. Gogineni et al., *Probiotics: History and Evolution*, J. ANCIENT DISEASES & PREVENTIVE REMEDIES (Aug. 2013), http://esciencecentral.org/journals/probiotics-history-and-evolution-2329-8731.1000107.pdf; Keith Nunes, *United*

Preventing deceptive claims[15] about the health-related benefits of nutritional products is an important goal of federal and state consumer protection policy. Promoting nutritional products through deceptive claims can cause a variety of harms. The most obvious is the financial exploitation of consumers through deceptively induced sales. Even more troubling is the potential for harm by giving consumers false hope that nutritional products are the best response to health problems. In the case of some nutritional products, Internet ads claim that they can improve symptoms related to serious illnesses, including chronic diseases or chronic pain.[16] Such

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States Poised to Lead Functional Food Market, FOOD BUS. NEWS (Dec. 10, 2014), http://www.foodbusinessnews.net/articles/news_home/Business_News/2014/12/United_States_poised_to_lead_f.aspx?ID=%7B3E104CB5-F892-46A3-B989-4A798CBB1B66%7D&cck=1 (stating that the leading product categories that will help the U.S. surpass Japan as the number one consumer of functional foods in the world is dairy foods that contain probiotics and products containing whole grains).

[13] *See* Gregor Reid et al., *Potential Uses of Probiotics in Clinical Practice*, 16 CLINICAL MICROBIOLOGY REVIEWS 658 (2003) (stating that "[m]any so-called probiotic products have not been properly identified, documented, manufactured under good manufacturing practices or proven clinically, yet various companies make claims that lead consumers and caregivers to believe they are using reliable products").

[14] *See* Melody J. Slashinski et al., *"Snake-oil," "Quack Medicine," and "Industrially Cultured Organisms": Biovalue and the Commercialization of Human Microbiome Research*, BMC MED. ETHICS (Oct. 2012), http://www.biomedcentral.com/content/pdf/1472-6939-13-28.pdf.

[15] In this article, we use the general term "deceptive" to encompass the making of express or implied health claims that are false, misleading, or unsupported by competent and reliable scientific evidence. The term "unsubstantiated" refers to the last of these unlawful practices. *See generally* U.S. FED. TRADE COMM'N, ENFORCEMENT POLICY STATEMENT ON FOOD ADVERTISING (May 13, 1994), https://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising.

[16] In remarks to Congress, David Vladeck, former Director of the FTC Bureau of Consumer Protection, stated that "Consumers suffering from serious health ailments are particularly vulnerable and sometimes desperate. The

claims might lead consumers to forgo medically recommended therapies. Consumers who are taking prescription drugs face the additional risk that some of these products, in particular dietary supplements, may result in harmful interactions.[17]

Claims made by foods and dietary supplement manufacturers are regulated by both the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC).[18] FDA regulates labeling, while the FTC regulates advertising.[19] Under the Food, Drug and Cosmetic (FD&C) Act, labels on these products must not be false or misleading.[20] Under the FTC Act, claims in advertising made about foods and dietary supplements may not be "unfair" or "deceptive".[21]

While FDA and the FTC have made some efforts to challenge companies making deceptive health claims,[22] lack of resources for enforcement, the difficulty of policing advertising on the

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marketing of unfounded treatments to such people offers a type of false hope that is particularly cruel." Vladeck, *supra* note 3. Vulnerable populations often include senior citizens and adolescents. *See* Azizi, *supra* note 7, at 447.

[17] *See* H-H. Tsai et al., *Evaluation of Documented Drug Interactions and Contraindications Associated with Herbs and Dietary Supplements: A Systematic Literature Review*, 66 INT'L J. CLINICAL PRACTICE 1056 (2012).

[18] *See infra* Section III.

[19] Advertisements include claims made in newspapers and magazines, on television or radio, online, in the mail, or on billboards or buses. *See Truth in Advertising*, U.S. FED. TRADE COMM'N, www.ftc.gov/news-events/media-resources/truth-advertising (last visited Aug. 18, 2015).

[20] *See* 21 U.S.C. § 343(a) (2012); *see also infra* Section III.A.

[21] *See* 15 U.S.C. § 45(a)(1) (2012); *see also infra* Section III.B.

[22] *See, e.g.*, Vladeck, *supra* note 3; Taylor, *supra* note 2. *See also* Sarah Klein, *POM-boozled: Do Health Drinks Live Up to Their Labels?*, CNN HEALTH (Oct. 27, 2010), http://www.cnn.com/2010/HEALTH/10/27/health.pom.drink.labels/ (noting that the FTC and FDA have been "cracking down on food and beverage makers for allegedly overselling the health benefits of their products"); *infra* Section III.C.

Internet, and the lure of profit by food and dietary supplement manufacturers make it virtually impossible for FDA and the FTC to keep pace with the marketing strategies for these products.[23] Moreover, FDA's regulatory power over these manufacturers has actually declined over the last few decades due to limitations placed on the agency by Congress and the courts.[24] In addition, it is unlikely that these enforcement mechanisms adequately deter "quick hit" marketers unconcerned about long-term business or reputation.

In order to bolster the enforcement tools available to combat the problem of deceptive health claims for nutritional products, we propose a limited private right of action under the Federal Trade Commission Act. As background to this proposal, in Section II of this article we expand on the problem of deceptive health claims for foods and dietary supplements amidst the growing demand for these products. In Section III, we describe the current legal standards under the FD&C and FTC Acts and state consumer protection laws governing deceptive claims made by nutritional product manufacturers and current enforcement efforts aimed at ensuring compliance with the laws. In Section IV, we describe the limits of existing law and enforcement capabilities of the relevant federal agencies as well as the limits and shortcomings of state laws and their use by consumers. In Section V, we describe the benefits, risks and contours of the proposed limited private right of action, with an emphasis on creating an approach that will augment existing enforcement tools and lead to more effective consumer protection without undermining important federal agency control and enforcement goals. In Appendix A, we offer suggested

[23] *See* Natasha Singer, *Foods With Benefits, or So They Say*, N.Y. TIMES (May 14, 2011), http://www.nytimes.com/2011/05/15/business/15food.html; *see also infra* Section IV.

[24] *See* Editors, *supra* note 1. *See also* 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/; *infra* Section IV.

language for a statutory amendment to the FTC Act establishing the proposed private right of action.

II. THE PROBLEM OF DECEPTIVE CLAIMS IN THE MARKETING OF NUTRITIONAL PRODUCTS

Several prominent news stories have reported a growing prevalence of deceptive health claims for nutritional products sold at grocery and drug stores.[25] For example, a 2011 *New York Times* article quotes consumer advocates and nutritionists as stating that "shoppers are being bamboozled by slick marketing" of these products and that these products are not about health, but about marketing.[26] Similarly, a 2010 *Scientific American* article warned consumers that many supermarket health claims are not supported by science and the government does not endorse them.[27] These articles and others provide numerous examples of companies that lack substantiation for their claims or even ignore evidence that shows their product clearly does not do what they claim it does.[28] The claims are being made for two types of products: foods with

[25] *See* Consumers Union of U. S. Inc., *supra* note 6; Singer, *supra* note 23; Herper & Ruiz, *supra* note 7; Matthew Herper, *Wacky Food Health Claims*, FORBES (May 19, 2010) http://www.forbes.com/2010/05/19/food-claims-supplements-lifestyle-health-yogurt-margarine.html; Gyorgy Scrinis, *That's Not Natural or Organic: How Big Food Misleads*, SALON (July 20, 2013), http://www.salon.com/2013/07/20/thats_not_natural_or_organic_how_big_food_misleads/; Garance Burke, *Many Health Supplement Claims Misleading, Illegal*, WASH. TIMES (Oct. 3, 2012), http://www.washingtontimes.com/news/2012/oct/3/many-health-supplement-claims-misleading-illegal/?page=all.

[26] Singer, *supra* note 23.

[27] Editors, *supra* note 1.

[28] *See* Herper & Ruiz, *supra* note 7 (describing how Lifeway Foods, the maker of Probugs, a yogurt-like beverage for kids, ignored clinical trials results in making its claims).

alleged health benefits (also called functional foods[29]); and dietary supplements, such as vitamins, minerals, and herbs, intended to add nutritional value to the diet. Both consumer groups and government agencies have weighed in on the extent of the problem.

The Center for Science in the Public Interest (CSPI), a consumer advocacy organization with a mission to carry out "innovative research and advocacy programs in health and nutrition, and to provide consumers with current, useful information about their health and well-being,"[30] has made food labeling and deceptive health claims a priority in its advocacy program. In April 2013, the organization initiated its "Stop the Lying Labels" campaign.[31] In an email to members of a CSPI listserv, Michael Jacobson, the organization's executive director, stated that in his forty-plus years of dealing with the food industry, he has "never encountered such bold deception and disregard for the law" as he sees now in the area of food labeling.[32]

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[29] *See* Zeratsky, *supra* note 4.

[30] *Mission Statement*, CTR. FOR SCIENCE IN THE PUB. INTEREST, http://cspinet.org/about/mission.html (last visited Aug. 18, 2015).

[31] Michael F. Jacobson, *CSPI's Year-End Report to the Membership*, CTR. FOR SCIENCE IN THE PUB. INTEREST (Nov. 7, 2013), http://cspinet.org/about/CSPI-Year-End-Report-2013.pdf.

[32] E-mail from Michael Jacobson, Exec. Dir., Ctr. for Science in the Pub. Interest, to Diane Hoffmann, Professor of Law, Univ. Maryland Francis King Carey School of Law (Apr. 29, 2013, 08:31 EST) (on file with author). Jacobson provides the following examples: "General Mills' false claims that some of its corn-syrup-drenched products are 'natural'. . . Coca-Cola Company's deceptive health claims about its Vitamin water (which would be better called Sugar water). . . Amway's deceptive claims about "immunity system boosters" in its Nutrilite products (which do nothing to boost your immunity). . . Campbell's misleading labeling about sodium in its soups by pretending that people consume smaller serving sizes . . . and Dr. Pepper Snapple group's made-up claims of benefits from the antioxidants it adds to some of its 7UP sugar drinks, which promote obesity, not health." *Id.*

Similarly, government reports and statements have been critical of claims being made by dietary supplement manufacturers—in particular, structure/function claims.[33] The criticism is that these claims go outside the bounds of the regulatory limits on them and bleed into the disease claim (i.e., drug) category,[34] thus requiring premarketing approval by FDA, or that manufacturers have not done the studies necessary to substantiate their claims. In 2010, the Government Accountability Office (GAO) issued a report in which it described numerous examples of deceptive or questionable marketing practices by dietary supplement manufacturers and retailers. Most egregious of the practices they found were suspect claims that a dietary supplement "prevented or cured extremely serious diseases, such as cancer and cardiovascular diseases" or that it reduced the symptoms of Alzheimer's disease.[35]

The FTC has also asserted that the food and dietary supplement industries are making health claims that are often "false or unproven." In particular, the agency cites a "trend in food advertising toward making unproven claims that eating certain foods can improve health and even reduce the risk of serious illnesses such as prostate cancer and heart disease."[36]

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[33] These are "statements that describe the role of a nutrient or dietary ingredient intended to affect the structure or function in humans or that characterize the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function . . . ." 21 C.F.R. § 101.93(f) (2014). *See infra* notes 78-82 and accompanying text.

[34] *See* U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: STRUCTURE/FUNCTION CLAIMS, SMALL ENTITY COMPLIANCE GUIDE (Jan. 9, 2002), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/ucm103340.htm. *See infra* notes 60 and 61 and accompanying text.

[35] Testimony of Gregory D. Kutz, *supra* note 10.

[36] *Health and Fitness Claims*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/media-resources/truth-advertising/health-claims (last visited Aug. 18, 2015).

While there is little hard evidence of the extent of the problem, a walk through a supermarket or pharmacy reveals the pervasiveness of health claims on product labels. Moreover, the growing demand for these products suggests that the problem will increase over the next several years. Markets for both dietary supplements and functional foods are booming. A 2012 Department of Health and Human Services (DHHS) Office of Inspector General (OIG) report on structure/function claims about dietary supplements states that in this country, "dietary supplements are a $20 billion-per-year industry and are used by 80 percent of adults for a wide range of purposes."[37] The worldwide market for these products is also flourishing. According to a 2013 article in *Forbes*, "[o]ne of the fastest growing industries in the world is the nutritional supplement group. . . . Producing about $32 billion in revenue for just nutritional supplements alone in 2012, it is projected to double that by topping $60 billion in 2021."[38] The FTC suggests on its website that consumers have turned to supplements as a result of a "downturn in the economy" and as a way to "avoid expensive doctor visits and prescription medications."[39]

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[37] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 1 (citing Natural Products Foundation, *What is the Current Economic Contribution of the Dietary Supplement Industry to the U.S. Economy?*, NATURAL PRODUCTS FOUND. (rev. Mar. 2011), https://www.npainfo.org/App_Themes/NPA/docs/policy/Econ%20One%20sheet%203-11%20final.pdf). *See also* Farin Kamangar & Ashkan Emadi, *Vitamin and Mineral Supplements: Do We Really Need Them?*, 3 INT'L J. PREVENTIVE MED. 221 (2012) (estimating total sales of nutritional supplements in the United States in 2010 to have been over $28 billion).

[38] David Lariviere, *Nutritional Supplements Flexing Muscles as Growth Industry*, FORBES (Apr. 18, 2013), http://www.forbes.com/sites/davidlariviere/2013/04/18/nutritional-supplements-flexing-their-muscles-as-growth-industry/ (citing figures from the *Nutritional Business Journal*).

[39] *Health and Fitness Claims*, *supra* note 36.

The market for functional foods and beverages is growing at an even greater rate than dietary supplements, with the global market for these products reaching over $170 billion in 2013.[40] According to one source, "this booming category now accounts for 5% of the overall food market and is driving growth for the food industry as a whole."[41] This same source also attributes this sales growth to consumers looking to these products as a health solution. In particular, consumers are looking to functional foods as a way to manage "chronic conditions, such as diabetes, [cardio-vascular disease] or obesity."[42] Claimed benefits of these foods include boosting energy levels, improving or maintaining gut, bone and heart health, managing weight, and sharpening mental faculties.[43] One of the fastest growing segments of both the dietary supplement and functional food markets is probiotics, in large part due to manufacturers' claims for the role of probiotics in wellness and health improvement.[44]

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[40] Maggie Hennessy, *What's Driving Growth in Functional Food and Beverages? A Convergence of Nutrition, Convenience and Taste*, NUTRAINGREDIENTS-USA.COM (Sept. 27, 2013), http://www.nutraingredients-usa.com/Markets/What-s-driving-growth-in-functional-food-and-beverages-A-convergence-of-nutrition-convenience-and-taste.

[41] *Id.*

[42] *Id.*

[43] PRICE WATERHOUSE COOPERS, LEVERAGING GROWTH IN THE EMERGING FUNCTIONAL FOODS INDUSTRY: TRENDS AND MARKET OPPORTUNITIES 9 (Aug. 2009), http://www.pwc.com/us/en/transaction-services/publications/assets/functional-foods.pdf.

[44] *See* Hank Schultz, *Supplement Sales Hit $11.5 Billion in U.S., Report Says*, NUTRAINGREDIENTS-USA.COM (Sept. 20, 2012), http://www.nutraingredients-usa.com/Markets/Supplement-sales-hit-11.5-billion-in-U.S.-report-says (stating that in terms of different segments of the dietary supplement market, "digestive supplements are doing very well right now, especially probiotics"). *See also International Probiotics (Functional Foods, Dietary Supplements, Specialty Nutrients, Animal Feed) Market – Forecasts to 2019*, MARKETWIRED (July 2, 2014),

The functional food market consists of a number of large multinational companies,[45] but smaller participants are "successfully creating and defending niches in the market."[46] Large segments of the market include soft drinks (primarily enhanced water and energy drinks) and dairy products, especially yogurts. Both consumer demand and the potential for premium pricing by manufacturers and retailers[47] are attracting suppliers to this market.

Some observers differentiate between major manufacturers of nutritional products, with significant investments in brand reputations, and smaller manufacturers, some of which operate on the fringe of legality. Steve Mister, president of the Council for Responsible Nutrition, a trade association representing dietary supplement and functional food manufacturers, describes the supplement business as a "tale of two industries. There's a mainstream, responsible industry. Then there is this sort of shadow industry, the smaller guys playing around the fringes. The

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http://www.marketwired.com/press-release/international-probiotics-functional-foods-dietary-supplements-specialty-nutrients-animal-1926353.htm; Jane E. Brody, *Putting Good Bacteria to Work*, N.Y. TIMES (Sept. 14, 2004), http://www.nytimes.com/2004/09/14/health/14brod.html; *supra* note 12.

[45] Multinationals in the functional food market include PepsiCo, Coca-Cola, General Mills, Kellogg, Kraft, Nestle, Danone, Unilever and Yakult. *See* PRICE WATERHOUSE COOPERS, *supra* note 43, at 8.

[46] PRICE WATERHOUSE COOPERS, *supra* note 43, at 5.

[47] *See id.* at 10 (stating that "[a]lthough these products typically require greater initial R&D and ingredient costs, price premiums may reach 30 percent or higher, depending on the product").

problem is how we distinguish between the two."[48] He characterizes some members of the industry as "rogue players" who "are poisoning the reputation of the industry" for everyone.[49]

III. REGULATION OF HEALTH CLAIMS AND RECENT EFFORTS TO COMBAT DECEPTIVE CLAIMS

Federal statutes regulating deceptive health claims include the Food Drug and Cosmetic Act,[50] the Dietary Supplement Health and Education Act,[51] the Nutrition Labeling and Education Act,[52] and the Federal Trade Commission Act.[53] Each statute, augmented by agency regulations

[48] Alison Young, *Unmasking the People Behind Risky Pills: A USA Today Investigation*, USA TODAY (Dec. 20, 2013), http://www.usatoday.com/story/news/nation/2013/12/19/dietary-supplements-executives-criminal-records-spiked/4114451/.

[49] Steve Mister, *The Supplement Industry's 'Identity' Crisis*, NATURAL PRODUCTS INSIDER (Feb. 10, 2012), http://www.naturalproductsinsider.com/articles/2012/02/the-supplement-industry-s-identity-crisis.aspx (describing mislabeling and the use of substandard ingredients).

[50] Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (codified at 21 U.S.C. §§ 301–399).

[51] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4332 (codified at 21 U.S.C. §§ 301, 321, 342-343, 350(b) and 42 U.S.C. §287).

[52] Nutrition Labeling and Education Act (NLEA) of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343).

[53] 15 U.S.C. §§ 41-58 (2012). The Lanham Act also establishes a cause of action for false advertising. *See* 15 U.S.C. § 1125(a) (2012). However, only those who allege an injury to commercial interests have standing to bring a Lanham Act false advertising claim; consumers do not. Lexmark Int'l, Inc. v. Static Control Components, Inc., 134 S. Ct. 1377, 1390 (2014). *See also* POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234 (2014). Although consumers do not have a right of action under the Lanham Act, theories of Lanham Act liability and related burden of proof obligations may be pertinent to analysis of a state law based false advertising claim. *See In re* GNC Corp., 789 F.3d 505 (4th Cir. 2015).

and guidance documents, has a separate framework for establishing when claims violate the law. In addition to these federal laws, state consumer protection laws provide standards for making claims about consumer products and another enforcement avenue for consumers harmed by deceptive advertising.

A. *FDA*

FDA is responsible for assuring that foods and dietary supplements are properly labeled and, if they make claims about the products, that such claims are not false or misleading.[54] Food labeling is in large part governed by the Nutrition Labeling and Education Act (NLEA) of 1990, which requires most foods to include nutrition labeling and "requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements."[55] In addition, under the FD&C Act, foods and dietary supplements may not be adulterated or misbranded.[56] A product is misbranded if its label is "false or misleading in any particular"[57] or it is not in compliance with labeling requirements.[58] As to claims, FDA statutes and regulations permit manufacturers of foods and dietary supplements to make three types of claims on their labels: health, nutrient content, and structure/function claims.[59] Foods and dietary supplements

[54] 21 U.S.C. §§ 331(a), 343(a) (2012).

[55] U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE (Jan. 2013), http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf [hereinafter A FOOD LABELING GUIDE].

[56] 21 U.S.C. §§ 342-343 (2012).

[57] § 343(a)(1).

[58] § 343(a)(2).

[59] *See Label Claims for Conventional Foods and Dietary Supplements*, U.S. FOOD & DRUG ADMIN. (Dec. 2013), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm111447.htm [hereinafter *Label Claims*].

may not make disease claims, which are claims that describe the effect of a substance on the diagnosis, treatment, mitigation, cure or prevention of disease.[60] Any product that makes a disease claim is considered a drug and must go through the extensive and costly drug approval process prior to marketing.[61]

Of the three types of claims permissible for dietary supplements and foods, only claims in the health claim category require premarket approval by FDA. These claims include "health claims" and "qualified health claims." Prior to 1990, health claims on food products were prohibited. It was only after the passage of the NLEA[62] that health claims were permitted.[63]

FDA defines health claims as claims made on the label or in labeling of a food or dietary supplement that characterize the relationship between the labeled substance and reduced risk of a disease or health-related condition.[64] Health claims for foods *and* dietary supplements may be approved by FDA if there is "significant scientific agreement" that the claimed relationship between the nutritional product and reduction of risk of disease is true. FDA responds to a petition for approval and authorizes these types of health claims based on an extensive review of the scientific literature and by promulgation of a specific regulation permitting the claim.[65] An

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[60] *See* § 321(g)(1).

[61] *See Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN. (Oct. 27, 2014), http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ (describing the drug approval process).

[62] Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified at 21 U.S.C. § 343).

[63] *Id. See also* Constance J. Geiger, *Health Claims: History, Current Regulatory Status, and Consumer Research*, 98 J. AM. DIETETIC ASS'N 1312 (1998).

[64] U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE, *supra* note 55, at 80.

[65] *See Label Claims*, *supra* note 59. This mechanism of approval for health claims was established by the Nutrition Labeling and Education Act of 1990. *Id.*

example of a health claim approved under this process is "adequate calcium throughout life, as part of a well-balanced diet, may reduce the risk of osteoporosis".[66]

Under the Food and Drug Administration Modernization Act of 1997 (FDAMA), manufacturers may also make health claims for foods (but not dietary supplements) if the health claim is based on an "'authoritative statement' from a scientific body of the U.S. Government[67] or the National Academy of Sciences."[68] A food manufacturer or distributor that intends to make such a claim must submit a notification to FDA, which has 120 days to respond if it finds that the notification does not comply with FDAMA.[69] Marketing under this route does not require promulgation of a regulation; however, FDA may prohibit or modify such a claim by regulation.[70]

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[66] Health Claims: Calcium, Vitamin D, and Osteoporosis, 21 C.F.R. § 101.72(e) (2014).

[67] *Label Claims*, *supra* note 59. FDAMA specifically lists the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) as scientific bodies that would satisfy the statutory requirement. 21 U.S.C. § 343(r)(2)(G)(i) (2012). FDA has also stated that the Surgeon General within the Department of Health and Human Services, the Food and Nutrition Service, the Food Safety and Inspection Service, and the Agricultural Research Service within the Department of Agriculture, may serve as qualified "scientific bodies." *See Guidance for Industry: Notification of a Health Claim or Nutrient Content Claim Based on an Authoritative Statement of a Scientific* Body, U.S. FOOD & DRUG ADMIN. (July 11, 1998), http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm056975.htm [hereinafter *Notification of a Health Claim*].

[68] *Label Claims*, *supra* note 59.

[69] In such case, the submitter may revise the notification and resubmit it. The food may not be marketed with the revised claim until at least 120 days after resubmission. *Notification of a Health Claim*, *supra* note 67.

[70] *Id*.

An additional type of health claim, the "qualified health claim" (QHC), was established by FDA in response to a court's decision that a dietary supplement manufacturer has a First Amendment right to make health claims based on less scientific evidence than the standard of "significant scientific agreement," as long as such claims do not mislead consumers.[71] QHCs can be made for both foods and dietary supplements and differ from other health claims in that they must include a disclaimer or be otherwise qualified.[72] Manufacturers or distributors wishing to make a QHC must submit a petition to FDA summarizing the scientific data in support of the claim the petitioner wishes to make, including copies of computer literature searches, all research articles relied upon for support of the petition, and information about any adverse consequences from the food or dietary supplement for any segment of the U.S. population.[73]

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[71] *See* Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999). In *Pearson*, the plaintiffs (dietary supplement manufacturers) challenged FDA's health claim regulations for dietary supplements and the agency's decision not to approve health claims for four specific substance/disease relationships. The U.S. Court of Appeals for the D.C. Circuit held that the First Amendment does not permit the FDA to reject health claims that the agency determines to be potentially misleading, unless the agency also reasonably determines that no disclaimer would eliminate the potential deception. *Id.*

[72] An example of a QHC is: "One small study suggests that chromium picolinate may reduce the risk of insulin resistance. . . FDA concludes, however, that the existence of such a relationship . . . is highly uncertain." *Qualified Health Claims: Letter of Enforcement Discretion – Chromium Picolinate and Insulin Resistance (Docket No. 2004Q-0144)*, U.S. FOOD & DRUG ADMIN. (Aug. 25, 2005), http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073017.htm.

[73] *See* A FOOD LABELING GUIDE, *supra* note 55, at 83. This guidance document states:

> Within 15 days of receipt, FDA will acknowledge the petition. Within 45 days of receipt, FDA will file the petition and a docket number will be assigned. . . . At the time of filing, FDA will post the petition on the FDA webpage for a 60-day public comment period. During this time, written comments may be submitted to the docket. On or before 270 days after receipt of the petition, a

Food manufacturers may make a second type of claim, "nutrient content claims." Subject to FDA's criteria,[74] a manufacturer may make claims, for example, that a product is good, excellent, enriched/fortified or high potency with respect to vitamins, minerals, fiber, or protein; that a product is "lite" or "light" with regard to calories or sodium; or even that a product is "healthy."[75] Such claims can be used on labels without review by FDA, as long as they comply with all FDA definitions and rules.[76] All other nutrient content claims are prohibited.[77]

Foods and dietary supplement manufacturers can also make structure/function claims,[78] which are claims that describe the role of a nutrient or dietary ingredient intended to affect the normal structure or functions of the body in humans.[79] Although there is no premarket approval

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> final decision will be sent to the petitioner in the form of a letter as to whether FDA intends to exercise enforcement discretion with respect to a QHC or deny the petition. The letter will be posted on FDA's website. Extensions beyond 270 days can be granted upon mutual agreement between the petitioner and the agency.

Id.

[74] *Id.* at 87.

[75] *Id.* at 91–94. Historically the claim "healthy" "has received special scrutiny and guidelines from the FDA because "[it] is a very useful advertising term. According to FDA guidelines, a product must have low total fat content as well as low levels of saturated fat, sodium, and cholesterol to qualify as a 'healthy' food." Betty J. Parker, *Food for Health-The Use of Nutrient Content, Health, and Structure/function Claims in Food Advertisements*, J. ADVERTISING, Fall 2003, at 47, 48–49. *See also* 21 C.F.R. § 101.65(d)(2) (2014).

[76] FDA deems a food misbranded if it bears a nutrient content claim unless the agency has issued a regulation authorizing the claim and the claim is made consistent with the regulation. 21 U.S.C. § 343(r)(6) (2012).

[77] U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE, *supra* note 55, at 72 (citing 21 C.F.R. § 101.13(b)).

[78] Along with structure/function claims, the Dietary Supplement Health and Education Act of 1994 (DSHEA) also permits general well-being and nutrient deficiency disease claims for dietary supplements. Neither of these claims is subject to premarket approval. *See Label Claims*, *supra* note 59.

[79] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 4 ("For example, a supplement may claim that it 'curbs appetite to help with weight loss,' but it may not claim to 'aid weight loss to treat obesity' because obesity is a

for these claims, the manufacturer is responsible for ensuring their truthfulness and for having substantiation to support the claims.[80] For dietary supplements (but not foods) making structure/function claims, the manufacturer must notify FDA within 30 days of placing the product on the market. The notification must include an attestation by the manufacturer that the "[manufacturer] has substantiation that the claim is truthful and not misleading."[81] In addition, dietary supplement manufacturers making structure/function claims must include a disclaimer that the claim has not been evaluated by FDA and that the product is "not intended to 'diagnose, treat, cure or prevent any disease.'"[82]

Of each of the three types of claims that nutritional product manufacturers may make, structure/function claims are especially problematic in terms of consumer deception. The fact that these claims do not require premarket approval creates at least the opportunity for claims

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disease. Similarly, a supplement may claim to 'support immunity,' but may not claim to 'boost the immune system against colds and flu' because the latter references specific diseases.").

[80] *See id.* FDA has set forth guidance on what types of evidence can be used for claim substantiation. *See Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Dec. 2008), http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm073200.htm. To meet the substantiation requirement, evidence must be "competent and reliable scientific evidence." *Id.* In determining whether the standard is met, FDA considers: "(1) the meaning of the claim(s) being made; (2) the relationship of the evidence to the claim; (3) the quality of the evidence [e.g., randomized controlled trials are given considerable weight although manufacturers may use other human or nonhuman studies]; and (4) the totality of the evidence [both favorable and unfavorable.]" *Id*.

[81] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 6 (citing 21 C.F.R. § 101.93(a)(2) (2014)).

[82] *Label Claims*, *supra* note 59.

that lack scientific support and even outright false statements.[83] Structure/function claims are also used much more frequently than health claims apparently because they allow companies to bypass the approval process required for health claims.[84] The OIG and GAO have issued several reports critical of structure/function claims, especially as they relate to dietary supplements.[85]

B. *FTC*

The FTC's requirements regarding substantiation for health related product claims differ from those of FDA. Unlike FDA, the FTC does not require pre-market approval of claims, nor does it make regulatory distinctions between product categories (e.g., drug, supplement, food), nor between types of claims (e.g., health, nutrient content, structure/function).[86] However, the FTC has legal authority to take action against false or misleading claims for many types of products and services. These include foods, drugs, and dietary supplements.[87]

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[83] *See* CSPI REPORTS: INT'L, *Marketplace Implications and Consumer Impact*, *in* FUNCTIONAL FOODS: PUBLIC HEALTH BOON OR 21ST CENTURY QUACKERY? (1998), https://cspinet.org/reports/functional_foods/usa_market.html.

[84] *See* Parker, *supra* note 75, at 49. *See also* CSPI REPORTS INT'L, *supra* note 83 (stating that "[t]o avoid FDA approval requirements, some companies have begun making structure/function claims in lieu of health claims.").

[85] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9; OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVICES, DIETARY SUPPLEMENT LABELS: AN ASSESSMENT (Mar. 2003), https://oig.hhs.gov/oei/reports/oei-01-01-00121.pdf; Testimony of Gregory D. Kutz, *supra* note 9; U.S. GOV'T ACCOUNTABILITY OFFICE,GAO-09-250, REPORT TO CONGRESSIONAL REQUESTERS: DIETARY SUPPLEMENTS: FDA SHOULD TAKE FURTHER ACTIONS TO IMPROVE OVERSIGHT AND CONSUMER UNDERSTANDING (Jan. 2009), http://www.gao.gov/assets/290/285372.pdf.

[86] Michelle Rusk, Att'y, U.S. Fed. Trade Comm'n, Div. of Advertising Practices, Staff Presentation at the Inst. of Medicine Food Forum Workshop: Health Claims and FTC Advertising Law (Feb. 23, 2012), http://iom.nationalacademies.org/~/media/1EBC076FE7CC4AC0BB922166367899FC.ashx.

[87] *See* Anne V. Maher, *Marketing Dietary Supplements and Functional Foods in the USA: The Federal Trade Commission's Advertising Substantiation Requirements*, *in* NUTRACEUTICAL AND FUNCTIONAL FOOD REGULATIONS

The FTC's jurisdiction over health claims stems from three provisions of the FTC Act. Section 5 of the Act prohibits "unfair or deceptive acts or practices in or affecting commerce."[88] Section 12 prohibits false advertisements for foods, drugs, devices, services, or cosmetics,[89] and Section 15 defines false advertisement for the purpose of section 12 as one that is "misleading in a material respect."[90] In a separate policy statement, FTC has explained that in its enforcement of these provisions it looks to whether the claim contains a misrepresentation or omission of fact that is likely to mislead a consumer acting reasonably under the circumstances, and whether that representation is material to a consumer's purchasing decision.[91] Thus false claims, claims made without disclosure of material facts, or unsubstantiated claims may all violate the law.

The FTC interprets ads from the perspective of a reasonable consumer in the target audience.[92] For some advertising, this audience is the general population. If, however, a manufacturer targets its product to a particular subgroup, the ad will be evaluated from the perspective of how it is likely to be interpreted by a reasonable member of that group.[93] Although ads may have more than one reasonable interpretation, where an ad conveys more than one meaning, only one of which is misleading, a seller is liable for the misleading interpretation

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IN THE UNITED STATES AND AROUND THE WORLD 47, 48 (Debasis Bagchi ed., 2008), (stating that the FTC "has authority to take legal action against false and misleading claims for nearly every type of product and service, including products which are also regulated by the . . . FDA, such as dietary supplements and functional foods.").

[88] 15 U.S.C. § 45(a)(1) (2012).

[89] § 52.

[90] § 55(a)(1).

[91] *FTC Policy Statement on Deception*, U.S. FED. TRADE COMM'N (Oct. 14, 1983), https://www.ftc.gov/public-statements/1983/10/ftc-policy-statement-deception.

[92] *Id*.

[93] *Id.*

even if non-misleading interpretations are possible.[94] Consumers may be especially susceptible to health claims, because they usually lack the knowledge to assess claims referring to physiology or metabolic processes and may be especially impressed by purported scientific evidence bolstering the claims.[95]

In the FTC's long-held view, making claims without a reasonable basis is a deceptive practice. In determining whether there is a "reasonable basis" for a claim, the FTC will consider: "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."[96] Where an advertisement represents, either expressly or by implication, that the claim is supported by a certain amount or level of substantiation, the advertiser must possess, at the time the claim is made, at least that level of support for the claim.[97]

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[94] *Id.*

[95] For example, POM Wonderful, the marketer of pomegranate juice products claimed to have various health benefits, "thought their products [*sic*] 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." *In re* POM Wonderful LLC, 155 F.T.C. 1, 42 (2013).

[96] *FTC Policy Statement Regarding Advertising Substantiation*, U.S. FED. TRADE COMM'N (Mar. 11, 1983), https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation; *see also* DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 8–9 (2001), https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf ; *see also* In re Pfizer Inc., 81 F.T.C. 23 (1972).

[97] *FTC Policy Statement Regarding Advertising Substantiation*, *supra* note 96. *See also Enforcement Policy Statement on Food Advertising*, U.S. FED. TRADE COMM'N (May 13, 1994), https://www.ftc.gov/public-statements/1994/05/enforcement-policy-statement-food-advertising [hereinafter *Food Policy Statement*]. FTC's

Although the FTC does not have separate rules governing foods and dietary supplements, it has issued industry guidance documents for both products.[98] The Commission's Enforcement Policy Statement on Food Advertising was made public in May 1994. This was prior to the passage of DSHEA, which as discussed above, allows dietary supplement manufacturers to make structure/function claims without FDA approval prior to marketing. As a result, the statement focuses on health claims and nutrient content claims. The subsequent passage of DSHEA raised numerous questions about the FTC's approach to applying its consumer protection laws to dietary supplements. The guidance document for dietary supplement manufacturers states that the FTC's "approach to supplement advertising is best illustrated by its Enforcement Policy Statement on Food Advertising" and that in general the FTC gives "great deference to an FDA determination of whether there is adequate support for a health claim."[99]

Both guidance documents provide that health-related claims must be substantiated by competent and reliable scientific evidence.[100] More specifically, this is evidence consisting of

> tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, conducted and evaluated in an objective manner

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Bureau of Consumer Protection website on "Health Claims" states that "Companies must support their advertising claims with solid proof. This is especially true for businesses that market food, over-the-counter drugs, dietary supplements, contact lenses, and other health-related products." *Health Claims*, U.S. FED. TRADE COMM'N, http://business.ftc.gov/advertising-and-marketing/health-claims.

[98] *See Food Policy Statement*, *supra* note 97; *see* DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 96.

[99] DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 96, at 1.

[100] *Id.* at 9; *Enforcement Policy Statement on Food Advertising*, *supra* note 97.

> by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.[101]

In evaluating health claims for foods and dietary supplements the FTC will look to "well-designed studies, including clinical research and other forms of reliable and probative scientific evidence."[102] Furthermore, the FTC states that it will apply the same "significant scientific agreement" standard applied by FDA to claims "about the relationship between a nutrient or substance in a food and a disease or health-related condition."[103]

In evaluating a structure/function claim for a dietary supplement, the FTC will assess whether the claim may convey an implied claim that the product will treat a disease. If so, the manufacturer will need to provide substantiation of the implied disease treatment claim.[104] The industry guidance document for dietary supplements states that for substantiation there "is no fixed formula for the number or type of studies required or for more specific parameters like sample size and study duration. There are, however, a number of considerations to guide an advertiser in assessing the adequacy of the scientific support for a specific advertising claim."[105] These include whether the advertiser has the level of support it claims to have; whether experts

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[101] DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 96, at 9; *Enforcement Policy Statement on Food Advertising*, *supra* note 97.

[102] *Enforcement Policy Statement on Food Advertising*, *supra* note 97.

[103] *Id.*

[104] The FTC industry guidance document on advertising dietary supplements provides an example of this:

> An ad for a dietary supplement called 'Arthricure' claims that the product maintains joint health and mobility into old age. The 'before' picture shows an elderly woman using a walker. The 'after' picture shows her dancing with her husband. The images and product name likely convey implied claims that the product is effective in the treatment of the symptoms of arthritis, and may also imply that the product can cure or mitigate the disease. The advertiser must be able to substantiate these implied claims.

DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 96, at 5.

[105] *Id.* at 9.

in the relevant area of study would generally agree that the amount and type of evidence for the particular claim is sufficient; whether any research conducted was well designed, implemented and analyzed; whether the totality of the evidence supports the claim; and whether the evidence is relevant to the specific claim.[106]

Although FDA regulates labeling, the FTC will also evaluate dietary supplement labels if they are being used by an advertiser to promote the product and will follow an approach similar to FDA's review of such materials in the context of labeling.[107]

C. *Recent Enforcement Efforts by FDA and the FTC Against Nutritional Product Manufacturers for Deceptive Claims*

Under a memorandum of understanding (MOU) originally executed in 1954, FDA and the FTC share jurisdiction for enforcement of claims made by manufacturers of health-related products.[108] The FDA has primary authority for overseeing the advertising of prescription drugs and the labeling[109] of drugs, supplements, foods, devices and cosmetics. With the exception of

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[106] *Id.* at 9–18.

[107] *Id.* at 24.

[108] The allocation of responsibility for enforcement of food and dietary supplement labels and claims is set forth in a memorandum of understanding between the two agencies. *See* Memorandum of Understanding Between the Federal Trade Commission and The Food and Drug Administration (1971), MOU 225-71-8003,http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm115791.htm.

[109] Labeling is interpreted broadly to include "visual, audio or other material that bears a strong contextual relationship to the product." John E. Villafranco & Andrew B. Lustigman, *Regulation of Dietary Supplement Advertising: Current Claims of Interest to the Federal Trade Commission and National Advertising Division*, 62 FOOD & DRUG L.J. 709, 711 (2007) (citing 21 U.S.C. § 321(m) and Kordel v. United States, 335 U.S. 345 (1948)).

prescription drugs, the FTC has primary authority for overseeing advertising of health-related products. The MOU did not address claims made on the Internet, but "both agencies have asserted jurisdiction over claims appearing on company websites."[110] The agencies coordinate closely on food and dietary supplement policy issues.[111]

FDA and the FTC have a variety of enforcement tools available to address deceptive claims. For example, FDA can ask companies to voluntarily recall any product that has already entered the distribution chain.[112] In addition, FDA can send a warning letter to a firm stating that enforcement actions may be forthcoming if corrections are not made.[113] If violations are not

[110] Maher, *supra* note 87, at 48.

[111] *See* John E. Villafranco, Raqiyyah R. Pippins, & Kristi L. Wolff, *Working Together: How Growing FDA And FTC Collaboration Changes the Regulatory Landscape for Food and Dietary Supplement Marketers*, NUTRITION OUTLOOK (May 2011), http://www.kelleydrye.com/publications/articles/1485/_res/id=Files/index=0/Villafranco_Pippins_Wolff_Working%20Together_Nutritional%20Outlook_%20May%202011.pdf ("Early in the Obama Administration, the FDA and FTC expressed a commitment to interagency collaboration in regulating the promotion of food, beverage, and dietary supplement products, and established 'working groups' to share information regarding marketing activities for such products."). *See also* Sarah Roller & Raquiyyah Pippins, *Marketing Nutrition & Health-Related Benefits of Food & Beverage Products: Enforcement, Litigation & Liability Issues*, 65 FOOD & DRUG L.J. 447 (2010).

[112] *See* 21 CFR §§ 7.40-7.42, 7.45 (2014).

[113] *See* U.S. FOOD & DRUG ADMIN., *Warning Letters, in* REGULATORY PROCEDURES MANUAL, http://www.fda.gov/iceci/compliancemanuals/regulatoryproceduresmanual/ucm176870.htm (last visited Aug. 19, 2015).

corrected, FDA can seize and remove the product from the marketplace.[114] Both FDA and the FTC can enjoin a firm from continuing a practice that violates labeling or advertising statutes and regulations, i.e., seek an injunction[115] or cease and desist order. In addition, the FDA can recommend criminal prosecution of a company engaging in criminal conduct,[116] and the FTC can assess civil monetary penalties, order refunds to consumers, and require corrective advertising, disclosures, and other informational remedies aimed at rectifying the deception.[117]

During the mid-2000s, FDA was criticized by public interest groups, Congress and the GAO for its inability to keep up with the prevalence of food labeling violations by taking necessary enforcement actions.[118] CSPI pointed out the small number of warning letters issued by the

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[114] *See* U.S. FOOD & DRUG ADMIN., *Seizure, in* REGULATORY PROCEDURES MANUAL, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176733.htm (last visited Aug. 19, 2015).

[115] U.S. FOOD & DRUG ADMIN., *Injunctions, in* REGULATORY PROCEDURES MANUAL, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176734.htm (last visited Aug. 19, 2015).

[116] *See* 21 U.S.C. § 333(a)(1) (2012); U.S. FOOD & DRUG ADMIN., *Prosecution, in* REGULATORY PROCEDURES MANUAL, http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176738.htm (last visited Aug. 19, 2015); *see also* John W. Lundquist & Sandra L. Conroy, *Defending Against Food & Drug Prosecutions*, THE CHAMPION (July 1997), http://www.nacdl.org/CHAMPION/ARTICLES/97jul02.htm. While the law allows for civil monetary penalties against drug and medical device manufacturers it does not provide for civil penalties for violations by food and dietary supplement manufacturers. *See* 21 U.S.C. § 335b (2012).

[117] *Advertising FAQ's: A Guide for Small Business*, U.S. FED. TRADE COMM'N (Apr. 2001), https://www.ftc.gov/tips-advice/business-center/guidance/advertising-faqs-guide-small-business.

[118] *See* Nicole Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, GOVERNANCE STUDIES AT BROOKINGS 8 (June 2014), http://www.brookings.edu/~/media/research/files/papers/2014/06/26-food-labeling-litigation/negowetti_food-

agency in light of the apparent growing numbers of labels that did not comply with the law and asserted that FDA had "all but abdicated its responsibility to police inaccurate nutrition statements and misleading health-related claims on food labels."[119] In 2009 and 2010, FDA issued two open letters to the food industry urging manufacturers to comply with labeling requirements and in 2010, as part of an enforcement initiative, issued seventeen Warning Letters in one day to food manufacturers that were alleged to have made unsubstantiated or misleading health and nutrient content claims.[120] From January 2011 to June 2012, FDA issued "numerous warning letters" to food manufacturers for failure to comply with requirements for food labeling and health claims.[121] Since June 2012, FDA has continued to issue warning letters at the rate of about sixty per year[122] to food and dietary supplement manufacturers whose labels or claims

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labeling-litigation.pdf (citing Center for Science in the Public Interest, *Rebuttal to FDA Report to Congress on Agency Enforcement Actions Regarding Health-Related Claims on Food Labels* (July 18, 2006), http://cspinet.org/new/pdf/fn5rep.pdf [hereinafter *Rebuttal to FDA Report*]; S. REP. NO. 109-92, at 153 (2005); H.R. REP. NO. 109-102, at 83 (2005); and U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-08-597, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS (Sept. 2008), http://www.gao.gov/new.items/do8597.pdf).

[119] Negowetti, *supra* note 118 (quoting *Rebuttal to FDA Report*).

[120] *Id. See also* ABA Section of Litigation, Food & Supplements Second Annual Workshop, *Food Labeling: How to Avoid an FDA or FTC Enforcement Action* 3 (June 12, 2012), http://www.americanbar.org/content/dam/aba/administrative/litigation/materials/2012_food_supplements_2nd_annual_cle_wrkshp/2012_aba_panel3_food_labeling_how_to_avoid_an_fda_or_ftc_enforcement_action.authcheckdam.pdf; *Summary of 17 Warning Letters Issued by FDA on February 22, 2010 for Alleged Food Labeling Violations*, KELLER AND HECKMAN LLP (Feb. 22, 2010), http://www.khlaw.com/3640.

[121] ABA Section of Litigation, *supra* note 120.

[122] *See Warning Letters*, U.S. FOOD & DRUG ADMIN. (2015), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm; *see also 2014 Year-End FDA*

violate the law but has not generally engaged in other methods of enforcement against these companies.[123] Moreover, FDA has issued very few warning letters for certain types of claims, specifically qualified health claims. According to a recent article, the "FDA has issued only seven warning letters referencing qualified health claims" and has stated that "promotional health-related claims are not a high enforcement priority."[124]

The FTC has been somewhat more active in enforcement of laws under its jurisdiction regarding deceptive health claims.[125] In a prepared statement given to the Senate Special Committee on Aging as part of a hearing on deceptive marketing of dietary supplements in 2010, the FTC stated that over the past decade (2000-2010) it had filed "well over 100 law enforcement actions challenging claims about the efficacy or safety of a wide variety of supplements"[126] and

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Compliance and Enforcement Update-Food and Dietary Supplements, GIBSON DUNN (Mar. 2, 2015), http://www.gibsondunn.com/publications/Documents/2014-Year-End-FDA-Compliance-and-Enforcement-Update-Food-and-Dietary-Supplements.pdf (stating that in 2014 FDA issued 252 warning letters for conventional foods and 58 for dietary supplements. The letters for foods primarily cited violations of current good manufacturing practices while those for dietary supplements were for what we have described as deceptive health claims, i.e., improperly marketing products as dietary supplements when those products were actually new drugs.)

[123] *See Warning Letters*, *supra* note 122.

[124] Peter E. Masaitis & Evan W. Woolley, *Enforcement of FDA Qualified Health Claims: Who's on the Case?*, INSIDE COUNSEL MAGAZINE (Jan. 9, 2015), http://www.insidecounsel.com/2015/01/09/enforcement-of-fda-qualified-health-claims-whos-on.

[125] *See* ABA Section of Litigation, *supra* note 120.

[126] *Deceptive Marketing of Dietary Supplements: FTC Enforcement Activities*, U.S. FED. TRADE COMM'N 4 (May 26, 2010), https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-deceptive-marketing-dietary-supplements/100526dietarysupplementstatement.pdf (statement prepared for Senate Special Committee on Aging hearing). *See also Health and Fitness Claims*, *supra* note 36 (stating that

that it "focused its enforcement on national advertising campaigns for products with unproven benefits, products promoted to treat or cure serious diseases, products that may present significant safety concerns to consumers, and products that are deceptively marketed to vulnerable populations, such as children or the elderly."[127] Recent examples of major FTC enforcement actions include cases against Nestlé Healthcare Nutrition, Inc. (a subsidiary of Nestlé S.A.), the Dannon Company, and POM Wonderful, LLC.

In 2010, the FTC brought an action against Nestlé Healthcare Nutrition, Inc. for claims made about its product, Boost Kid Essentials.[128] The product is a nutritional drink for children with probiotics embedded in a straw that comes with the drink. Advertisements for the product claimed that consumption of the drink would reduce illness in children, protect children from colds and flu by strengthening their immune system, and help children up to age thirteen recover more quickly from diarrhea. The FTC alleged in a complaint brought against the manufacturer that these claims were unsubstantiated and thus violated the FTC Act. This was the agency's first complaint challenging deceptive advertising of a probiotic product. In response, the company agreed as part of a settlement to stop claiming that BOOST Kid Essentials would (1) reduce the risk of colds, flu, and other upper respiratory tract infections unless the FDA approved the claim[129] and (2) "reduce children's sick-day absences and the duration of acute diarrhea in

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"over the last decade, the FTC has filed one hundred and twenty cases challenging health claims made for supplements.").

[127] *Deceptive Marketing of Dietary Supplements*, *supra* note 126.

[128] *In re* Nestlé Healthcare Nutrition, Inc., Complaint filed by the U.S. Federal Trade Commission (2010), https://www.ftc.gov/sites/default/files/documents/cases/2010/07/100714nestlecmpt.pdf.

[129] *FTC Approves Final Order Settling Charges That Nestlé Subsidiary Made Deceptive Health Claims for BOOST Kid Essentials*, U.S. FED. TRADE COMM'N (Jan. 18, 2011), https://www.ftc.gov/news-events/press-

children up to age 13, unless the claims [were] true and backed by at least two well-designed human clinical studies."[130]

In a second action in 2010, the FTC entered into a settlement with the Dannon Company, Inc. after alleging in a complaint that the company had engaged in deceptive advertising by exaggerating the health benefits of its Activia yogurt and DanActive dairy drink.[131] In its complaint the FTC stated that "Dannon claimed in nationwide advertising campaigns that DanActive helps prevent colds and flu, and that one daily serving of Activia relieves temporary irregularity and helps with 'slow transit time'" without sufficient evidence to back these claims.[132] Similar to the settlement with BOOST Kid Essentials, the FTC required that Dannon refrain from claiming that "any yogurt, dairy drink, or probiotic food or drink reduces the

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releases/2011/01/ftc-approves-final-order-settling-charges-nestle-subsidiary-made. The FTC further required that the regulation be based on a finding that "there is significant scientific agreement among experts qualified by scientific training and experience to evaluate such claims, considering the totality of publicly available scientific evidence." Nestlé HealthCare Nutrition, Inc.; Analysis of Proposed Consent Order to Aid Public Comment, 75 Fed. Reg. 42,752, 42,753 (July 22, 2010).

[130] *FTC Approves Final Order*, *supra* note 129. The settlement also prohibits Nestlé HCN "from making any claims about the health benefits, performance, or efficacy of any probiotic and nutrition drinks that it sells at retail, unless the claims are true and backed by competent and reliable scientific evidence" and "from misrepresenting any tests or studies." *Id.*

[131] *See In re* The Dannon Company, Inc. Agreement Containing Consent Order (2010), https://www.ftc.gov/sites/default/files/documents/cases/2010/12/101215dannonagree.pdf.

[132] Press Release, U.S. Fed. Trade Comm'n, Dannon Agrees to Drop Exaggerated Health Claims for Activia Yogurt and DanActive Dairy Drink (Dec. 15, 2010), https://www.ftc.gov/news-events/press-releases/2010/12/dannon-agrees-drop-exaggerated-health-claims-activia-yogurt.

likelihood of getting a cold or the flu, unless the claim is approved by the Food and Drug Administration."[133]

Another enforcement action involved the pomegranate juice products marketed by POM Wonderful. On September 24, 2010, the FTC issued an administrative complaint alleging that POM Wonderful engaged in deceptive acts and practices and disseminated false advertising in violation of Sections 5(a) and 12 of the FTC Act, through the marketing of its juice and related products.[134] On review of an administrative law judge's initial decision, the FTC found that POM Wonderful had made deceptive claims in thirty-six advertisements.[135] The FTC held that POM Wonderful, without adequate substantiation, had made disease efficacy claims—namely, that its products could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction and that they were clinically proven to work.[136] For example, several ads claimed that "eight ounces of POM a day can reduce plaque in the arteries by up to 30%!" The FTC wrote that "[s]uch references tend to communicate that the product's attributes are supported by scientific research because a reduction in the amount of plaque in an individual's

[133] *Id.* Prior to this action by the FTC, in 2009 the Dannon Co. settled a false advertising lawsuit regarding these products brought by private plaintiffs. *See* Timothy Williams, *Dannon Settles With F.T.C. Over Some Health Claims*, N.Y. TIMES (Dec. 15, 2010), http://www.nytimes.com/2010/12/16/business/16yogurt.html; *see also infra* notes 161-163 and accompanying text.

[134] Complaint at 19, *In re* POM Wonderful LLC, 155 F.T.C. 1 (Sept. 24, 2010) (No. 9344), http://www.ftc.gov/sites/default/files/documents/cases/2010/09/100927admincmplt.pdf.

[135] *In re* POM Wonderful LLC, 155 F.T.C. 1, 9 (2013).

[136] *Id*. at 38.

arteries cannot be known through casual observation, i.e., it must be measured by a medical professional."[137]

The FTC prohibited POM Wonderful from making disease-related efficacy claims unless the claims are supported by "competent and reliable scientific evidence," which the FTC defined as at least two clinical trials that are "randomized, well controlled, based on valid end points, and conducted by persons qualified by training and experience to conduct such studies." The agency further required that the studies "yield statistically significant results, and . . . be double-blinded unless [POM Wonderful could] demonstrate that blinding [could not] be effectively implemented given the nature of the intervention."[138] POM Wonderful appealed the FTC's order, arguing that the FTC erred in its findings, imposed an unlawful remedy by requiring two randomized clinical trials, and transgressed First Amendment protection of commercial speech. The D.C. Circuit, however, largely rejected POM Wonderful's contentions, holding that the FTC had substantial evidence in support of its findings and that POM Wonderful's claims were not entitled to First Amendment protection.[139] One modification ordered by the appellate court related to the remedy: the FTC's requirement for *two* clinical trials in support of disease-related claims was deemed unjustifiably rigid and hence a First Amendment violation; one high-quality trial might suffice to substantiate a claim. This modification is significant in that it pushes back on the

[137] *In re* POM Wonderful LLC, 155 F.T.C. 1, app. A, at A1-A2 (2013), http://www.ftc.gov/sites/default/files/documents/cases/2013/01/130116pomappendixa.pdf.

[138] *In re* POM Wonderful LLC, 155 F.T.C. 1 (2013).

[139] POM Wonderful, LLC v. Fed. Trade Comm'n, 777 F.3d 478 (D.C. Cir. 2015).

agency's efforts to harmonize its regulation of health claims with FDA, in particular its substantiation requirement.[140]

The FTC has continued to bring high-profile enforcement actions against other foods and dietary supplement manufacturers over the past few years. According to the 2014 Year-End FDA Compliance and Enforcement Update on food and dietary supplements, prepared by the law firm Gibson Dunn, in 2014 the FTC "stepped up its scrutiny of health-related claims," in particular for weight loss products, and announced that deceptive health claims remained "an ongoing FTC priority with respect to deceptive advertising practices."[141]

D. *State Consumer Protection Laws*

Most states have what are commonly "referred to as 'mini-FTC' Acts or UDAP (Unfair or Deceptive Acts or Practices) laws."[142] While these laws vary across states, most state UDAP laws provide state attorneys general with a broad array of remedies to combat consumer fraud and deception. UDAP statutes have also been used by private litigants in class action suits for alleged unfair and deceptive business practices.[143]

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[140] *See* Villafranco, Pippins, & Wolff, *supra* note 111. *See also* Douglas W. Hyman, *The Regulation of Health Claims in Food Advertising: Have the FTC and the FDA Finally Reached a Common Ground?*, 51 FOOD & DRUG L.J. 191 (1996).

[141] GIBSON DUNN, *supra* note 122. During the year the agency entered into "multiple weight-loss product settlements, most of which required the defendants to substantiate any future weight-loss claims with at least two adequate and well-controlled human studies." *Id.*

[142] DIANE E. HOFFMANN ET AL., FINAL REPORT: FEDERAL REGULATION OF PROBIOTICS: AN ANALYSIS OF THE EXISTING REGULATORY FRAMEWORK AND RECOMMENDATIONS FOR ALTERNATIVE FRAMEWORKS 85–86 (Nov. 15, 2012), http://www.law.umaryland.edu/programs/health/events/probiotics/documents/FinalWhitePaper.pdf.

[143] *Id.* at 86.

UDAP statutes generally allow a state enforcement agency, usually the attorney general, to obtain a court order prohibiting a seller from engaging in a particular unfair or deceptive practice.[144] An attorney general may also ask the court to impose civil monetary penalties for violations of the law and to order the seller to return payments to consumers.[145] For example, the California Attorney General used that state's UDAP law to seek injunctive relief and civil penalties for allegedly unsubstantiated claims that certain ingredients in a multi-vitamin pill could protect against prostate cancer.[146] Despite differences in state UDAP laws, it is possible for attorneys general to act collectively, if a national marketer is engaged in the same practices in all states.[147]

Most statutes also allow consumers to seek similar remedies, e.g., "return of payments or compensation for . . . consumer loss, . . . injunction[s] against repetition of the deceptive

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[144] Carolyn L. Carter, *Consumer Protection in the States: A 50-State Report on Unfair and Deceptive Acts and Practices Statutes*, NAT'L CONSUMER LAW CENTER 6 (Feb. 2009), http://www.msfraud.org/law/lounge/UnfairandDeceptiveActs09.pdf.

[145] *Id.*

[146] *See* Complaint for Injunction, Civil Penalties, and Other Equitable Relief, California v. Bayer Healthcare LLC (Cal. Super. Ct. Oct. 26, 2010) (No. 37-2010-0010-3098-CU-MC-CTL), http://oag.ca.gov/system/files/attachments/press_releases/n2007_bayer_complaint.pdf. The case was settled soon after filing for $3.3 million. Press Release, Cal. Office of the Att'y Gen., Brown Announces $3 Million Settlement over Misleading Claims that Multivitamins Can Reduce Cancer Risk (Oct. 26, 2010), http://oag.ca.gov/news/press-releases/brown-announces-3-million-settlement-over-misleading-claims-multivitamins-can.

[147] *See, e.g.*, Assurance of Voluntary Compliance, *In re* Warner Lambert Company LLC (May 11, 2004), http://apps.americanbar.org/antitrust/at-committees/at-state/pdf/settlements/cp/warner-lambert.pdf (describing a settlement with fifty states regarding promotional and marketing practices for off-label uses of a prescription drug).

practices, and, in most states, reimbursement for attorneys' fees."[148] According to a 2009 report by the National Consumer Law Center, "[b]efore the adoption of state UDAP statutes in the 1970s and 1980s, neither consumers nor state agencies had effective tools against fraud and abuse in the consumer marketplace."[149] Moreover, in most states, there was no state agency responsible for combatting consumer fraud and abuse.[150] Claims based on common law fraud posed numerous obstacles to consumers who would have to, for example, establish the seller's state of mind.[151] Even if a consumer had a reasonable chance of success, finding an attorney to take the case was challenging, as few states had any provisions for reimbursing consumers for attorneys' fees.[152]

In recent years, consumers and public interest groups have used state UDAP laws to challenge food labeling and health claims. The Center for Science in the Public Interest has been a leader in these legal actions, often initiating a lawsuit or joining with other plaintiffs. In several cases the Center's legal action preceded suits filed by state attorneys general. Examples of the latter include cases against Coca-Cola for making fraudulent claims about Enviga, an artificially sweetened green tea soda,[153] and Bayer Healthcare, for claims that its One A Day men's

[148] *See* Carter, *supra* note 144, at 6.

[149] *Id.* at 5.

[150] *Id.*

[151] *Id*.

[152] *Id.* at 5–6.

[153] Coca-Cola marketed the drink as a weight loss product claiming that it had "negative calories" and labeled it as "the calorie burner" on its cans. CSPI scientists reviewed the studies relied on by Coke and determined that Enviga was simply "a highly caffeinated and overpriced diet soda." *Watchdog Group Sues Coke, Nestlé, for Bogus "Enviga" Claims*, CTR. FOR SCIENCE IN THE PUB. INTEREST (Feb. 1, 2007), http://www.cspinet.org/new/200702011.html. In 2007, CSPI filed suit alleging that the claims "were made without

multivitamins reduced the risk of prostate cancer.[154] While very few CSPI cases have been finally adjudicated, they have resulted in numerous settlements with food and dietary supplement manufacturers.[155] Moreover, in some cases CSPI threatened but did not file suit and was able to negotiate a change in labeling or claims with the manufacturer.[156]

In addition to the legal actions brought by CSPI and state attorneys general, consumer advocacy groups have brought numerous suits. Just over the last four years consumers have filed "more than 150 . . . class action lawsuits against food and beverage companies."[157] Most of the suits have been for alleged violations of food labeling laws. Others have been for claims that, although not directly violating FDA food labeling laws, are alleged to be misleading under state

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prior substantiation and no evidence that most consumers would realize any calorie-burning benefit." Negowetti, *supra* note 118, at 17 ("Following the filing of this lawsuit, approximately 28 state attorneys general investigated the claims and ultimately settled for $650,000."). The company also agreed to stop making overt weight-loss claims for the product. *Id*.

[154] CSPI sued Bayer in 2009 alleging that the claims were deceptive and lacked scientific evidence. Although that lawsuit was dismissed on procedural grounds, while CSPI was preparing to refile "the Attorneys General of Oregon, California, and Illinois announced a broad settlement with Bayer on the same issues." *Litigation Project-Closed Cases*, Ctr. for Science in the Pub. Interest, http://cspinet.org/litigation/closed.html (last visited Aug. 19, 2015).

[155] *See id.* (describing cases against Airborne for deceptive claims regarding its cold remedy; Aurora Dairy for selling its non-organic dairy products as "organic"; Dr. Pepper Snapple Group for misleading antioxidant claims on its labels, and General Mills for misleading claims about its "the nutritional and health qualities of its "fruit" snacks.).

[156] *See id.* (listing agreements with Pfizer Consumer HealthCare for health claims made about Centrum Dietary Supplements, Pepsico for claims that its IZZE sparkling juices are "natural and fortified," Quaker Oats for claims that its oatmeal lowered cholesterol, and Smart Balance for claims that its Blended Butter Sticks help block cholesterol.).

[157] Negowetti, *supra* note 118, at 1.

law. Many of the suits have involved foods labeled as "all natural,"[158] "nutritious," or "healthful."[159] Although almost none of these lawsuits have as yet been adjudicated,[160] in some instances, the litigation has resulted in significant settlements. For instance, in 2010 the Dannon Company settled a false advertising lawsuit and agreed to establish a $35 million fund to reimburse consumers who bought its Activia and DanActive yogurts.[161] The class action lawsuit alleged that Dannon made misrepresentations when marketing its Activia and DanActive yogurts by claiming nonexistent health benefits.[162] The settlement may have paved the way for subsequent lawsuits.[163]

IV. LIMITATIONS OF LAW AND ENFORCEMENT CAPACITY

A. FDA

[158] The large majority of cases (over 100) have alleged that food products have inappropriately used the label "natural" and that use of the term is misleading. *See id*. at 11.

[159] *Id.* at 10.

[160] *Id.* (as of June 2014).

[161] *See* Amended Stipulation of Settlement at 8, Gemelas v. The Dannon Company, Inc., 2010 WL 377068 (N.D. Ohio Jan. 20, 2010) (No. 1:08-cv-00236). The complaint alleged violations of two Ohio consumer protection statutes and breach of express warranty. Class Action Complaint, Gemelas v. The Dannon Company, Inc., 2008 WL 824363 (N.D. Ohio Jan. 29, 2008) (No. 1:08-cv-00236).

[162] Class Action Complaint, Gemelas v. The Dannon Company, Inc. As part of the settlement, the company agreed to make changes to the labeling and advertising of Activia and DanActive. Stipulation of Settlement, Gemelas v. The Dannon Company, Inc., 2009 WL 3197886 (N.D. Ohio Sept. 18, 2009) (No. 1:08-cv-00236). DanActive labels that said the yogurt has "a positive effect on your digestive tract's immune system" were reworded to say the yogurt will "interact with your digestive tract's immune system." *Id.*

[163] Negowetti, *supra* note 118, at 9.

While FDA has stepped up its actions against food and dietary supplement manufacturers, the agency is hindered in its ability to curtail illegal claims in part because of limitations on its enforcement authority and enforcement methods**.** FDA's "principal enforcement tool" when confronted with a noncompliant food label "is to issue a Warning Letter to notify the manufacturer.'[164] Although FDA has other enforcement mechanisms that are more severe, including recall, seizure, civil monetary penalties, and injunctive relief, the law significantly limits their use in cases of misbranding.[165] As a result, according to one author, "the FDA primarily seeks voluntary compliance from food companies when food products are misleading or mislabeled" and these "Warning Letters provide little incentive or threat for companies to avoid or discontinue use of misleading claims on food labels."[166]

FDA is also limited in its ability to monitor health claims that bypass required premarket approval or nutrient content claims that are not consistent with pre-approved claims. In addition, because structure/function claims do not require pre-market approval, FDA is stymied in its ability to ensure that these claims are backed up by scientific evidence. Although dietary

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[164] *Id.* at 3.

[165] *See id.* at 4 (citing 21 U.S.C. §§ 333(f)(2)(a), 334 (a)(1), 336) (stating that "The FDA may enforce compliance with a recall order or impose civil monetary fines when adulteration or misbranding of food 'will cause serious adverse health consequences of death,' such as when a label is missing allergen information. The FDA may condemn and seize misbranded foods only after the company receives proper notice and the opportunity to respond and the FDA has 'probable cause to believe . . . that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer.' Injunctions or criminal prosecutions are rarely used for food misbranding because the FD&C Act expressly provides that these enforcement actions should not be initiated for 'minor violations' when the 'public interest' may be adequately served by a written warning.").

[166] *Id.*

supplement manufacturers must submit a notification to FDA of their claim 30 days prior to marketing their product, "[t]he number of manufacturers that do not submit structure/function claims to FDA is unknown."[167] FDA reviews all notifications submitted by dietary supplement manufacturers to ensure they meet "the definition of a structure/function claim. If [they do] not, FDA sends a letter to the manufacturer notifying it that the claim is not in compliance and follows up as needed."[168] A fundamental gap in the agency's enforcement ability is that the law does not require manufacturers to submit the substantiation the manufacturer relied on to make its claim and, unlike the FTC, FDA "may not compel manufacturers to produce substantiation upon request."[169] As a result, FDA "has limited authority to enforce the substantiation requirement"[170] and many manufacturers do not have adequate substantiation for their claims.[171]

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[167] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 6 n.34.

[168] *Id.* at 6.

[169] *Id.* at 5. *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-11-102, FOOD LABELING: FDA NEEDS TO REASSESS ITS APPROACH TO PROTECTING CONSUMERS FROM FALSE OR MISLEADING CLAIMS 25 (Jan. 2011), http://www.gao.gov/assets/320/314473.pdf.

[170] STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 6.

[171] This was confirmed by the OIG in a 2012 report describing its analysis of structure/function claims and related substantiation documents "on a purposive sample of 127 dietary supplements marketed for weight loss or immune system support in retail stores and on the Internet." *Id.* at 7. The OIG found that "[i]n contrast to FDA guidance, most substantiation was not derived from human studies," and "10 percent of the documents appeared to have no significance in supporting structure/function claims." *Id.* at 11–12. Furthermore, only 2% of the human studies that the OIG reviewed looked at the products in the sample; 4% had results that contradicted the claims made; 85% were not randomized clinical trials; 49% were not based on populations similar to those that would be consuming the supplements; and 34% focused on a disease, rather than a structure/function endpoint, and of these, 20% "had prohibited disease claims" including treating diseases "such as influenza, the common cold, herpes, and HIV." *Id.* at

Moreover, once a product is on the market, if FDA believes that a structure/function claim is not truthful or is misleading, in any legal proceeding the burden is on FDA to prove that the claim is false or misleading[172] rather than on the manufacturer to prove that the claim is true and not deceptive.

FDA has also been limited in its enforcement efforts by First Amendment protections of commercial speech. As discussed in Section III. A. above, the entire category of "qualified health claims" came into being as a result of litigation establishing that FDA must allow claims with less than substantial evidence of their truth as long as they include disclaimers. The agency cannot simply bar such claims unless it can meet the burdensome test of demonstrating the inadequacy of the disclaimer.[173]

A further constraint on FDA's enforcement capabilities is lack of resources. In order to weed out noncompliant food labels and deceptive claims, FDA must rely on consumer complaints, proactive monitoring of Internet advertising, and physically reviewing labels at retail stores.[174] The latter two methods might root out more regulatory violations but are extremely labor-intensive. FDA has conceded that it is overwhelmed and is "struggling to police this booming

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12–16. Ten percent of the documents submitted did not qualify as substantiation – for example, one was a "30-year-old handwritten college term paper." *Id.* at 15.

[172] *Id.* at 4–5. *See also* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 169, at 27.

[173] *See* Pearson v. Shalala, 164 F.3d 650, 659 (D.C. Cir. 1999). *See also* Alliance for Natural Health v. Sebelius, 714 F. Supp. 2d 48, 61–62 (D.D.C. 2010); Alliance for Natural Health v. Sebelius, 786 F. Supp. 2d 1, 13–14 (D.D.C. 2011).

[174] While the agency conducts Internet surveillance to find supplements making such claims, it has not expanded its surveillance to retail stores. STRUCTURE/FUNCTION CLAIMS FAIL, *supra* note 9, at 3.

market."[175] In a letter published in *The Atlantic* in 2010, Michael Taylor, FDA Deputy Commissioner for Foods, confirmed that the agency can only reach the tip of the iceberg of noncompliant claims, stating that although FDA issued 20 enforcement letters to food companies that were marketing misbranded products in February 2010, these letters "addressed just a small subset of the universe of products making dubious marketing claims."[176] He further stated that although FDA would undoubtedly issue more letters on labeling violations, he did not see FDA "eradicating questionable health claims . . . any time soon," given that FDA has "no pre-market review authority over such claims, and, under prevailing legal doctrines concerning 'commercial free speech,' the evidentiary requirements placed on FDA to prove that such claims are misleading are significant and costly to meet."[177] Moreover, he acknowledged that FDA is "conscious of the cleverness of marketing folks, . . . Going after them one-by-one with the legal and resource restraints [the agency] work[s] under is a little like playing Whac-a-Mole, with one hand tied behind your back."[178]

Mr. Taylor's reference to "resource constraints" reflects a mismatch between FDA's statutory responsibilities and its budget that has been noted more generally by former HHS Secretary Tommy Thompson. According to Thompson, who spoke at an Institute of Medicine meeting on Challenges for the FDA,

> the FDA has been chronically underfunded in carrying out its responsibilities for ensuring the safety of drugs, medical devices, and the nation's food supply. While the FDA is commonly viewed as the global gold standard for consumer

[175] Singer, *supra* note 23.

[176] Taylor, *supra* note 2.

[177] *Id.*

[178] *Id.*

> protection, it faces stiff competition for scarce resources and over the past 20 years has been tasked to do far more with its limited resources.[179]

More recently, David Kessler, former FDA Commissioner and a board member of CSPI, stated that "[t]he importance of CSPI's Stop the Lying Labels campaign is only going to grow in these days of slashed government budgets, when agencies cut back on even their most basic public services."[180]

B. FTC

While the FTC has recently taken a number of actions against food and dietary supplement manufacturers for deceptive claims, there are also significant limitations on the FTC's approach to these violations of the law. Although the FTC has a broad range of enforcement actions it can take against manufacturers, it frequently relies on voluntary consent orders to gain compliance from offending companies.[181] When a company signs such an order, it

[179] INST. OF MEDICINE, CHALLENGES FOR THE FDA: THE FUTURE OF DRUG SAFETY, WORKSHOP SUMMARY 15 (2007), http://www.ncbi.nlm.nih.gov/books/NBK52930/pdf/TOC.pdf . *See also* Associated Press, *FDA Commissioner Margaret Hamburg: 2013 Budget Cuts Mean Less Safe Food*, POLITICO (Feb. 28, 2013), http://www.politico.com/story/2013/02/fda-commissioner-margaret-hamburg-2013-budget-cuts-mean-less-safe-food-88241.html.

[180] E-mail from Michael Jacobson to Diane Hoffmann, *supra* note 32. *See also* Taylor, *supra* note 2 ("establishing 'a systematic regulatory framework to prohibit misleading health-related claims' . . . is a noble goal and one we can readily embrace conceptually. But it's a tall order, especially considering the other high-priority nutrition and food safety initiatives that compete for FDA's finite resources.").

[181] Alexandra Ledyard, *Snake Oil in Your Pomegranate Juice: Food Health Claims and the FTC*, 47 U.S.F. L. REV. 783, 794 (2013).

need not admit that it violated the law, only that it will stop the practices identified by the agency.[182]

Also, like FDA, the FTC has limited enforcement resources and, given the number of companies marketing nutritional products, it cannot investigate and prosecute every case.[183] As a result, the FTC tends to target large companies, hoping that these actions will be a deterrent to other companies engaging in similar practices. Whether this strategy deters other large companies is unclear, but it is unlikely that it prevents smaller businesses from advertising their products on the Internet with deceptive claims. The bifurcated nutritional product industry—with a handful of multinational corporations and hundreds of smaller businesses, a number of which have been described as "rogue" or "fringe" operators[184]—creates challenges for the

[182] *Id.* at 794 & n.95 (citing *Consumer Protection: Law Enforcement*, U.S. FED. TRADE COMM'N (July 27, 2007), http://www.ftc.gov/bcp/menus/resources/enforcement.shtm). *See also* Fed. Trade Comm'n, *The Enforcers*, GUIDE TO ANTITRUST LAWS, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/enforcers (last visited Aug. 19, 2015) ("If the FTC believes that a person or company has violated the law . . . , the agency may attempt to obtain voluntary compliance by entering into a consent order with the company. 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 . . . .") *See also* Carol Brophy, *An Agency "Warning Letter" Does Not a Lawsuit Make: Sometimes a "Warning Letter" is Really Just a Warning*, SEDGWICK LAW (Nov. 2012), http://www.sedgwicklaw.com/an-agency-warning-letter-does-not-a-lawsuit-make-sometimes-a-warning-letter-is-really-just-a-warning-11-13-2012/.

[183] *Health Fraud and the Elderly: A Continuing Health Epidemic, Prepared Statement Before the S. Spec. Comm. on Aging*, FED. TRADE COMM'N (Sept. 10, 2001), http://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-dietary-supplement-fraud/healthfraud.pdf (prepared testimony of Howard Beales, Dir. of the Bureau of Consumer Protection, FTC).

[184] *See* Young, *supra* note 48 and accompanying text.

federal agencies attempting to regulate that market. To the extent that such fringe players seek quick profits from deceptive practices and then shift corporate identities, they present a particularly difficult target for FDA and FTC enforcement efforts.[185]

C. State consumer protection laws

While consumers are taking advantage of state UDAP laws to bring suits against nutritional product manufacturers making deceptive claims, there are also problems and inefficiencies to such state-based action. These problems include: 1) limits on the substantive provisions of state laws and differences in what they prohibit; 2) uncertainty as to how state courts will rule in these cases; 3) potential inconsistencies in outcomes from state to state as well as potential inconsistencies with federal enforcement policies; and 4) potential for over-reaching by plaintiffs who seek damages by bringing suits without a bona fide claim in hopes of an inflated settlement. As to the first of these, the National Consumer Law Center has observed that state UDAP statutes are too variable and constricted to be a strong deterrent to false health claims:

> The effectiveness of UDAP laws varies widely from state to state. The holes are glaring. Legislation or court decisions in dozens of states have narrowed the scope of UDAP laws or granted sweeping exemptions to entire industries. Other states have placed substantial legal obstacles in the path of officials charged with UDAP enforcement, or imposed ceilings as low as $1,000 on civil penalties. And several

[185] *See, e.g.*, Michael R. Ward & Michael J. Lee, *Internet Shopping, Consumer Search and Product Branding*, 9 J. PRODUCT & BRAND MGMT. 6, 8 (2000) (stating that "[b]ecause of the low costs of setting up a Web site, unreputable [*sic*] firms offering low quality products could potentially claim their products are of high quality, earn a profit before the ruse is uncovered, and then quickly disappear").

> states have stacked the financial deck against consumers who go to court to enforce the law themselves.[186]

Also, although the large majority of the claims seem to be brought in California, private litigants in California (and other states) are unable to argue that an advertised health benefit is deceptive because it lacks substantiation. California courts have stated:

> Claims that rest on a lack of substantiation, instead of provable falsehood, are not cognizable under the California consumer protection laws. . . . Challenges based on a lack of substantiation are left to the Attorney General and other prosecuting authorities; private plaintiffs, in contrast, have the burden of proving that advertising is actually false or misleading.[187]

This can be a significant burden.[188]

As to the second and third problems, while over 100 cases have been brought against food manufacturers by litigants in state courts, almost none have been decided, creating uncertainty as to whether the state laws actually will be interpreted in a way that will lead to positive outcomes for plaintiffs, or indeed whether state courts will play a positive role in developing sound public policy regarding health claims. The latter is of particular concern to FDA and the FTC, which seek consistency across enforcement actions. The proliferation of suits, in the absence of some

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[186] Carter, *supra* note 144, at 3. *See also* NAT'L CONSUMER LAW CENTER, *Appendix B: State-by-State Summaries of State UDAP Statutes*, *in* CONSUMER PROTECTION IN THE STATES (Jan. 10, 2009), https://www.nclc.org/images/pdf/udap/analysis-state-summaries.pdf.

[187] Bronson v. Johnson & Johnson, Inc., 2013 WL 1629191, *8 (N.D. Cal. Apr. 16, 2013) (No. C 12-04184 CRB). *See also, e.g.*, Scheuerman v. Nestlé Healthcare Nutrition, Inc., 2012 WL 2916827, *6 (D.N.J. July 17, 2012) (Nos. 10-3684(FSH)(PS), 10-5628(FSH)(PS)).

[188] *See, e.g. In re* GNC Corp. 789 F.3d 505, 513–16 (4th Cir. 2015) (holding that a claim cannot be literally false (as distinct from misleading) if even one expert agrees with it). *But see also* Fed. Trade Comm'n v. Pantron I Corp., 33 F.3d 1088, 1100 (9th Cir. 1994) (holding that the FTC "is not required to prove that a products is 'wholly ineffective' in order to carry its burden of showing that the seller's representations of product efficacy are 'false'").

overall framework, potentially undermines the federal agencies' goal of a coherent and authoritative set of laws and policies to guide the regulated community. From the perspective of risk-averse nutritional product manufacturers, inconsistencies in outcomes from state to state would create costly uncertainty,[189] as well as the burden of having to market their products differently in different states.

Finally, as to the fourth problem, the opportunity for generous damages for plaintiffs and contingency fees for their attorneys may lead to overreaching, i.e., bringing suits that lack legitimacy. A manufacturer might make a business judgment to settle such claims, despite their lack of merit, in order to avoid the costs associated with protracted litigation.[190]

V. A LIMITED FEDERAL PRIVATE RIGHT OF ACTION AS A SUPPLEMENT TO GOVERNMENT ENFORCEMENT

Laws that empower government agencies to protect consumers are predicated on market failure: in many areas, "key information necessary for consumers to make a sensible choice between rival brands, or to decide whether to buy the product at all, is absent."[191] Yet, this corrective itself can fail when the federal enforcement regime is disproportionately small,

[189] *See* Roller & Pippins, *supra* note 111, at 447.

[190] *See* Brophy, *supra* note 182 (asserting that plaintiffs' attorneys often bring these suits based on FDA or FTC "press releases, warning letters and complaints" which do not establish the law).

[191] Robert Pitofsky, *Beyond Nader: Consumer Protection and the Regulation of Advertising*, 90 HARV. L. REV 661, 664 (1977).

measured against the size or nature of the marketplace to be policed. "[R]egulation is only as good as the enforcement mechanisms underlying it."[192]

One congressional response to the problem of insufficient federal protection of statutory consumer rights has been to enlist state attorneys general as additional law enforcers. For example, the Consumer Product Safety Act authorizes state attorneys general to seek injunctive relief for a violation "that affects or may affect such State or its residents . . . ."[193] Similar provisions may be found, for instance, in the Telemarketing and Consumer Fraud and Abuse Prevention Act,[194] the Children's Online Privacy Protection Act,[195] and the Restore Online Shoppers' Confidence Act.[196]

A second strategy is to broaden enforcement even more, by granting rights of action to non-governmental actors. One commentator's summary of the rationale for private rights of action to vindicate civil rights laws is no less persuasive for consumer protection laws: "Even [a] . . . well-funded, vigorous public enforcement agency could only do so much. Private litigation engages a multitude of private actors to bring their resources to rooting out [unlawful activity]."[197]

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[192] J. Maria Glover, *The Structural Role of Private Enforcement Mechanisms in Public Law*, 53 WM. & MARY L. REV. 1137, 1142 (2012).

[193] 15 U.S.C. § 2073(b)(1) (2012).

[194] § 6103.

[195] § 6504.

[196] § 8405.

[197] Olati Johnson, *Beyond the Private Attorney General: Equality Directives in American Law* 9 (Columbia Law Sch. Pub. Law & Legal Theory, Working Paper No. 9204, 2012), http://lsr.nellco.org/columbia_pllt/9204/. Versions of this argument likewise have been presented in support of unsuccessful claims for judicial recognition of an implied private right of action under the FTC Act. *See, e.g.*, Carlson v. Coca-Cola Co., 483 F.2d 279, 281 (9th Cir.

Within the broad category of consumer protection laws, Congress has authorized private rights of action in, for example, the Consumer Product Safety Act,[198] the Fair Credit Reporting Act,[199] the Equal Credit Opportunity Act,[200] and the Real Estate Settlements Procedures Act.[201] Within the narrower category of consumer protection laws aimed at preventing deceptive marketing practices, private rights of action are found in the Hobby Protection Act,[202] the

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1973) (Solomon, J., dissenting). It is well established that there is no private right of action under the FTC Act. *See, e.g.*, Holloway v. Bristol-Myers Corporation, 485 F.2d 986 (D.C. Cir. 1973).

[198] 15 U.S.C. § 2072(a) (2012) ("Any person who shall sustain injury by reason of any knowing (including willful) violation of a consumer product safety rule, or any other rule or order issued by the [Consumer Product Safety] Commission may sue any person who knowingly (including willfully) violated any such rule or order . . . ."). The statute provides for attorneys' and expert witnesses' fees. *Id.*

[199] "Any consumer" with respect to whom certain willful violations of the Fair Credit Reporting Act (FCRA) occurred may be awarded actual damages (within statutory limits), punitive damages, and costs including attorneys' fees. 15 U.S.C. § 1681n (2012). Not all provisions of the FCRA are encompassed by this private right of action, however. *See* Longman v. Wachovia Bank, N.A., 702 F.3d 148, 151–52 (2d Cir. 2012).

[200] A creditor that violates statutory or regulatory requirements is liable to "an aggrieved applicant" for actual damages, punitive damages (within statutory limits), and costs including attorneys' fees. 15 U.S.C. § 1691e (2012).

[201] This statute contains three private causes of action: (1) Anyone who violates certain notice requirements is liable to "the borrower" for actual damages, additional damages in cases of a pattern or practice of noncompliance (within statutory limits), and costs including attorneys' fees. 12 U.S.C. § 2605(f) (2012). (2) Anyone who gives or receives kickbacks or unearned fees in connection with settlement services is liable to "the person or persons charged for the settlement service" for treble damages and costs including attorneys' fees. 12 U.S.C. § 2607(d)(2), (5) (2012). (3) Any seller who requires the purchase of title insurance from a particular title company is liable to "the buyer" for treble damages. 12 U.S.C. § 2608(b) (2010).

[202] The statute specifies certain requirements for "imitation political items" and "imitation numismatic items" and provides that violations of these requirements are violations of the Federal Trade Commission Act. 15 U.S.C.

National Gold and Silver Stamping Act,[203] and the Truth in Lending Act ("TILA").[204] Referring to TILA, the FTC has stated as follows: "Since the Act provides for a private right of action, use of that provision should be encouraged where the public interest and the cost benefit [*sic*] indicate that Commission action is not warranted."[205]

As discussed in Sections II and IV above, the market for nutritional products is marred by claims of benefit that consumers are unable to evaluate on their own and that government enforcement agencies are unable to police adequately—in the FDA's case, because of limitations on its regulatory authority over many of these products; in both the FDA's and FTC's case, because their resources are insufficient given the breadth of their responsibilities. Nor are state consumer protection laws sufficient, given nationwide marketing and the difficulty of pursuing elusive out-of-state defendants.[206] Hence, correcting abuses in this market segment entails

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§ 2101(a), (b) (2012). The statute authorizes "any interested person" to seek injunctive relief and damages for violations and provides for costs and attorneys' fees. 15 U.S.C. § 2102 (2012).

[203] "Customers," as well as competitors, of precious metal manufacturers or dealers who violate certain requirements related to markings and tolerance from stated quality may sue for injunctive relief and damages and may be awarded costs and attorneys' fees. 15 U.S.C. § 298(b) (2012).

[204] Violations of the Truth in Lending Act or its implementing regulation (adopted by the Federal Reserve Board) are deemed to be violations of the Federal Trade Commission Act. 15 U.S.C. § 1607(c) (2012). Individual and class actions are authorized against creditors who fail to comply with the Act; actual damages, statutory damages under certain circumstances, and costs and attorneys' fees may be awarded. 15 U.S.C. § 1640 (2012).

[205] FED. TRADE COMM'N, OPERATING MANUAL CHAPTER 9: SPECIAL STATUTES 2, https://www.ftc.gov/sites/default/files/attachments/ftc-administrative-staff-manuals/ch09specialstatutes.pdf (last visited Aug. 19, 2015).

[206] *See supra* notes 48–49 and accompanying text regarding "fringe" manufacturers.

augmented enforcement of existing federal law, through the grant of a right of action to non-federal parties.

Set against this point is the argument that such a right of action poses risks to the agencies' role in setting policy. State attorneys general have different constituencies and political incentives, "open[ing] up new outlets for state-centered policy" at variance with what federal agencies might perceive to be in the broader national interest.[207] Non-federal litigants, for example, might seek to apply the broad standard of "unfair or deceptive" conduct in ways inconsistent with criteria developed by the FTC.[208] In addition, private litigants may have economic incentives to bring actions primarily for the purpose of extracting settlements from possibly innocent defendants, akin to the concern about "strike suits" in class action securities fraud litigation.[209]

Seeking to balance the competing considerations of expanding enforcement opportunities for non-federal agencies and concerns of federal agencies for developing a set of coherent laws and consistent policies, we propose that Congress allow a limited group of non-governmental plaintiffs to seek enforcement of FTC Act standards in the advertising and marketing of nutritional products. Creating a federal private right of action but limiting those who may bring actions to state attorneys general and consumer protection organizations should make it easier for

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[207] Margaret H. Lemos, *State Enforcement of Federal Law*, 86 N.Y.U. L. REV. 698, 698 (2011).

[208] *See* Henry N. Butler & Joshua D. Wright, *Are State Consumer Protection Acts Really Little-FTC Acts?*, 63 FLA. L. REV. 163, 188 (2011) (presenting evidence that state acts "may allow consumers to pursue different types of claims, including many that do not involve conduct that would be illegal under FTC standards for consumer protection.").

[209] *See, e.g.*, Richard F. Conklin, *Why "Or" Really Means "Or": In Defense of the Plain Meaning of the Private Securities Reform Act's Safe Harbor Provision*, 51 B.C. L. REV. 1209, 1210 (2010).

these public interest oriented plaintiffs to coordinate and work together. This federal private right of action should be an attractive and more efficient alternative to bringing actions under each state's consumer protection laws.

The following are the key features of the proposed Nutritional Products Consumer Protection Act. Appendix A provides draft statutory language for an amendment to the Federal Trade Commission Act embodying these features.

Products covered (§(a)(1) and (2)). The Act would apply to "nutritional products," a term encompassing "food" and "dietary supplements." The latter two terms would be defined as they are in the FD&C Act.

Substantive requirement (§(b)). The Act would prohibit those who sell nutritional products in interstate commerce from engaging in "an unfair or deceptive act or practice, within the meaning of Section 5 of [the FTC] Act." This incorporation of FTC Act standards allows the extensive body of law developed over the last century to be applied to the marketing of nutritional products and would deter plaintiffs from advancing novel theories of liability unmoored to this body of law. This provision is also drafted to ensure against encroachments on FDA's authority by providing that a seller's "use of any material that has been reviewed and approved by [FDA] may not be deemed to be a violation" of the Act.

Plaintiffs authorized (§(a)(3)). As discussed above, Congress has frequently empowered state attorneys general to bring enforcement actions under statutes otherwise reserved for federal agency enforcement. We propose a similar role in this statute. Consumer protection lawyers in the offices of state attorneys general are experienced litigators, familiar with the "unfair or deceptive" standard. Given competing priorities and shrinking budgets, however, state attorneys general may not themselves be able to achieve the desired deterrent effect.

Hence, we propose that the right of action be extended to a limited group of private attorneys general: non-profit organizations. Non-profits such as the Center for Science in the Public Interest[210] and the Consumer Federation of America[211] have relevant expertise concerning food and nutrition and an organizational commitment to preventing the harm of false or unsubstantiated claims.[212] Affording a right of action to attorneys general and expert non-profit organizations would harness their resources to protect consumers in a marketing arena badly needing additional enforcement without serious risk of "overzealous or otherwise socially undesirable enforcement efforts."[213]

Remedies (§(c)). Injunctive relief and damages would be authorized. To provide the incentive common in consumer protection legislation, the proposed Act would allow for the award of attorneys' fees to a prevailing plaintiff.

Preservation of FDA/FTC authority (§(d) and (e)(1)). The Act would require advance notice of an action to the FDA and FTC and would afford the two agencies an

[210] CSPI's litigation docket includes several cases alleging false or misleading claims in the marketing of foods and beverages. *Litigation Project – Current Docket*, CTR. FOR SCIENCE IN THE PUB. INTEREST, http://www.cspinet.org/litigation/current.html (last visited Aug. 19, 2015).

[211] Nutrition is one of the Federation's areas of focus. *Nutrition*, CONSUMER FED. OF AM., http://www.consumerfed.org/issues/food-and-agriculture/nutrition (last visited Aug. 19, 2015).

[212] We assume that suits authorized under the proposed statute would ordinarily meet the criteria for associational standing. *See, e.g.*, United Food & Commercial Workers Local 751 v. Brown Group Inc., 517 U.S. 544, 553 (1996).

[213] David Freeman Engstrom, *Harnessing the Private Attorney General: Evidence from Qui Tam Litigation*, 112 COLUM. L. REV. 1244, 1253 (2012).

unconditional right to intervene.[214] All existing FDA and FTC enforcement authority would be unaffected.

Non-preemption (§(e)(2)). State UDAP laws would be unaffected by the Act.

VI. CONCLUSION

The number of deceptive health claims being made by nutritional product manufacturers is large and growing. The federal agencies tasked with enforcing the laws that prohibit such claims are limited in their enforcement actions by statutory and First Amendment constraints but more significantly by insufficient resources to adequately police this market. State consumer protection laws are helping in some states to curtail these wrongful claims, but enforcement via different state laws is likely to lead to inconsistencies across states and with federal enforcement policies. In response to this expanding problem, we propose a limited private right of action under the Federal Trade Commission Act to allow state attorneys general and non-profit organizations to bring enforcement actions in federal court to enforce provisions of the FTC Act prohibiting deceptive nutritional product claims. Such a right would augment badly needed protection for consumers without impairing the federal agencies' enforcement efforts and goals.

[214] This provision is adapted from a provision in the Consumer Financial Protection Act of 2010. 12 U.S.C. § 5552 (2012).

APPENDIX A

Nutritional Products Consumer Protection Act

15 U.S.C. §_____.

(a) For purposes of this section:

(1) The terms “food,” “dietary supplement,” “person,” and “State” have the meaning provided for these terms in the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321.

(2) The term “nutritional product” means a food or dietary supplement.

(3) The term “authorized plaintiff” means:

(i) The Attorney General of a State; or

(ii) A person that is a tax-exempt organization under § 501(c)(3) of the Internal Revenue Code.

(b) A person may not commit an unfair or deceptive act or practice, within the meaning of Section 5 of this Act, in connection with the selling or offering for sale in interstate commerce of any nutritional product. A person’s use of any material that has been reviewed and approved by the Food and Drug Administration may not be deemed to be a violation of this subsection.

(c) (1) If any person violates subsection (b) of this section, an authorized plaintiff may commence a civil action for injunctive relief restraining such violation and for damages in any United States District Court for a district in which the defendant resides or has an agent.

(2) In any civil action under this subsection, the court may award to an authorized plaintiff the costs of the suit, including reasonable attorneys’ fees.

(d) (1) At least 30 days before initiating any action authorized by subsection (c) of this section, an authorized plaintiff shall timely provide a copy of the complete complaint to be filed and written notice describing such action, to the Commission and the Food and Drug Administration.

(2) The written notice required under this paragraph shall, at a minimum, describe:

(i) the identity of the parties;

(ii) the alleged facts underlying the proceeding; and

(iii) the relationship, if any, to any proceeding, including any rulemaking, undertaken by the Commission, the Food and Drug Administration, or another Federal agency.

(3) In any action authorized by subsection (c) of this section, the Commission or the Food and Drug Administration may—

(i) intervene in the action as a party; and

(ii) appeal any order or judgment, to the same extent as any other party in the proceeding.

(e) Nothing in this section impairs or preempts:

(1) any enforcement authority of the Commission or the Food and Drug Administration; or

(2) any cause of action available to an authorized plaintiff under State law.