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The Crazy Maze of Food Labeling and Food Claims Laws

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THE CRAZY MAZE OF FOOD LABELING AND FOOD CLAIMS LAWS

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INTRODUCTION

There is a de facto right in America to know what contents make up the food we consume.[1] The United States Department of Agriculture ("USDA") regulates food labels and label claims made on meat, poultry, and egg products,[2] and the United States Food and Drug Administration ("FDA") regulates the labeling and labeling claims on all other foods.[3] The mission of the FDA is to protect the health of the public.[4]

The FDA has the monumental task of identifying and remedying unsubstantiated product claims. Consider the various teas sold at cancerherbtea.com, which touted their ability to heal cancer and dozens of similar claims as described in a recent FDA Warning Letter.[5] Some of the unsubstantiated claims included: "Cancer Herb Tea 'You have nothing to lose but your cancer,' " "Proven to help kill the cancer cells, try out the natural herbal

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[1] MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES 254 (2016). Roberts notes that although it is not expressly stated in U.S. law, the concept of the consumer's right to know the contents in food is apparent when one considers the increased consumer demand for food information. *Id*.

[2] U.S. Dep't of Agric., Food and Safety Inspection Serv., *Labeling/Label Approval*, http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling (last updated Dec. 16, 2016); ROBERTS, *supra* note 1, at 208.

[3] *What Does FDA Regulate?*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (last updated Aug. 7, 2018); ROBERTS, *supra* note 1, at 208.

[4] *What We Do*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/AboutFDA/WhatWeDo/default.htm (last updated March 28, 2018).

[5] U.S. Food & Drug Admin., Warning Letter on cancerherbtea.com (Feb. 26, 2015) https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2015/ucm435681.htm.

remedy which is successfully battling the disease!," and "help[s] reduce and kill bad cancer cells but also helps with . . . diabetes, insomnia, arthritis, [and] reduces fever . . . ."[6] Another time-consuming responsibility of the FDA is monitoring the marketing of powerful drugs as dietary supplements. For instance, the FDA recently sent a Warning Letter to Andropharm, LLC because the company did not have the required FDA pre-approval to market its dietary supplement that contained synthetic steroids.[7] The FDA noted that anabolic steroids could cause serious health consequences, including "liver toxicity, testicular atrophy and male infertility, breast enlargement in males, short stature in children, adverse effects on blood lipid levels, and a potential to increase the risk of heart attack and stroke."[8] This Article critiques the role of the FDA in providing consumers with accurate and relevant food label information, identifies impediments in the pursuit of its mission, and offers solutions to those impediments.

Part I of this Article traces the history of U.S. food labeling and health claims laws. Current food laws and their regulation have developed over time. The first federal legislation was passed in the early 1900s. The food laws of today have certainly been influenced by past food laws, which were largely a reaction to societal events. A brief summary of the historical development of our nation's important food laws should serve to illustrate this point. Next, Part II demonstrates the significant hurdles that prevent the FDA from fulfilling its mission of consumer safety. The FDA has too many regulations to enforce, too many products and establishments to keep up with, and not enough staff or funding to adequately do either. Currently, supplement manufactures are not required to submit safety evidence before selling products.[9] Therefore, the FDA does not investigate safety issues until becoming aware of a widespread health concern. The

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[6] *Id.* (omission in original).

[7] U.S. Food & Drug Admin., Warning Letter on Andropharm, LLC (June 5, 2017) https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2017/ucm561975.htm.

[8] *Id.*

[9] Maggie Dickens, Comment, *Safe Until Proven Unsafe: Solving the Growing Debate Around Dietary Supplement Regulation*, 15 WAKE FOREST J. BUS. & INTELL. PROP. L. 576, 577–89 (2015); Natalie R. Bilbrough, Comment, *The FDA, Congress, and Mobile Health Apps: Lessons from DSHEA and the Regulation of Dietary Supplements*, 74 MD. L. REV. 921, 944–46 (2015); Andrea M. Pezzullo, Note, *The Crusade Against Misleading Labels*, 49 SUFFOLK U. L. REV. 323, 338 (2016).

administrative hurdles are not internal to the FDA. The FDA is one of several agencies responsible for the regulation of food, and there are differing rules and key term definitions between agency regulations. Having varying rules and term definitions makes for conflicting laws and consumer confusion.

Part III reviews studies on the effectiveness of food labels and health claims, as well as how the courts have treated health claims. Finally, Part IV argues that food and nutrition supplement laws should be streamlined. Although several authors ably identify solutions for how this may be accomplished, the sheer number of solutions that have been posited over the past several years is too plentiful to reasonably implement. Therefore, this Article suggests a combination of a few solutions that, taken together, are manageable implementations, which will maximize positive change in food law protections. The proposed improvements to food laws will be limited to establishing a simple mandatory front-of-package labeling scheme that will include: (1) eliminating structure/function claims; (2) greatly revising and simplifying nutrition content claims laws; (3) having the FDA issue letter grades for products based on evidence of health claims while allowing agreed-on health claims language to appear on the label; and (4) deferring to the expertise of the FDA in the courts.

I. HISTORY OF U.S. FOOD LABEL LAWS & HEALTH CLAIMS

Congress first recognized the need to protect citizens purchasing food by passing the first national legislative act relating to food law, the Pure Food and Drug Act, in 1906.[10] The Act prohibited adulterated foods or drugs and false and misleading statements describing the overall identity of the product, but did not require the listing of specific ingredients or nutritional content.[11] Congress amended the Pure Food and

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[10] ROBERTS, *supra* note 1, at 210; Pure Food Act, Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

[11] §§ 1-13, 34 Stat. at 768–72; ROBERTS, *supra* note 1, at 210–11; Jason M. Szanyi, *Brain Food: Bringing Psychological Insights to Bear on Modern Nutrition Labeling Efforts*, 65 FOOD & DRUG L.J. 159, 159 (2010); Josh Dhyani, *Science-Based Food Labels: Improving Regulations & Preventing Consumer Deception Through Limited Information Disclosure Requirements*, 26 ALB. L.J. SCI. & TECH. 1, 7 (2016). The Act defined a drug product as being "adulterated" if it lacked the typical "standard of strength, quality, or purity." § 7, 34 Stat. at 769. A food product was considered to be "adulterated" if the strength of the product was diluted by additives or if a critical component of the food had been replaced by an inferior substance or

Drug Act in 1912 to address drug product claims and impute liability to manufacturers for false claims as to "the curative or therapeutic effect" of the product or any of its ingredients.[12] The 1938 Federal Food, Drug, and Cosmetic Act ("FDCA") added a definition for "labeling" to U.S. food laws, which included graphic or written matter affixed to or shipped with a product.[13]

In 1966, Congress passed the Fair Packaging and Labeling Act, establishing the requirements of net quantity content labeling, label placement, label format standards, the requirement that the manufacturer be listed on the label, and forbidding nonfunctional "slack-fill," where there is substantially less of a product relative to the size of the package.[14] A subsequent regulation, enacted in 1973, augmented the Fair Packaging and Labeling Act by requiring full nutrition labeling if a manufacturer included any nutritional information, made a nutrition claim, or added "vitamin[s], mineral[s], or protein[s]" to the food.[15]

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abstracted from the food. *Id.* at 769–70. A food product was said to be misbranded if, inter alia, a statement about the product was "false or misleading." Intent to deceive was a requirement for a finding of liability. *Id.* at 770–71. The law gave the government the authority to chemically test food but the burden of proof fell on the government. *Id.* at 769. Section 4 of the Act stated that chemical examinations of food and drug product are to be made in order to identify adulterated or misbranded food. *Id.*

[12] An Act to Amend Section Eight of the Food and Drugs Act, Pub. L. No. 62–301, 37 Stat. 416–17 (1912).

[13] Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75–717, § 1, 52 Stat. 1040–41 (1938) (codified at 21 U.S.C. § 301 (2012)); ROBERTS, *supra* note 1, at 211. This Act kept the food testing provision from the Pure Food and Drug Act, but added a provision for factory and transport vehicle inspections. 52 Stat. at 1056–57.

[14] Dhyani, *supra* note 11, at 14; Fair Packaging and Labeling Act, Pub. L. No. 89–755, 80 Stat. 1296–99 (1966). The definition of misrepresentation includes the representation or implication that a product was offered "at a price lower than the ordinary and customary retail sale price or that a . . . price advantage is accorded . . . by reason of the size of that package or the quantity of its contents." § 5, 80 Stat. at 1299.

[15] Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act and the Fair Package and Labeling Act, 38 Fed. Reg. 6951, 6959–61 (Mar. 14, 1973) (to be codified at 21 C.F.R. pt. 1). If "vitamin[s], mineral[s], or protein[s]" were added to the food, then serving size, servings per container, calories, protein, carbohydrate, fat, and percentage of recommended daily allowances had to be added to the label. *Id.* at 6959–60. If cholesterol information was included on the label, full nutritional labeling was required. *Id.* at 6962; *see also id.* at 6952. The regulation stated that a product could not claim to be a "significant source" of a nutrient unless it contained at least ten percent of the Recommended Dietary Allowance per serving, and could not claim to be "nutritionally superior" to another product unless there was at least 10 percent more of the nutrient in the product per serving. *Id.* at 6960.

Congress responded to the need for consistent food labeling by passing the Nutrition Labeling and Education Act of 1990 ("NLEA"), which created mandatory food labeling requirements and qualified nutrient claim parameters.[16] The NLEA required certain nutritional facts including calories, serving size, number of servings per container, total fat, total calories, saturated fat, cholesterol, sugars, and sodium be displayed on all food products.[17] The NLEA also forbade nutrition content claims if the term was not already defined by the FDA.[18] Further, the NLEA restricted the use of health claims in marketing and branding unless the FDA had issued a regulation allowing the claim.[19] In 1997, the FDA began to allow health claims if a scientific body of the government had published an "authoritative statement" in support of the claim.[20]

In an effort to provide citizens with more useful information regarding dietary supplements,[21] Congress amended the Federal Food, Drug, and Cosmetic Act, with the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[22] Under the DSHEA, the burden to prove that a supplement is adulterated or

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[16] Camille Currey, Note, *Despite What You've Been Sold – Unwrapping the Falsities Surrounding Food Labels*, 118 W. VA. L. REV. 1279, 1293 (2016); ROBERTS, *supra* note 1, at 231; Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, 2357-61 (1990) (codified at 21 U.S.C. § 301 (2012)); Dhyani, *supra* note 11, at 16–17.

[17] § 2, 104 Stat. at 2353. However, food sold at restaurants was exempt from the NLEA. *See* § 2, 104 Stat. at 2355.

[18] ROBERTS, *supra* note 1, at 231; § 2, 104 Stat. at 2357–58.

[19] ROBERTS, *supra* note 1, at 231; § 3, 104 Stat. at 2357, 2359–60.

[20] ROBERTS, *supra* note 1, at 231–32 (citing § 343 of the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, 2350–51). In addition, the NLEA required the FDA to define the terms "free," "low," "light," "reduced," "less," and "high." § 2, 104 Stat. at 2361. These terms were defined in the final regulation Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms. Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, Definitions of Nutrient Content Claims for the Fat, Fatty Acid, and Cholesterol Content of Food, 58 Fed. Reg. 2302, 2412 (Jan. 6, 1993) (to be codified at 1 C.F.R. pts. 5, 101).

[21] ROBERTS, *supra* note 1, at 322; *see also*, Regulation of Dietary Supplements, 58 Fed. Reg. 33690, 33691 (June 18, 1993) (The Dietary Supplement Task Force was established in May of 1991 to review dietary supplement rules, in part because of two significant public health outbreaks related to the use of dietary supplements. In May of 1992, the task force submitted its report, identifying "the safety of ingredients in dietary supplements as the overriding concern for FDA as it develops a regulatory framework to distinguish among dietary supplement products.").

[22] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994).

contains false or misleading labeling shifts to the FDA.[23] The DSHEA only applies to supplements that contain ingredients first marketed after October 14, 1994.[24] The DSHEA allows product removal proceedings to commence only if it is determined that the claim rises to the stratospheric level of being an "imminent hazard to public health or safety."[25] The DSHEA allows supplement manufacturers to make a nutrition claim provided they include a disclaimer stating that the FDA had not evaluated the claim.[26]

In order to increase consumer safety,[27] in 2006, Congress amended the Federal Food, Drug, and Cosmetic Act with the Dietary Supplement and Nonprescription Drug Consumer Protection Act.[28] Section 3 of the amended act requires dietary supplement manufacturers to submit reports of "serious adverse event[s]" to the FDA.[29] The Act defines a "Serious [A]dverse [E]vent" as an event leading to death, hospitalization, a "life-threatening experience," "persistent or significant disability or incapacity," "a congenital anomaly or birth defect," or which requires medical intervention.[30] This system is necessary because U.S. law treats nutritional supplements as food and not medication, so there is no need to prove safety or effectiveness *before* a product enters the market.[31] The FDA does not investigate health concerns unless there are enough reported "serious adverse events."[32] However, even though reporting is required, it is estimated that only two percent of serious adverse

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[23] *Id.* at 4328-29.

[24] *Id*. at 4331-32; Bilbrough, *supra* note 9, at 946.

[25] § 4, 108 Stat. at 4328; Bilbrough, *supra* note 9, at 946.

[26] § 4, 108 Stat. at 4329; *see also* Bilbrough, *supra* note 9, at 948.

[27] S. REP. NO. 109–324, at 1–2 (2006) (Conf. Rep.), *reprinted in* 2006 U.S.C.C.A.N. 1841, 1841–42.

[28] Dietary Supplement and Nonprescription Drug Consumer Protection Act, Pub. L. No. 109–462, 120 Stat. 3469 (2006).

[29] *Id.* at 3472–73.

[30] *Id.*

[31] Rick Schmitt, *Supplement Pills That Promise Too Much*, AARP BULLETIN (June 2016), https://www.aarp.org/health/drugs-supplements/info-2016/drug-vitamin-supplement-claims.html.

[32] ROBERTS, *supra* note 1, at 326–27. Because there is no pre-approval required for food, "the FDA relies on the adverse event reporting system" to identify product safety issues. *Id.* at 326; *FDA Adverse Event Reporting System (FAERS): Latest Quarterly Data Files*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm082193.htm (last visited Sept. 22, 2018).

events were reported to the FDA.[33] The FDA also does not pre-approve food labels for nutritional content accuracy.[34] Instead, the FDA spot checks manufacturers after consumer complaints are lodged.[35]

Several types of claims can be advertised on packaging labels. First, "structure/function claims" are allowed to describe the role an ingredient plays in the "normal structure or function of the human body."[36] Nutrition content claims, which state the nutritional makeup of the product, are allowed as long as the FDA has defined the ingredient.[37] Third, "health claims" state that the product reduces the chances of obtaining a disease or alleviates a health condition.[38] If there is some credible evidence to support the health claim, but not to the level that satisfies a significant scientific agreement standard, then an FDA crafted disclaimer that qualifies the claim must appear on the product label.[39] This is called a "Qualified Health Claim."[40] Since the early 2000s, courts have required the FDA to issue carefully worded disclaimers for qualified health claims, instead of categorically denying them.[41] Unqualified health claims or authorized health claims are approved by the FDA if they meet the high evidentiary standard of significant scientific agreement.[42] According to the FDA:

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[33] Bilbrough, *supra* note 9, at 949 (citing Richard Potomac, *Are You Sure You Want to Eat That?: U.S. Government and Private Regulation of Domestically Produced and Marketed Dietary Supplements*, 23 LOY. CONSUMER L. REV. 54, 66 (2010)).

[34] ROBERTS, *supra* note 1, at 212; Lisa Heinzerling, *The Varieties and Limits of Transparency in U.S. Food Law*, 70 FOOD & DRUG L.J. 11, 18 (2015).

[35] ROBERTS, *supra* note 1, at 212.

[36] *Structure/Function Claims*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/Food/LabelingNutrition/ucm2006881.htm (last updated Dec. 14, 2017) [hereinafter *Structure/Function Claims*]. An example of a "structure/function claim" is "calcium builds strong bones." *Id*.

[37] Nutrition Labeling and Education Act of 1990, Pub. L. 101–535, 104 Stat. 2353, 2357–58 (1990) (codified at 21 U.S.C. § 343).

[38] *Label Claims for Conventional Foods and Dietary Supplements*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/Food/LabelingNutrition/ucm111447.htm (last updated June 19, 2018) [hereinafter *Label Claims*]; *Question and Answers on Health Claims in Food Labeling*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/Food/LabelingNutrition/ucm207974.htm (last updated Dec. 13, 2017).

[39] *Questions and Answers on Health Claims in Food Labeling*, *supra* note 38.

[40] *Id.*

[41] *See infra* Part III.C.

[42] *See Authorized Health Claims That Meet The Significant Scientific Agreement (SSA) Standard*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/Food/LabelingNutrition/ucm2006876.htm (last updated Jan, 12, 2018).

> To be approved by the FDA as an authorized health claim, there must be significant scientific agreement ("SSA") among qualified experts that the claim is supported by the totality of publicly available scientific evidence for a substance/disease relationship. The SSA standard is intended to be a strong standard that provides a high level of confidence in the validity of the substance/disease relationship.[43]

II. PROBLEMS WITH U.S. FOOD LAW GOVERNANCE

There are estimated to be between 50,000 and 100,000 dietary supplements currently being sold.[44] The number of supplements for the FDA to monitor, combined with the lack of pre-approval laws, causes investigations into health-related claims to commence after too many people have been injured because the FDA relies on consumer reports through the adverse event system.[45] When regulators obtain convictions for illegal behavior, the penalty is often a civil fine that, although substantial, still pales in comparison to the money that is made because of the false claims.[46] For example, Dannon recently claimed that its Activia yogurt regulates digestion and its DanActive drink helps prevent the flu and colds.[47] In 2010, The FTC reached a $21 million settlement with Dannon.[48] In the meantime, it is suspected that Dannon made more than that amount[49] in the $3.7 billion U.S. Greek yogurt market.[50]

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[43] *Id.* (citation omitted); *see also* U.S. Food & Drug Admin., Guidance for Industry: Evidence-Based Review System For the Scientific Evaluation of Human Claims, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm073332.htm (last updated Sept. 19, 2018). This document provides a full explanation of the evidentiary standard used by the FDA.

[44] Schmitt, *supra* note 31.

[45] *Id.*

[46] *Id.*; Dickens, *supra* note 9, at 587 (noting that "[t]he economic growth of the industry due to the ability to escape regulations is too large for miniscule settlements to deter the industry from changing its own practices.").

[47] Currey, *supra* note 16, at 1279-80; Press Release, 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.

[48] Bailey Mosier, *Dannon Fined $21M for False Marketing*, EMPOWHER (Dec. 16, 2010), http://www.empowher.com/healthy-eating/content/dannon-fined-21m-false-marketing?page=0,0.

[49] Currey, *supra* note 16, at 1279–80. *See generally* Schmitt, *supra* note 31. Paying a large fine is a minor cost of doing business.

[50] *U.S. Greek Yogurt Market – Statistics & Facts*, STATISTA, https://www.statista.com/topics/2351/greek-yogurt/ (last visited Sept. 29, 2018).

The dietary supplement industry is very large and has its share of false advertising claims. A senior attorney for AARP Foundation Litigation stated that the cost of supplements sold with inaccurate claims is in the billions of dollars.[51] The potential profits incentivize companies to keep marketing their products in the same way and treat government fines as the "cost of doing business."[52] Further, even after issuing fines, the FTC sometimes permits a company to market a product with a new message that can still seem to be misleading. For example, CVS Pharmacy, Walmart, Walgreens, Rite Aid, and others sold BrainStrong Adult with DHA, an ingredient that marketers promoted as "[c]linically shown to improve adult memory."[53] A 2014 FTC Consent Order forbid the manufacturers from making any representation, either explicitly or implicitly, that their products "improve[] memory in adults" or "prevent[] cognitive decline . . . in adults" without "reliable scientific evidence."[54] However, one of the successor manufacturers of BrainStrong Adult subsequently offered a similar product for sale, and marketed the product with claims of "pure DHA for memory support."[55] The change from using the phrase "improves memory in adults" to "memory support" seems to violate the 2014 FTC order that forbade implied claims of memory enhancement.[56] Two subsequent class action lawsuits against CVS will determine if similar advertising is acceptable as it pertains to another of their products containing DHA.[57] The product is still being sold with the new message intact.[58]

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[51] Schmitt, *supra* note 31.

[52] *Id.*

[53] Press Release, Fed. Trade Comm'n, Supplement Marketers Settle FTC Charges that "BrainStrong Adult" Memory Improvement Claims Are Deceptive (June 9, 2014), https://www.ftc.gov/news-events/press-releases/2014/06/supplement-marketers-settle-ftc-charges-brainstrong-adult-memory.

[54] *Id.*; I-Health, Inc., F.T.C. 1, 3 (2014), 2014 WL 4252391.

[55] *Short Memory Lands CVS Brain Supplement in Legal Trouble*, TRUTH IN ADVERTISING (June 7, 2016), https://www.truthinadvertising.org/memory-lands-cvs-supplement-in-trouble/.

[56] *Id.*

[57] *Id.*

[58] *CVS Health Algal-900 DHA Softgels*, CVS PHARMACY, https://www.cvs.com/shop/cvs-health-algal-900-dha-softgels-prodid-1070656?skuId=794904 (last visited Sept. 28, 2018).

The marketers of the popular supplement Prevagen are making similar memory claims.[59] Further, the Prevagen television commercial states that it is "clinically proven to improve short term memory."[60] Prevagen states that a "double-blinded, placebo-controlled trial," which is detailed on its website,[61] supports their claims even though they note the FDA did not review the statement.[62] The experiment in question, named the Madison Study, consisted of 218 subjects with "self-reported memory concerns."[63] The manufacturer of Prevagen, Quincy Bioscience, sponsored the study.[64] Quantitative tests were administered at five intervals during the ninety-day period.[65] The results showed that "Prevagen demonstrated the ability to improve aspects of cognitive function in older participants with either normal cognitive aging or very mild impairment."[66] There are two major concerns with the methodology. First, there are concerns of bias because the study was sponsored by the manufacturer. Second, the participants have "self-reported memory concerns" as opposed to medically documented memory concerns.

FDA administrators admit the disadvantages they face in their ability to catch false advertisements.[67] Recent examples of the scope of false advertising include claims that Amberen would

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[59] *TINA.org to FTC: Prevagen is Making Unsupported Memory Claims*, TRUTH IN ADVERTISING (Sept. 20, 2015), https://www.truthinadvertising.org/prevagen-ftc-complaint/; *Madison Memory Study: A Randomized, Double-Blinded, Placebo-Controlled Trial of Apoaequorin in Community-Dwelling, Older Adults*, QUINCY BIOSCIENCE (Aug. 1, 2016), http://www.prevagen.com/wp-content/uploads/2017/02/ClinicalTrialSynopsis-cmk816.pdf [hereinafter *Madison Memory Study*].

[60] This author first noted watching the commercial on the CNN channel on Tuesday morning, August 2, 2016 and has seen it on air through February 2018. The commercial noted it was available at CVS.

[61] *Madison Memory Study, supra* note 59, at 1.

[62] PREVAGEN, https://www.prevagen.com (last visited Sept. 28, 2018).

[63] *Madison Memory Study, supra* note 59, at 4.

[64] *Id.* at 1.

[65] *Id.* at 2–3.

[66] *Id.* at 9.

[67] Michael Taylor, *How the FDA is Picking Its Food Label Battles*, THE ATLANTIC (July 19, 2010), https://www.theatlantic.com/health/archive/2010/07/how-the-fda-is-picking-its-food-label-battles/59927/. Taylor, then Deputy Commissioner for Foods at the FDA, noted that the FDA is forced to pick its battles concerning marketing claims, stating "[w]e have 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. Moreover, meeting them requires tapping the same team of nutritionists, labeling experts, and lawyers who are working on our other nutrition initiatives." *Id. See also infra* Part IV.C.

relieve symptoms of menopause,[68] a product claiming it prevents gray hair,[69] that the health benefits of Eukanuba dog food were scientifically proven,[70] and that POM Wonderful's Pomegranate Juice and POMx supplements "could treat, prevent, or reduce the risk of heart disease, prostate cancer, and erectile dysfunction, and were clinically proven to have such benefits."[71]

A. Problems Related to the FDA

The problems with the FDA and its regulatory ability have been widely written about and many of the articles are summarized below.

The FDA has too much to regulate. Considering the health supplement portion of the FDA's duties alone shows how inadequately the FDA is staffed. Over half of the U.S. population take health supplements.[72] The FDA must also regulate over 500,000 food products, "tens of thousands" of companies, and scores of new products that are introduced each year in the U.S. market.[73] In addition, there are reportedly over 1,000 food additives on the FDA substance inventory list that they have not investigated.[74] However, the Center for Food Safety and Applied Nutrition within the FDA, which is in charge of nutrition,

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[68] Press Release, Fed. Trade Comm'n, Marketers of Dietary Supplement Amberen Settle FTC Charges Regarding Misleading Weight-Loss and Menopause Relief Claims (May 20, 2016), https://www.ftc.gov/news-events/press-releases/2016/05/marketers-dietary-supplement-amberen-settle-ftc-charges-regarding.

[69] Press Release, Fed. Trade Comm'n, FTC Challenges Markters' Baseless Claims That Their Supplements Prevent or Reverse Gray Hair (May 13, 2015), https://www.ftc.gov/news-events/press-releases/2015/05/ftc-challenges-marketers-baseless-claims-their-supplements.

[70] Press Release, Fed. Trade Comm'n, FTC Approves Final Order Settling Charges that Mars Petcare Made False Health Claims for Its Eukanuba Brand Dog Food (Dec. 13, 2016), https://www.ftc.gov/news-events/press-releases/2016/12/ftc-approves-final-order-settling-charges-mars-petcare-made-false.

[71] Press Release, Fed. Trade Comm'n, Statement of FTC Chairwoman Edith Ramirez Regarding Supreme Court's Decision Not to Review POM Wonderful Case (May 2, 2016), https://www.ftc.gov/news-events/press-releases/2016/05/statement-ftc-chairwoman-edith-ramirez-regarding-supreme-courts.

[72] Madison Park, *Half of Americans Use Supplements*, CNN (Apr. 13, 2011), http://edition.cnn.com/2011/HEALTH/04/13/supplements.dietary/index.html.

[73] *See* Heinzerling, *supra* note 34, at 15.

[74] Brett M. Paben, *Lack of Interest in Consumer Interests: FDA's Narrow Perspective on Food Labeling and Label Statements Undermines a Century of Agency Leadership*, 13 RUTGERS J.L. & PUB. POL'Y 174, 186 (2015) (citing the Substances Added to Foods list, formerly called Everything Added to Food in the United States (EAFUS) at http://www.accessdata.fda.gov/scripts/fcn/fcnnavigation.cfm?rpt=eafus listing).

labeling, and dietary supplements, has just over 1,000 employees,[75] raising the issue of how consumers are to stay safe (make healthy choices/know what they are eating) if the FDA cannot keep up.[76]

Further, some authors view the FDA as a reactionary body since it has stopped random sampling of foods, and since there are limited pre-market approval requirements.[77] There is no pre-market approval requirement for dietary supplements except for products that contain ingredients first marketed after October 14, 1994, and there is no scientific testing requirement at all.[78] When the FDA last conducted random sampling twenty years ago, it found that between 30% and 50% of all 300 products tested listed some vitamin amounts on the Nutrition Facts panel that substantially differed from the actual amounts.[79]

The FDA's authority has been eroded by recent court decisions. Traditionally, the courts gave the FDA the highest deference in interpreting its regulations, but this is no longer the case for product claims.[80] Although the FDA creates its own procedures and rules,[81] fewer than half of consumers feel that the FDA provides adequate information on food content.[82]

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[75] U.S. FOOD AND DRUG ADMIN., FOOD AND DRUG ADMINISTRATION DISTRIBUTION OF FULL-TIME EQUIVALENT (FTE) EMPLOYMENT PROGRAM LEVEL, http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM301553.pdf (last visited Sept. 28, 2018).

[76] Paben, *supra* note 74, at 186.

[77] Dickens, *supra* note 9, at 577–78 ("[R]egulations covering dietary supplements are somewhat laxed."). Dickens goes on to state as examples that dietary supplements require no pre-market approval and that they are presumed safe until the FDA is alerted to an issue. *Id.* Bilbrough, *supra* note 9, at 944–47 (noting that the "FDA now has a purely reactionary role" because there is no pre-market approval for dietary supplements unless they contain a new ingredient. Further, the FDA has very high burden of proof when investigating a potentially harmful product); U.S. GOV'T ACCOUNTABILITY OFFICE, FOOD LABELING: FDA NEEDS TO BETTER LEVERAGE RESOURCES, IMPROVE OVERSIGHT, AND EFFECTIVELY USE AVAILABLE DATA TO HELP CONSUMERS SELECT HEALTHY FOODS 17 (2008).

[78] Dickens, *supra* note 9, at 577-80; Bilbrough, *supra* note 9, at 944–46; Pezzullo, *supra* note 9, at 338.

[79] *Id.* The FDA characterizes this substantial difference to be outside the allowable range. *Id.; see also* Heinzerling, *supra* note 34, at 17.

[80] Paben, *supra* note 74, at 205–06 (referencing Auer Deference, per the case Auer v. Robbins, 519 U.S. 452, 461 (1997)); *see also infra* Part III.C.

[81] Paben, *supra* note 74, at 174.

[82] *Id.* at 176–77 (citing INTERNATIONAL FOOD INFORMATION COUNCIL FOUNDATION, 2014 FOOD AND HEALTH SURVEY (2014)).

The FDA does not investigate a supplement until notified of a problem.[83] Due to their limited resources, the FDA must prioritize which complaints to pursue, which often means taking action on products for which the most claims have been made.[84] Further, unlike the prescription industry, dietary supplement manufacturers are not required to submit evidence of safety via clinical trials to the FDA before their products are offered for sale.[85] Additionally, the FDA sees itself as only being able to act on "proven health and safety risks," which precludes it from taking any proactive measures.[86] For all of these reasons, the FDA is considered a reactionary force, as opposed to a proactive agency.[87]

Some authors believe the problem with the FDA and other agencies tasked with regulating food is the regulatory fragmentation caused by the different missions, cultures, and regulations of these agencies, and because of manufacturer influence.[88] An example of regulatory fragmentation is that the USDA requires pre-approval of product labels but the FDA does not.[89] Another source of fragmentation is the number of agencies with the power to regulate food laws. In 2011, the Government Accountability Office reported that there were fifteen agencies with the authority to regulate food safety.[90]

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[83] Dickens, *supra* note 9*,* at 578.

[84] Taylor, *supra* note 67 (noting how incredibly difficult and fruitless it is to go after companies and their teams of creative marketers).

[85] Dickens, *supra* note 9*,* at 580–81.

[86] Melissa Mortazavi, *Tort As Democracy: Lessons From the Food Wars*, 57 ARIZ. L. REV. 929, 942 (2015) (citing All. for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166, 179 (D.D.C. 2000)).

[87] Dickens, *supra* note 9, at 577–78; Bilbrough, *supra* note 9, at 946; Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J. L. & MED. 617, 639 (2013).

[88] *See* Heinzerling, *supra* note 34, at 14, 18; Christine Donovan*,* Note, *If FDA Does Not Regulate Food, Who Will? A Study of Hormones and Antibiotics in Meat Production*, 41 AM. J.L. & MED. 459, 467 (2015) (describing the fragmented authority between the FDA and USDA); Richard A. Merrill & Jeffrey K. Francer, *Organizing Federal Food Safety Regulations*, 31 SETON HALL L. REV. 61, 127–128 (2000) (noting that there is no single voice advocating for food safety, causing lack of accountability, ineffective allocation of resources, and lack of consistent policy); Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-Fault Fix,* 35 N.Y.U. REV. L. & SOC. CHANGE 793, 808–10 (2012) (FDA is subject to manufacturer influence); Bilbrough, *supra* note 9, at 942–46 (DSHEA was strongly influenced by the supplement industry).

[89] Heinzerling, *supra* note 34, at 18; ROBERTS, *supra* note 1, at 212.

[90] Dan Flynn, *GAO Report Calls for Single Food Safety Agency*, FOOD SAFETY NEWS (Mar. 2, 2011), http://www.foodsafetynews.com/2011/03/call-for-one-food-safety-agency-leads-historic-gao-report/#.V9ngaPkrLIU.

Authors have noted that FDA regulations can be contradictory, misleading, or ambiguous.[91] For instance, in determining whether chain restaurants fall under the nutritional information burdens of the Affordable Care Act ("ACA"), the FDA defined the term "[l]ocation" as a "fixed position or site," which eliminated all mobile establishments from the ACA menu requirements.[92] Another example is the phrase "all natural," which suggests that no harmful ingredients are present in the product, although that is not always the case.[93] About two-thirds of consumers believe that "natural" means that there are no artificial ingredients in the product.[94] Yet the FDA has not defined the term.[95] The FDA cannot enforce its food laws when there is regulatory ambiguity.[96]

Voluntary industry programs, often called "third party verification," provide standards that compete with FDA regulations. For instance, the "Facts Up Front" labeling program, created by the Grocery Manufacturers Association and the Food Marketing Institute, includes a set of voluntary front-of-package labeling guidelines.[97] Its voluntary nature suggests that manufacturers of unhealthy products will not choose to use the system at all.[98] Having the industry, whose goal is to maximize

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[91] Paben, *supra* note 74, at 185–86 (FDA has not defined "natural," leading to confused consumers; FDA policies are designed to "assure ambiguity"); Stephanie Russ, *Does This Law Make My Butt Look Big? Part II: No, But Food Does: An Overview of the FDA's Menu Labeling Requirements*, 35 FRANCHISE L.J. 61, 61–64 (2015). In describing the new food regulations pertaining to the Affordable Care Act ("ACA") (79 Fed. Reg. 71157), Russ describes what can only be viewed as a complex set of regulations that both expand and limit establishments that are required to abide by labeling provisions of the ACA. Restaurants are now covered, but not unless they are part of a chain of twenty or more restaurants. *Id.* Schools are not covered. *Id.* Mobile food services, such as food trucks, trains or airplanes, are exempt from regulation. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71156, 71159 (Dec. 1, 2014) (to be codified at 21 C.F.R. pts. 11, 101) [hereinafter Food Labeling 2014].

[92] Food Labeling 2014, *supra* note 91, at 71254.

[93] Dickens, *supra* note 9, at 584.

[94] Paben, *supra* note 74, at 185 (citing CONSUMER REP. NAT'L RES. CTR., FOOD LABELS SURVEY (2014)).

[95] *Id.*; U.S. Food & Drug Admin., "Natural" on Food Labeling, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm456090.htm (last updated Nov. 11, 2017).

[96] *See* Paben, *supra* note 74, at 186; Pomeranz, *supra* note 87, at 628.

[97] Grocery Manufacturers Ass'n, *Facts-Up-Front Front of Package Labeling Initiative*, GMA, http://www.gmaonline.org/issues-policy/health-nutrition/facts-up-front-front-of-pack-labeling-initiative/ (last visited Sept. 28, 2018).

[98] Currey, *supra* note 16, at 1302–04.

profits, craft such a program will likely lead to lax standards.[99] Similarly, industry-initiated eco-labels, which are not regulated by the FDA, convey messages, logos, stamps, or seals, tout only the positive and ignore the negative.[100] The FDA should be able to ban any competing labeling standards.

B. Problems With U.S. Food Laws

There are concerns with the Dietary Supplement Health and Education Act of 1994 ("DSHEA") and with other food labeling laws.

In enacting DSHEA, Congress noted that one of the most important functions of the federal government is improving the health of its citizens, and that nutritional supplementation plays an important role in achieving that function.[101] Congress noted that about 50% of Americans utilized dietary supplements.[102] Although the FDA had proposed stricter supplement regulations such as requiring pre-approval of supplements that make drug claims,[103] DSHEA was met with strong pushback from the supplement industry.[104] As mentioned earlier, this influence led Congress to include the following changes when enacting the

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[99] *Id.* at 1303 (citing Center of Science in the Public Interest Executive Director Michael Jacobsen, who states that manufactures are free to only highlight the healthy components of the food, and not the unhealthy components, under the Facts Up Front Program) (citations omitted).

[100] Paben, *supra* note 74, at 187–88 (stating that in the U.S., manufactures use environmental claims on eco-labels as they see fit since they are not regulated, and that such labels "provide little value to the consumer and are often mere 'greenwashing.' ").

[101] Dietary Supplement Health and Education Act of 1994, Pub. L. 103-417,108 Stat. 4325, 4325 (1994).

[102] *Id.* at 4326.

[103] Regulation of Dietary Supplements, 58 Fed. Reg. 33690, 33697 (June 18, 1993).

[104] Arnold I. Friede, *Dietary Supplements: Background for Dialogue Between the Industry and the Medical Profession*, 53 FOOD & DRUG L.J. 413, 419 (1998) ("The dietary supplement industry fought long and hard . . . for the relief provided by DSHEA from what was perceived to be arbitrary, onerous, and unnecessary regulation."); Bilbrough, *supra* note 9*,* at 942–46 ("The FDA's proposal was followed by industry pushback . . . ."); Jennifer Kay Braman, Note, *Food for Sport or Faustian Bargain: Regulating Performance Enhancing Dietary Supplements*, 47 CLEV. ST. L. REV. 417, 426–427 (1999) (noting "the enormous influence of the dietary supplement business."); *see also* 139 CONG. REC. S4577-4578 (daily ed. Apr. 7, 1993) (Statement of Sen. Hatch). Hatch decidedly criticized the FDA for being anti-consumer over the prior thirty years, including how it handled DSHEA (S. 784), suggesting industry hostility toward the FDA and noting industry support for DSHEA. Hatch was, however, careful not to attribute his condemnation to the industry. Rather, his argument was framed from the standpoint of a loss of consumer choice.

DSHEA: (1) the burden to prove adulteration or false or misleading information shifted to the FDA,[105] (2) the law only applied to new supplement ingredients,[106] (3) the DSHEA established an "imminent hazard" standard of proof in order to remove a product from sale,[107] and (4) it allowed manufacturers to use unsubstantiated product label claims as long as a disclaimer was included stating the FDA had not evaluated the claim.[108] The manufacturer-friendly nature of the DSHEA encouraged the introduction of many more supplement products into the market at the time of the passage of the DSHEA. Congress noted that in 1994 there were about 4,000 dietary supplements in the marketplace, with total annual sales of about $4 billion.[109] By 2012, the estimate was 55,000 supplements in the marketplace.[110] Today, it is estimated that the U.S. supplement industry rakes in $37 billion annually.[111] For the reasons stated above, experts believe that the DSHEA is lax, which attracts manufacturers who are intent on maximizing profits with little regulatory oversight.[112] Lobbyists have incentive to put millions of dollars into keeping DSHEA the same.[113]

Consumers are confused by food labels and label claims.[114] For instance, having food labels on the back of products is less effective than the front.[115] Authors note that "hidden trade-off

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[105] § 4, 109 Stat. at 4328–29.

[106] § 8, 109 Stat. at 4331–32; Bilbrough, *supra* note 9, at 946.

[107] § 4, 109 Stat. at 4328; Bilbrough, *supra* note 9, at 946.

[108] § 6, 109 Stat. at 4329; *see* Bilbrough, *supra* note 9, at 948.

[109] § 3, 109 Stat, at 4326; Bilbrough, *supra* note 9, at 947.

[110] Bilbrough, *supra* note 9, at 947.

[111] John Bradley, *NBJ: The US Supplement Industry is $37 billion, not $12 Billion*, NUTRITION BUSINESS JOURNAL (June 1, 2015), http://www.nutraingredients-usa.com/Markets/NBJ-The-US-supplement-industry-is-37-billion-not-12-billion; *see also* Baird, *Retail Sales of Vitamins & Nutritional Supplements in the United States from 2000 to 2017 (in Billion U.S. dollars),* STATISTA, http://www.statista.com/statistics/235801/retail-sales-of-vitamins-and-nutritional-supplements-in-the-us/ (last visited Sept. 28, 2018).

[112] Dickens, *supra* note 9, at 583–84, 587.

[113] Melanie Zanona, *How the Dietary Supplement Industry Masters the Hill*, CQ WEEKLY (June 1, 2015), http://melaniezanona.com/dietarysupplements/.

[114] Paben, *supra* note 74, at 175.

[115] Marianne Smith Edge et al., *The Impact of Variations in a Fact-Based Front-of-Package Nutrition Labeling System on Consumer Comprehension*, 114 J. ACAD. NUTRITION & DIETETICS 843, 851 (2014) (although front-of-package labeling generally leads to increased accuracy in identifying product nutrition levels and lessens the necessity of perusing the nutrition facts label, such labeling is particularly helpful to those with lower education levels); Dhyani, *supra* note 11, at

claims" on the front of an item can mislead consumers into thinking products are healthier than they are.[116] These claims highlight healthy ingredients but fail to mention ingredients located on the back label that may be unhealthy or less healthy.[117] Manufacturers are tempted to highlight a beneficial component of a product and ignore the negative.[118]

C. More Limits to FDA Power: Recent Case Law Decisions

The recent court-imposed limits on food label claims have developed substantially over a forty-year period. In 1976, the United States Supreme Court held in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council* that an advertiser's purely economic motive is afforded First Amendment protection because the free flow of commercial information may be useful to the consumer.[119] That holding eventually affected food product claims. The 1980 Supreme Court case *Central Hudson Gas & Electric v. Public Service Commission of New York* introduced an intermediate level of scrutiny to examine whether the speech had First Amendment protections, which consisted of four parts: (1) whether the speech is lawful and not misleading, if so (2) "whether the asserted government interest is substantial," (3) "whether the regulation directly advances the governmental interest asserted," and (4) "whether it is not more extensive than is necessary to serve that interest."[120]

Subsequently, in *In re R.M.J.*, the Supreme Court held that although inherently misleading commercial speech may be prohibited in its entirety, potentially misleading speech may not

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30 (suggesting that the most important information should go on the front of the label); European Society of Cardiology, *Members of European Parliament Discuss Food Labeling and Hearth Health* (June 5, 2008), http://esciencenews.com/articles/2008/06/05/members.european.parliament.discuss.food.labeling.and.heart.health ("Front of pack labelling should allow consumers to know at a glance whether a product contributes to their health or not.").

[116] Dhyani, *supra* note 11, at 37–38.

[117] *Id.*

[118] Dickens, *supra* note 9, at 584.

[119] Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 762–65 (1976).

[120] Central Hudson Gas & Electric v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

be banned if it could be offered in a non-deceptive way.[121] The *In re R.M.J.* Court suggested that a disclaimer would suffice instead of an outright ban.[122]

Starting in 1999, and expanding on *In re R.M.J.,* a string of decisions curtailed the FDA's power to ban misleading speech. The trouble for the FDA started with *Pearson v. Shalala* ("*Pearson I*"), where the United States Court of Appeals for the District of Columbia struck down the FDA decision to unilaterally ban potentially misleading health claims on nutritional supplements because the court felt doing so was a violation of the fourth part of the *Central Hudson* test—the "reasonable fit" requirement.[123] The court held that an outright ban on potentially misleading health claims was unconstitutional and that instead the FDA could require that disclaimers be used.[124] The *Pearson I* court gave the FDA guidance when it noted that a health claim can be banned by the FDA when supporting evidence for the claim is weaker than contrary evidence.[125] The FDA revised its rules in light of the *Pearson I* decision, denied the claims of the manufacturer from *Pearson I*, and lost again when challenged in district court because of its refusal to issue disclaimers.[126] In 2001, *Pearson v. Thompson* ("*Pearson III"*) suggested that a disclaimer would have been appropriate instead of a complete denial of the health claim.[127] The D.C. District Court confirmed this position in *Whitaker v. Thompson*.[128]

The FDA finally took the direction of the courts by subsequently creating "qualified health claims": a new category of health claims supported by credible evidence.[129] The FDA will issue a disclaimer if it can remedy, or qualify, the health claim. If

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[121] In re R.M.J., 455 U.S. 191, 203 (1982).

[122] *Id.* at 201, 203.

[123] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 657 (D.C. Cir. 1999) (typically referred to as *Pearson I*, the first of three cases concerning the FDA and these plaintiffs).

[124] *Id.*

[125] *Id.* at 659 n.10 ("Similarly, we see no problem with the FDA imposing an outright ban on a claim where evidence in support of the claim is *qualitatively* weaker than evidence against the claim-for example, where the claim rests on only one or two old studies.") (emphasis added).

[126] Pearson v. Shalala (*Pearson II*), 130 F. Supp. 2d 105, 114 (D.D.C. 2001).

[127] Pearson v. Thompson (*Pearson III*), 141 F. Supp. 2d 105, 110–11 (D.D.C. 2001).

[128] Whitaker v. Thompson, 248 F. Supp. 2d 1, 16–17 (D.D.C. 2002).

[129] *Evidence-Based Review System*, *supra* note 43, at §§ II., III.A; ROBERTS, *supra* note 1, at 234.

a disclaimer cannot remedy the claim, it may be banned.[130] This new category of health claims is distinct from unqualified health claims, which are supported by significant scientific agreement and thus need no disclaimer of qualification.[131] The *Whitaker* court opined that rejecting a claim without offering any disclaimer at all should only be allowed in instances "where there was little-to-no scientific evidence in support of the claim *and* where the government could prove that the public would still be deceived by the claim even with the use of accompanying disclaimers."[132] However, *Pearson I*, the controlling Court of Appeals case, noted that the evidentiary standard to ban a claim is simply when supporting evidence is "outweighed" by non-supporting evidence.[133] The *Pearson I* court also noted that the FDA could ban a health claim if supporting evidence is "qualitatively weaker" than negative evidence,[134] which appears to be more in line with *Central Hudson's* "more likely to deceive" standard.[135]

Not only is the FDA prohibited from completely banning potentially misleading health claims without considering the issuance of a disclaimer, but three recent cases have also restricted its disclaimer language, holding that strongly worded verbiage effectively negates the claim and infringes on commercial speech rights.[136]

Finally, the courts have started to exercise a stricter standard of review for FDA actions. In a 2010 case, the United States District Court for the District of Columbia applied an independent review standard when deciding constitutional issues brought against the FDA, rather than the arbitrary and capricious standard of review that the Administrative Procedure Act calls for.[137] Although the court chose to review the FDA's decision under the independent review standard, it stated that it will give some deference to the FDA's expertise in weighing the

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[130] In re R.M.J., 455 U.S. 191, 203 (1982).

[131] *Questions and Answers on Health Claims in Food Labeling*, *supra* note 38.

[132] *Whitaker*, 248 F. Supp. 2d at 13.

[133] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 659 (D.C. Cir. 1999).

[134] *Id.* at 659 n.10.

[135] Central Hudson Gas & Electric v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563 (1980).

[136] All. for Nat. Health U.S. v. Sebelius, 714 F. Supp. 2d 48, 71 (D.D.C. 2010); All. for Nat. Health U.S. v. Sebelius, 786 F. Supp. 2d 1, 11–14 (D.D.C. 2011); Fleminger v. U.S. Dep't of Health and Human Serv., 854 F. Supp. 2d 192, 195 (D. Conn. 2012).

[137] *All. for Nat. Health U.S.*, 714 F. Supp. 2d at 48, 59–60.

scientific evidence in denying claims.[138] The independent review standard is nonetheless tougher than the arbitrary and capricious review standard. Under the arbitrary and capricious standard, a court cannot subvert the expertise of an agency's work.[139] However, under the independent review standard, a court independently assesses the agency's actions against the plaintiff's constitutional claims.[140]

III. ZEROING IN ON THE EFFECTIVENESS/EFFECT OF FOOD LABELS, HEALTH CLAIMS, DISCLAIMERS, AND COURT DECISIONS

Food labeling is the main means of disseminating nutrition content information and health claims to consumers. In addition to traditional package labeling, restaurants are beginning to provide nutritional information on their menus. This gives consumers the nutritional information to make healthy dining choices if they desire. The availability of nutritional information presented on a restaurant menu is similar to nutritional information presented on a food or nutritional supplement label, in that in both instances once consumers zero in on a specific item choice, item-specific nutritional information is visible. It is therefore important to analyze the effectiveness of the current labeling scheme while also determining if providing nutritional information in restaurants is useful. Considering that any set of laws will be compromised by non-compliance, it is also important to assess to what extent manufacturers are complying with the FDA's confusing choice of label laws. Finally, recent court decisions regarding commercial speech as it concerns label claims must be scrutinized as another means of assessing the effectiveness of the food law scheme.

A. Recent U.S. Food Studies Regarding the Effectiveness of Providing Nutrition Information

After summarizing the results of the following studies on the effectiveness of providing nutrition information, it is clear that the vast majority of consumers scrutinize nutrition information on product labels[141]—especially for an unfamiliar product[142]—and

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[138] *Id.* at 60.

[139] Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983); Marsh v. Oregon Nat. Res. Council, 490 U.S. 360, 376–78 (1989).

[140] Porter v. Califano, 592 F.2d 770, 780 (5th Cir. 1979).

[141] Brian Elbel et al., *Calorie Labeling and Food Choices: A First Look at the Effects on Low-Income People in New York City*, 28 HEALTH AFFAIRS w1110 (2009),

that nutrition labels are most effective when placed on the front of the package.[143] The presence of nutrition information effects health by affecting healthy choices.[144] Although health-conscious consumers use nutrition information effectively,[145] evidence shows that the absence of nutrition information causes most consumers to consistently underestimate the amount of calories they consume.[146] Further, the findings suggest that consumers who may not necessarily consider themselves health-conscious would make more conscious health choices if nutrition information was provided.[147]

Three studies from 2002 of 292 subjects indicated that providing nutritional information both on a product label and on a restaurant menu positively affected product attitude, nutrition attitude, and purchasing decisions.[148] This work is important because it tested the effectiveness of nutrition information for a

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http://content.healthaffairs.org/content/28/6/w1110.full.pdf+html; Smith Edge et al., *supra* note 116, at 845; Marian Burros, *Read Any Good Nutrition Labels Lately?,* N.Y. TIMES (Dec. 1, 2004), http://www.nytimes.com/2004/12/01/dining/read-any-good-nutrition-labels-lately.html?_r=0.

[142] Smith Edge et al., *supra* note 116, at 845.

[143] INT'L FOOD INFORMATION COUNCIL FOUNDATION, FRONT OF PACK LABELING CONSUMER RESEARCH PROJECT 34 (2011), https://www.foodinsight.org/Content/3651/IFIC%20FOP%20SLIDES%20for%20WEB2011.pdf; Smith Edge et al., *supra* note 116, at 851.

[144] Scot Burton & Elizabeth H. Creyer, *What Consumers Don't Know Can Hurt Them: Consumer Evaluations and Disease Risk Perceptions of Restaurant Menu Items*, 38 J. CONSUMER AFF. 121, 142 (2004) (inclusion of negative health information on labels changed decisions to not purchase products more than did labels that did not include any health information); Christina A. Roberto et al., *Evaluating the Impact of Menu Labeling on Food Choices and Intake*, 100 AM. J. PUB. HEALTH 312, 314, 316 (2010).

[145] Lisa J. Harnack, et al., *Effects of Calorie Labeling and Value Size Pricing on Fast Food Meal Choices: Results From an Experimental Trial*, 5 INT'L J. BEHAV. NUTRITION & PHYSICAL ACTIVITY 63, 68–71 (2008); Chung-Tung Jordan Lin et al., *Do Dietary Intakes Affect Search for Nutrient Information on Food Labels?*, 59 SOC. SCI. & MED. 1955, 1962 (2004) (This study was actually a combination of studies conducted in 1994, 1996 and 2000); Szanyi, *supra* note 11, at 162.

[146] Roberto et al., *supra* note 144, at 316; Burton & Creyer, *supra* note 144, at 142; Margo G. Wootan & Melissa Osborn, *Availability of Nutrition Information from Chain Restaurants in the United States*, 30 AM. J. PREVENTATIVE MED. 266, 268 (2006) (noting that even nutrition experts consistently underestimate the number of calories in restaurant meals); Burton et al., *Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants*, 96 AM. J. PUB. HEALTH 1669 (2006).

[147] Roberto et al., *supra* note 144, at 316.

[148] John C. Kozup et al., *Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items*, 67 J. MKTG. 19, 23 (2003).

packaged food item and a restaurant item, and because it also tested the effect of health claims, which will be discussed in the next section.

A 2004 survey by Burton & Creyer analyzed responses from 377 subjects after they saw a menu containing either no nutrition information, a healthy food menu with nutrition information, or an unhealthy food menu with nutrition information.[149] Survey results indicated that subjects were not aware of the unhealthy nutrient level of foods, and suggested that the provision of nutrition information affected "attitudes, perceptions, and judgments."[150] Two 2006 studies also measured the differences between consumer perception of nutrition levels against actual nutritional content.[151] In the first study, the 193 respondents who were given a "less-healthful" menu underestimated calorie content by almost 50%, fat content by 44 grams, and saturated fat content by 15 grams.[152] Sodium levels were also greatly underestimated: by 847 mg for "more-healthful" foods, 1,557 mg for "less-healthful" foods and a whopping 4,353 mg for "extremely unhealthful" foods.[153] In the second study, the 241 respondents were provided with nutrition information in restaurants.[154] This study showed that calorie and nutrient information "influenced attitudes, intentions, and choices."[155] Specifically, respondents limited "less-healthful" choices when the nutritional information was available.[156] The authors concluded that "[b]ecause our results showed that consumers substantially underestimated

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[149] Burton & Creyer, *supra* note 144, at 127–29. Survey questions asked respondents to indicate their perception of the nutrition level of the items on the menu they reviewed, as well as asking about item attitude and purchase intentions. *Id.* at 143, app.

[150] *Id.* at 121, 131.

[151] *Id.*

[152] *Id.* at 1671 (noting that the fat and saturated fat *underestimations* alone amounted to "more than 60% of the recommended daily values.").

[153] *Id.* The recommended daily sodium intake value is less than 2,400 mg., according to the FDA. U.S. FOOD & DRUG ADMIN., SODIUM IN YOUR DIET: USE THE NUTRITION LABEL AND REDUCE YOUR INTAKE 1, *in* FOOD FACTS (June 2018), http://www.fda.gov/downloads/food/ingredientspackaginglabeling/ucm315471.pdf.

[154] Burton et al., *supra* note 146, at 1672–73.

[155] *Id.* at 1674.

[156] *Id.* For a healthy choice: when a chef's salad was presented with just calorie information, there was no decrease in purchase from when no information was present. *Id.* But when other nutrition information was provided, there was a significant decrease in the purchase of the chef's salad, which makes sense because a chef's salad contains a moderate level of calories but a significantly high level of fats and saturated fats. *Id.*

calorie levels for less-healthful . . . items and that preference for the less-healthful items diminished when nutrition information was disclosed, provision of nutrition information . . . would appear helpful."[157]

In a telephone survey of 554 people in 2004, 85% of respondents reported that they read nutrition labels and 66% of them indicated that it was a factor in their purchasing decisions.[158] Another 2004 telephone survey of 649 community members found that over 66% often viewed food labels and 18.9% occasionally did.[159]

A 2005-2006 study of nearly 600 respondents who regularly frequented fast-food establishments found that nearly 60% of respondents chose "nutrition" as a very important purchasing factor and 83.5% felt it was at least a somewhat important factor.[160] There was an approximately 150-calorie difference in consumption for respondents who reported that nutritional information was important to their purchasing decisions compared to those who did not, and an approximately 300-calorie difference when price was also important.[161] In this study, the majority of respondents placed a high value on nutritional information, and chose fewer calories when given appropriate nutritional information compared to those who did not place as high a value on nutritional information. This result suggests that providing granular nutritional information would be quite useful to the large number of consumers who place a high value on nutritional information, which is also the suggestion of other studies from 1997-2010.[162]

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[157] *Id.*

[158] Burros, *supra* note 141.

[159] Rebecca A. Krukowski et al., *Consumers May Not Use or Understand Calorie Labeling in Restaurants*, 106 J. AM. DIETETIC ASS'N 917, 918 (2006).

[160] Harnack, et al., *supra* note 145, at 63, 68. Respondents received one of four menus—with varying nutritional information—in which to order their food from, and results were tabulated from this one-time order. *Id.* at 64–65.

[161] *Id.* at 69, 71 tbl. 8 (stating that the average caloric intake was "significantly lower" for participants who identified that nutrition was important and who received calorie plus price information).

[162] *See also* Lin et al., *supra* note 145, at 1962; Szanyi, *supra* note 11, at 162 n.27 (citing Matthew W. Kreuter et al., *Do Nutrition Label Readers Eat Healthier Diets? Behavioral Correlates of Adults' Use of Food Labels?*, 13 AM. J. PREVENTATIVE MED. 277 (1997)); CHRISTIAN A. GREGORY ET AL., U.S. DEPT. OF AGRICULTURE, CONSUMERS' USE OF NUTRITION INFORMATION WHEN EATING OUT 31, 33 (2014). (Consumers with healthy dietary habits are more likely to utilize health information if provided in restaurants: People who have utilized health information at restaurants, or indicate they'd do so if available, are likely to do so in the future; It is

A 2008 study of 1,156 low-income residents took a first look at the New York City ("NYC") restaurant labeling requirement.[163] Fast-food restaurant purchases by low-income participants were compared to purchases by low-income members in Newark, New Jersey, which does not have a restaurant labeling requirement, before and after the NYC labeling requirement took effect.[164] Fifty-four percent more NYC respondents noticed caloric information after the labeling mandate, while at the same time the percentage did not rise in Newark.[165] After the labeling mandate, nearly 28% of NYC responents indicated that caloric information influenced their purcasing decisions, and 88% indicated that they purchased fewer calories because of the labeling.[166] However, there was no significant decrease in the number of calories consumed[167] although information as to the value that participants placed on nutritional information was not ascertained.[168] Although the mandatory restaurant labeling law did not, at the time of this study, result in an overall significant reduction in calories being consumed, it is not known if the nutritional information positively affected the choices of health-conscious respondents. It is also not known if there were other variables that could have affected the respondents' purchasing choices. Perhaps the restaurant choices of low-income consumers are largely limited to fast-food establishments, which typically sell highly caloric food at low cost. Another possibility is that consumers will make their food selections by comparing items on a menu and they "will view high-calorie choices as more reasonable and healthy when they are presented among other high-calorie options."[169] Or these results may simply indicate that low-income consumers lack an understanding of their daily caloric needs.[170]

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suggested that health-conscious consumers actively look for health information but others do not).

[163] Elbel et al., *supra* note 141, at w1110.

[164] *Id.* at w1110–11.

[165] *Id.* at w1114–15; *see id.* at w1115 tbl. 1 (presenting a statistical graphic comparison of those in New York City and Newark who noticed caloric information and how it affected their purchases).

[166] *Id.*

[167] *Id.* at w1116–17.

[168] *Compare id.* at w1113–14, *with* Harnack et al., *supra* note 145.

[169] Szanyi, *supra* note 11, at 177.

[170] Krukowski et al., *supra* note 159, at 918.

When given the choice of a cheaper and healthier option, low-income consumers in general may exercise more health-conscious choices. For instance, about one third of respondents who noticed the nutritional information posted in Subway stores ate fewer calories as compared to patrons who did not notice the posted information.[171]

In 2007 and 2008, Subway, a fast food chain known for healthy options, was studied; 303 respondents were shown one of three menus to order a meal: a menu with no nutrition information, one with nutrition information, and one with nutrition information and a statement that the recommended daily caloric intake is 2,000 calories.[172] The three menu groups were compared to determine the difference between estimated calorie intake and actual intake.[173] Subjects whose menus had no nutrition information ordered on average approximately 330 more calories and consumed 177 more calories than subjects that had nutrition information.[174] The respondents whose menus did not have nutrition information were not as accurate as were the other groups in estimating caloric intake: nearly 75% of this group underestimated calorie consumption and 25.6% overestimated consumption, whereas the underestimated and overestimated totals for the two groups whose menus had nutrition information were nearly even, at about 50%.[175] This confirmed results from previous studies.[176]

Finally, in 2010, the International Food Information Council Federation administered a food label survey to 7,363 respondents designed to critique a proposed food label scheme change.[177] The survey found that 86% of respondents viewed food labels "regularly or occasionally" before purchasing a product for the first time, 85% "regularly or occasionally" read labels to compare

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[171] Mary T. Bassett et al., *Purchasing Behavior and Calorie Information at Fast-Food Chains in New York City, 2007*, 98 AM. J. PUB. HEALTH 1457, 1458 (2008). These respondents were part of a large study of 7,318 respondents who frequented several fast food establishments that provided nutrition information. *Id.* at 1457.

[172] Roberto et al., *supra* note 144, at 312–13. After the meal, a questionnaire was administered which was followed up with a recall interview the next evening. *Id.* at 313.

[173] *Id.* at 316.

[174] *Id.* at 315.

[175] *Id.*

[176] Kozup et al., *surpa* note 148, at 26.

[177] INT'L FOOD INFORMATION COUNCIL FOUNDATION, *supra* note 143, at 8; Smith Edge, *supra* note 116, at 844 (describing the study and also providing the data in table form).

nutritional values,[178] and significantly more nutritional information was comprehended when included on the front of package label.[179]

B. Studies Regarding the Effectiveness of Health, Structure/Function Claims, or Disclaimers

The dissemination of nutritional information about a food product is not limited to the factual display of nutrients on a label. It extends to claims that are allowed to be included on the label. Therefore, it is important that we analyze studies on the effectiveness of such claims. A summary of the results of the following studies on the effectiveness of health and structure/function claims suggest that (1) favorable health information is best left on the nutrition facts panel,[180] (2) the shorter the health claim the better,[181] (3) consumers are confused by the current scheme of front-of-package labeling practices,[182] and (4) manufacturers are largely not compliant with FDA rules regarding structure/function claims,[183] leading to more consumer confusion because of unreliable product information on the label. In addition, manufacturers do not always use the required FDA label disclaimers for qualified health claims.[184]

Kozup et al. tested nearly 300 subjects on the effectiveness of health claims and nutrition information on packaged products and restaurant menu items.[185] Respondents in both groups were shown a product with no nutrition information, positive nutrition information, or negative information, along with either a positive

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[178] INT'L FOOD INFORMATION COUNCIL FOUNDATION, *supra* note 143, at 123–24; Smith Edge, *supra* note 116, at 845.

[179] INT'L FOOD INFORMATION COUNCIL FOUNDATION, *supra* note 143, at 34; Smith Edge, *supra* note 116, at 851.

[180] Kozup et al., *supra* note 148, at 25 tbl 2.

[181] Brian Wansink et al., *Front-Panel Health Claims: When Less is More* 10 (Sept. 1, 2004), http://foodpsychology.cornell.edu/sites/default/files/unmanaged_files/Front-Label Health Claims Article.pdf.

[182] Brenda M. Derby & Alan S. Levy, *Effects of Strength of Science Disclaimers on the Communication Impacts of Health Claims* (Nov. 2005); Paben, *supra* note 74, at 175.

[183] DANIEL LEVINSON, DEP'T OF HEALTH AND HUMAN SERVS., OFFICE OF INSPECTOR GENERAL, DIETARY SUPPLEMENTS: STRUCTURE/FUNCTION CLAIMS FAIL TO MEET FEDERAL REQUIREMENTS 1, 9–12, 16 (2012).

[184] Paula Fitzgerald Bone & Karen Russo France, *Qualified Health Claims on Package Labels*, 28 J. PUB. POL'Y & MKTG. 253, 257 (2009).

[185] Kozup et al., *supra* note 148, at 22–23.

health claim or no health claim.[186] Thus, comparisons could be made between claims that matched or did not match nutrition information on the nutrition facts panel or menu, as well as to the effect of claims when the menu contained no nutrition information. Respondents who viewed the package label containing favorable nutrition information and the heart health claim recorded a positive effect on nutrition attitude, product attitude, and purchase intention as compared to respondents who viewed favorable nutrition information without a health claim.[187] However, the positive health claim, combined with negative nutrition information had a negative effect on product attitude, purchase intention, and perceived credibility, suggesting that consumers viewed health claims with skepticism and relied on the nutrition facts panel as the more accurate means of judging the healthfulness of a food.[188] Results were similar for the respondents who viewed the restaurant menu item.[189] Kozup et al. asserted that favorable nutrition information on the nutrition facts panel is a better indicator of product purchase and product attitude than favorable health claims.[190] Perhaps, the more accurate statement is that such is the case until food label laws are streamlined.

Wansink et al. studied whether the length of health claims affected respondents.[191] In the study, 118 participants were given the same product to view, but with either a short health claim or a longer claim on the label.[192] Results indicated that consumers who saw the shorter claim understood the product better and retained specific facts compared to those who saw the longer claim.[193]

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[186] *Id*. at 21–22, 25; *see id.* at 25 (Table 2 provides breakdown of mean scores by each of these factors).

[187] *Id*. at 25 tbl. 2.

[188] *Id*. at 25.

[189] *Id*. at 25 tbl. 2. For respondents who reviewed the restaurant menu item, the heart health claim also had a positive effect on nutrition attitude and intent to purchase in both the no-nutrition information and positive nutrition information groups, as well as having a positive effect on product attitude in the no-nutrition information group. *Id.* As with results from respondents who viewed the product label, the positive health claim had a negative effect on product attitude, purchase, and perceived credibility when combined with negative nutrition information on the menu. *Id*.

[190] *Id*. at 25.

[191] Wansink et al., *supra* note 181, at 3.

[192] *Id.* at 7–8.

[193] *Id*. at 10.

Derby and Levy tested over 1,900 respondents on the effects of disclaimers designed to convey the strength of scientific evidence of health claims.[194] They found that disclaimers did not satisfactorily convey such evidence except to respondents with strong health consciousness and respondents between ages 30-45.[195] Derby and Levy noted that text disclaimers were not reliable at conveying the strength of scientific evidence and that symbol disclaimers—report card grades instead of text—used in conjunction with the health claim often caused respondents to attribute a higher degree of healthfulness to a lower grade than to a superior healthy product without a grade.[196] They noted that respondents viewed the information as some sort of marketing endeavor, thus they reverted to their initial assessment of the products instead of relying on the letter grades.[197] At the least, these findings point to consumer uncertainty because of having different labeling mechanisms provided by different parties.

A 2006 study of nearly 1,300 product labels found few products that were able to use qualified health claims actually used them.[198] Instead, they often used "structure–function claims" or "nutrition content claims."[199] "Structure/function claims" describe the role an ingredient plays in the "normal structure or function of the human body."[200] Nutrition content claims state the nutritional makeup of the product, and are allowed as long as the FDA has defined the ingredient.[201] Less than 8% of the labels that were able to use unqualified health claims—those not requiring an FDA disclaimer—did so.[202] There was a large difference between the percentages of the types of claims used on foods versus supplements: structure/function claims were the most prevalent claim on supplements (42.6%), whereas nutrition content claims were most prevalent on foods (26.8%).[203] The authors of the study noted that plausible reasons for manufacturers not using qualified health claims are because

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[194] Derby & Levy, *supra* note 182, at 1–3, 17–18.

[195] *Id.* at 3, 32–34.

[196] *Id.* at 34.

[197] *Id.* at 37.

[198] Bone & France, *supra* note 184, at 253–55, 257.

[199] *Id.* at 253–54, 257.

[200] *Structure/Function Claims, supra* note 36.

[201] Nutrition Labeling and Education Act of 1990, Pub. L. 101-535, § 3, 104 Stat. 2353, 2357 (1990) (codified at 21 U.S.C. 343).

[202] Bone & France, *supra* note 184, at 257.

[203] *Id.*

nutrition content claims have few legal restrictions and because the use of structure-function claims are not subject to the high evidentiary standard associated with health claims, and they do not require pre-market approval.[204]

The studies discussed above focused on consumers' belief and reliance on health claims and nutritional labels. Another means of determining the effectiveness of food label laws is to study manufacturer compliance with FDA requirements. If there is substantial non-compliance with the FDA's laws, it could lead to consumer uncertainty or even false reliance on erroneous information on food labels. Based on substantial concerns for the accuracy of dietary supplement labels, the U.S. Department of Health and Human Services ("HHS") recently analyzed structure/function claims on 119 dietary supplements manufactured by U.S. companies.[205] Structure/function claims address a documented nutrient deficiency disease (e.g., high blood pressure, Rickets, Scurvy) and describe the positive role the product's nutrient or ingredient plays in addressing such a deficiency, or how the ingredient or nutrient positively affects the general well-being of the human body.[206] A structure/function claim cannot state that it "treat[s], cures, or prevents any disease."[207] For example, "calcium builds strong bones" is an allowable structure/function claim.[208] However, the statement "calcium prevents osteoporosis" is not allowed because it claims to prevent a specific disease. Since structure/function claims do not require pre-approval, the FDA requires three things from manufacturers: (1) substantiation documentation must be generated; (2) the FDA must be notified within thirty days of marketing the product; and (3) a disclaimer must be used stating that the FDA has not evaluated the statement.[209] Although the FDA cannot require documents be sent to them, the manufacturer must create substantiation documents for structure/function claims before the product is placed in the market.[210] In its study of structure/function claims of the 119 dietary supplements, HHS requested substantiation documents

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[204] *Id.*

[205] LEVINSON, *supra* note 183 at 1, 8–9.

[206] 21 U.S.C. § 343(r)(6)(A) (2012); *Structure/Function Claims*, *supra* note 36, at 1.

[207] 21 U.S.C. § 343(r)(6)(C).

[208] *Id.*; *Structure/Function Claims*, *supra* note 36.

[209] 21 U.S.C. § 343(r)(6)(C); *Structure/Function Claims*, *supra* note 36.

[210] LEVINSON, *supra* note 183, at 4-5.

and received them for seventy-two of the supplements.[211] Contrary to the FDA requirement, only about one-third of the substantiation documents were based on human studies.[212] HHS determined that none of the human studies satisfied all recommendations of the FDA, and in fact only 2% of the human studies pertained to the product in question.[213] Finally, over 20% of supplements contained prohibited disease treatment claims and 7% did not contain the required disclaimer that the statement has not been reviewed by the FDA.[214] HHS determined that the current system raises concerns of unreliability since all three of the FDA requirements for products making structure/function claims were largely unmet, and since 20% of supplements contained illegal disease prevention claims.[215]

A large 2006 study found that 147 supplement labels using structured/function claims did not use the mandatory disclaimer indicating the FDA has not evaluated the product, and that twenty labels made qualified health claims without the mandatory FDA disclaimer.[216]

C. Commercial Speech and Health Claims

No evaluation of the effectiveness of food label laws is complete without an analysis of how courts have applied the four-part commercial speech test to food label claims. By looking at how courts apply the test in different scenarios, inconsistencies and errors in applying the law may be uncovered.

As previously noted, the Supreme Court in *Central Hudson Gas & Electric Co. v. Public Service Commission of New York* set forth the four-part test for determining if a government restriction on commercial speech is valid: (1) whether the speech is lawful and not misleading, if so (2) "whether the asserted government interest is substantial," (3) "whether the regulation

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[211] *Id.* at 9.

[212] *Id.* at 11.

[213] *Id*. at 12.

[214] *Id*. at 16.

[215] *Id*. at 15–18. To be fair, HHS noted that the FDA's notification letter electronic storage system could not be searched by keyword. Therefore, although seventeen of the twenty-one letters the FDA was able to find were incomplete, it is not known with certainty if the remaining manufacturers did not submit a letter or if HHS simply could not retrieve them from the FDA storage system.

[216] Bone & France, *supra* note 184, at 257.

directly advances the governmental interest asserted," and (4) "whether it is not more extensive than is necessary to serve that interest."[217]

The government may satisfy the first prong of *Central Hudson* if it can prove that the language in question is either potentially or inherently misleading.[218] Inherently misleading speech can be fully banned.[219] If speech is potentially misleading, the FDA must consider whether the claim can be remedied with a disclaimer.[220] The FDA can ban potentially misleading speech if it provides substantial evidence that the speech is actually misleading and if a disclaimer cannot cure the misleading speech.[221] If the message targets a sophisticated audience, such as the promotion of CPA services that are directed at experienced business executives, the claim has been found not to be deceptive.[222] However, if the message in question targets the general public or a vulnerable population, courts are more likely to hold that the speech is misleading.[223] For instance, in *American Academy of Pain Management v. Joseph*, the Ninth Circuit held that when a group of doctors used the phrase "board certified" in advertisements even though they did not qualify as board certified according the statutory definition, it was inherently misleading to the general public and to other specific groups.[224] Along the same line, in *Association of National*

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[217] Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[218] Gerald Masoudi & Christopher Pruitt, *The Food & Drug Administration v. the First Amendment: A Survey of Recent FDA Enforcement*, 21 HEALTH MATRIX: J.L. & MED. 111, 121–122 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

[219] *Id*. at 121 (citing *In re R.M.J.*, 455 U.S. 191, 203 (1982)).

[220] *Id*. at 121–22 (citing Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002); and Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146 (1994)).

[221] *Id*. (citing Friedman v. Rogers, 440 U.S. 1, 12–17 (1979); Thompson v. W. States Med. Ctr., 535 U.S. 357, 376 (2002); and Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 146 (1994)).

[222] Krista Hessler Carver, *A Global View of the First Amendment Constraints on FDA*, 63 FOOD & DRUG L.J. 151, 172 (2008) (citing Edenfield v. Fane, 507 U.S. 761, 775–76 (1993)).

[223] *Id*. (citing Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 449, 465 (1985) for the court's blanket ban on in-person attorney solicitation "of vulnerable accident victims").

[224] American Acad. of Pain Mgmt. v. Joseph, 353 F.3d 1099, 1108–09 (9th Cir. 2004).

Advertisers, Inc. v. Lungren, the Ninth Circuit held that speech defining certain environmental terms differently than was required by law was potentially misleading to the public.[225]

Central Hudson states that a communication may be banned if it is "more likely to deceive the public than to inform it."[226] Since *Central Hudson*, a standard for weighing the evidence associated with health claims has developed: if a claim is supported by significant scientific agreement then no disclaimer is needed; if a claim is supported by credible evidence then it may be used subject to an FDA disclaimer unless a disclaimer cannot make the claim whole, in which case the FDA may ban the claim; and if the claim is not supported by even credible evidence, then the claim may be banned.[227] This evidence-based standard can be characterized as being less subjective and more fact-driven than the "more likely to deceive" standard, better serving the need to ensure reliable claims on the front label.[228]

In *In re R.M.J.,* the Supreme Court held that potentially misleading speech cannot be banned if it could be offered in a non-deceptive way.[229] The Court relied on *Bates vs. State Bar of Arizona*, which generally suggested the preference for the use of a disclaimer or an explanation over an outright ban for misleading speech.[230] The use of a disclaimer, however, was not a requirement in *Bates*, which concerned truthful speech, not misleading speech.[231] In fact, it was an extraneous comment about facts not at issue in the case. The Court in *Bates* noted that the benefits derived from commercial speech required its "accuracy and reliability" and then simply mentioned the use of a disclaimer as one possible course of action for misleading speech, as opposed to an outright ban, if the situation called for it.[232]

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[225] Ass'n of Nat'l Advertisers, Inc. v. Lungren, 44 F.3d 726, 731 (9th Cir. 1994).

[226] Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563 (1980).

[227] JAMES T. O'REILLY & KATHERINE A. VAN TASSEL, FOOD AND DRUG ADMINISTRATION § 10:66 (4th ed. 2017); *Evidence-Based Review System*, *supra* note 43.

[228] *Evidence-Based Review System*, *supra* note 43.

[229] In re R.M.J., 455 U.S. 191, 203 (1982) (citing Bates v. State Bar of Az., 433 U.S. 350, 375 (1977)).

[230] *Id.*

[231] Bates v. State Bar of Ariz., 433 U.S. 350, 384 (1977).

[232] *Id.* at 383–384. As relating to misleading speech, the *Bates* court in dicta stated:

> Indeed, the public and private benefits from commercial speech derive from confidence in its accuracy and reliability. Thus, the leeway for untruthful or misleading expression that has been allowed in other contexts has little

Therefore, *In re R.M.J.* misapplied *Bates* by relying on its dicta, and further by incorrectly interpreting a requirement for a disclaimer.

An important recent line of cases, which required the FDA to issue disclaimers instead of banning the health claims, are of limited scope and have misapplied the law. First, these decisions should be considered to be of limited scope because one is from the U.S. Court of Appeals for the District of Columbia and the other three are from federal district court, which by definition are of limited applicability geographically and as precedential value.[233] In fact, all four of these cases are from within the D.C. Circuit. Second, these cases misapplied the law because the health claims in question were not supported by significant scientific evidence, the sole standard when *Pearson I* was decided, or enough credible evidence to require a disclaimer.

The FDA initially had full support in the District of Columbia jurisdiction. In siding with the FDA's banning of the nutritional supplement health claims in question, the *Pearson I* trial court followed precedent at every turn when it held: (1) the FDA's conclusions were accorded a highly deferential standard of review; (2) that the FDA's adoption of the significant scientific agreement standard was valid; and (3) that the four health claims in question were properly banned for not having met that standard.[234] The trial court cited to the Supreme Court's precedent for its determination that the FDA is afforded a highly deferential standard of review—"[t]he Court may not substitute

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> force in the commercial arena. In fact, because the public lacks sophistication concerning legal services, misstatements that might be overlooked or deemed unimportant in other advertising may be found quite inappropriate in legal advertising. For example, advertising claims as to the quality of services a matter we do not address today are not susceptible of measurement or verification; accordingly, such claims may be so likely to be misleading as to warrant restriction. Similar objections might justify restraints on in-person solicitation. We do not foreclose the possibility that some limited supplementation, by way of warning or disclaimer or the like, might be required of even an advertisement of the kind ruled upon today so as to assure that the consumer is not misled.

Id. (internal citations omitted).

[233] The holdings of all of these cases apply to a small geographical area: the D.C. Circuit and not to other circuits. Further, district court opinions are not binding as precedent. They are only binding as to the litigants of the case: The FDA, Pearson, and the rest of the litigants in the three district court cases.

[234] Pearson v. Shalala (*Pearson I* (trial court)), 14 F. Supp. 2d 10, 15–19 (D.D.C. 1998).

its judgment for that of the agency."[235] The trial court cited to another Supreme Court case for authority that this high level of agency deference is especially important when there is a challenge to "an evaluation of complex scientific data within the agency's technical expertise."[236] The trial court then cited its very own circuit court for its holding that stated the judicial branch is not "to undertake comparative evaluations of conflicting scientific evidence."[237] The trial court cited to *In re R.M.J.* for its statement that a health claim is inherently misleading if consumers do not have the knowledge to evaluate it,[238] and also cited to the scientific evidence and comments the FDA evaluated when holding that the claims were rightfully banned for lack of evidentiary support.[239]

The D.C. Circuit in *Pearson I* unilaterally disagreed with the trial court, reversing its decision and banning the FDA disclaimers.[240] It relied on *In re R.M.J.* for its statement that a ban on a potentially misleading claim is illegal "if the information also may be presented in a way that is not deceptive."[241] In other words, the court implied that a claim must be allowed if a disclaimer can be crafted by the FDA that adds information to make the claim complete. *In re R.M.J.* relied on dicta from *Bates v. State Bar of Arizona* as authority for this requirement.[242] Even if the statements were merely potentially misleading, the use of a disclaimer was only one suggestion by the *In re R.M.J.* Court.[243] The use of a disclaimer was not a requirement by law. It is alarming that a disclaimer would be required with no direct evidence to support the claim, and therein is a fundamental problem with the court's holding in *Pearson I*.

Aside from the insistence that a disclaimer could remedy the banned claims at hand, the *Pearson I* court clearly went further than a reasonable reading of *In re R.M.J.* when suggesting that a

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[235] *Id.* at 15.

[236] *Id.* (citing Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1983)).

[237] *Id.* (citing Nat. Res. Def. Council, Inc. v. E.P.A., 824 F.2d 1211, 1216 (D.C. Cir. 1987)).

[238] *Id.* at 18 (citing In re R.M.J., 455 U.S. 191, 202 (1982)).

[239] *Id.* at 18–19.

[240] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 661 (D.C. Cir. 1999).

[241] *Id.* at 655 (citing *In re R.M.J.*, 455 U.S. at 203).

[242] *In re R.M.J.*, 455 U.S. at 203.

[243] *Id.*

disclaimer could rectify the ills of the first three claim denials—claims that had no supporting human studies on nutrition supplements had ever been undertaken.[244] The claims were simply not proven by the significant scientific agreement standard (there was no lesser credible evidence standard at this time) and should have been allowed to be banned. This holding leaves one to wonder if there would ever be a circumstance when an outright ban of health claims would be possible.

Similarly, the *Pearson I* court also required a disclaimer for the fourth claim that was outright rejected by the FDA, where the agency had banned the statement "0.8 mg of folic acid in a dietary supplement is more effective in reducing the risk of neural tube defects than a lower amount in foods in common form."[245] In justification, the court relied on one study that concluded that "[l]osses [of folic acid] in cooking and canning [foods] can be very high due to heat destruction."[246] This evidence was not pertinent to the claim because it had nothing to do with the effectiveness of folic acid in nutritional supplements and no study assessed the effectiveness of folic acid in nutritional supplements. Therefore, the claim should not have been allowed at all, because it was not supported by evidence.

The *Pearson I* court incorrectly determined that the arbitrary and capricious standard of the Administrative Procedure Act required the FDA to explain why a disclosure was not able to remedy the misleading claims,[247] as there was *no* evidence in direct support of the claims. In addition, this court used its own interpretation of highly scientific evidence,[248] even though the Supreme Court has held that a high level of agency deference is especially important when there is a challenge to "an evaluation of complex scientific data within the agency's

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[244] *Pearson I*, 164 F.3d at 658.

[245] *Id.* at 658–59.

[246] *Id.* at 659 (alteration in original) (quoting DIET AND HEALTH: IMPLICATIONS FOR REDUCING CHRONIC DISEASE RISK 67 (Committee on Diet and Health, Food and Nutrition Board 1989)).

[247] *Id.* at 660.

[248] *Id.* at 658–59.

technical expertise," [249] and although the judicial branch is not to "undertake comparative evaluations of conflicting scientific evidence."[250]

The holdings of *Pearson II*, *Pearson III*, and *Whitaker v. Thompson*, which are the progeny of the Court of Appeals decision in *Pearson I* and which required the FDA to issue disclaimers instead of banning those health claims, were improperly decided for the same reasons given for *Pearson I*. Further, *Pearson II* expanded on the *Pearson I* court's improper examination of the scientific evidence to show its disagreement with how the FDA weighed the evidence and, in doing so, ignored precedent from the Supreme Court.[251] In fact, this very court went against its pronouncement just three years earlier, when it had properly applied the Supreme Court's holding in *Baltimore Gas & Electric* stating that agency deference is especially necessary when evaluating "complex scientific data within the agency's technical expertise."[252] The *Pearson II* court justified its actions with statements such as it was merely undertaking "a cursory examination of the scientific literature" and that "[t]he mere absence of significant affirmative evidence in support of a particular claim . . . does not translate into negative evidence 'against' it."[253] Both quotes contradict the law. The evidentiary frameworks of significant scientific agreement and credible evidence are necessary to weigh all available evidence to determine if the claim is misleading or not. But, not having evidence to support a claim does not negate evidence to support a ban. Finally, the *Pearson II* court claimed that a disclaimer was necessary if there was any credible evidence at all to support the health claim,[254] even though *Pearson I* specifically stated that it was possible for the FDA to determine that a disclaimer will not cure a claim where evidence in support of the claim is weaker than evidence against it.[255]

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[249] *See* Pearson v. Shalala (*Pearson I* (trial court)), 14 F. Supp. 2d 10, 15 (D.D.C. 1998) (citing Baltimore Gas & Elec. Co. v. Nat. Res. Def. Council, Inc., 462 U.S. 87, 103 (1983)).

[250] *Id.*

[251] Pearson v. Shalala (*Pearson II*), 130 F. Supp. 2d 105, 114 (D.D.C. 2001).

[252] *Pearson I* (trial court), 14 F. Supp. 2d at 15.

[253] *Pearson II*, 130 F. Supp. 2d at 115.

[254] *Id.* at 118.

[255] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 659 (D.C. Cir. 1999).

The *Whitaker* court also discussed the amount of evidence needed to deny a health claim, stating an example that the *Pearson I* court gave for evidence being qualitatively weaker than contrary evidence defined a very narrow parameter for when a claim may be denied.[256] *Whitaker* also noted that the government's standard was to prove its action of banning disclaimers was the *least* restrictive means of achieving its goal.[257] However, the standard set out in *Central Hudson* was whether the fit between the government's ends and the means chosen to accomplish those ends is not necessarily perfect, but reasonable.[258] In addition, the *Whitaker* court, like the *Pearson* courts, did not follow Supreme Court precedent by not deferring to the FDA's expertise.[259]

Aside from the FDA's denial of the health claims in the *Pearson* cases and in *Whitaker* for lack of sufficient evidence, there are studies concluding that consumers are confused about label claims. These studies have found that consumers do not trust the current label scheme.[260] There is precedent for allowing studies to be submitted as evidence in courts. Courts have accepted evidence from studies and anecdotes from areas outside the jurisdiction of the court.[261] Perhaps the results of those studies may be coupled with cases such as *Williams v. Gerber Products Co*., where the Ninth Circuit held that "reasonable consumers" are not expected to "look beyond" the front of a product label "to discover the truth,"[262] to prove that incomplete health claims are actually misleading to consumers and should be banned. Either way, the best course of action is to defer to the FDA and its expertise to carefully review health claims for purposes of protecting the public. The front of the package is likely the only place the majority of consumers will look for

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[256] Whitaker v. Thompson, 248 F. Supp. 2d 1, 10–11 n.10 (D.D.C. 2002) (stating that a complete ban would be reasonable when "evidence in support of the claim is qualitatively weaker than evidence against the claim – for example, where the claim rests on only one or two old studies.") (emphasis omitted).

[257] *Whitaker*, 248 F. Supp. 2d at 9.

[258] Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[259] *Whitaker*, 248 F. Supp. 2d at 11.

[260] *See supra* Part IV.B.

[261] City of Renton v. Playtime Theatres, Inc., 475 U.S. 41, 50–51 (1986).

[262] Williams v. Gerber Prod. Co., 552 F.3d 934, 939–40 (9th Cir. 2008).

nutrition information.[263] Further, there is evidence that a health claim must be succinct in order to be effective, and brevity is not possible when supporting evidence is weak, as evidenced by the lengthy disclaimers the FDA crafted in the *Alliance I* and *Alliance II* cases as described below. For those reasons, the FDA must have the ability to ban speech without the use of a disclaimer to a higher degree than current case law allows.

The United States District Court for the District of Columbia also rejected the precisely accurate summary of evidence that the FDA included in its disclaimers in two fairly recent cases, holding that the language was too detailed to survive the reasonable fit prong of *Central Hudson*.[264] The fourth part of the *Central Hudson* test requires there be a reasonable fit between the government's objective and the restriction,[265] which one would think would be satisfied by limiting disclaimer language exactly to the available evidence regarding the claim at question. In fact, in order to assure compliance, the FDA guidance procedures for qualified health claims unequivocally state that a disclaimer "should include qualifying language that identifies limits to the level of scientific evidence . . . with specificity and accuracy."[266] In the first of two cases, *Alliance I*, the plaintiffs' claim stated that "[s]elenium may reduce the risk of prostate cancer. Scientific evidence supporting this claim is convincing but not yet conclusive."[267] After a thorough review of the evidence, the FDA found only two out of nine studies suggested that "[s]elenium may reduce the risk of prostate cancer."[268] Then the FDA issued the following disclaimer which mirrored their evidentiary findings: "Two weak studies suggest that selenium intake may reduce the risk of prostate cancer. However, four stronger studies and three weak studies showed no reduction in risk. Based on these studies, FDA concludes that it is highly unlikely that selenium supplements reduce the risk of prostate

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[263] INT'L FOOD INFORMATION COUNCIL FOUNDATION, *supra* note 143, at 34; Edge et al., *supra* note 115, at 851 (describing the above study and also providing the data in table form).

[264] All. for Nat. Health U.S. v. Sebelius, 714 F. Supp. 2d 48, 71 (D.D.C. 2010); All. for Nat. Health U.S. v. Sebelius, 786 F. Supp. 2d 1, 24 (D.D.C. 2011).

[265] Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 566 (1980).

[266] *Evidence-Based Review System*, *supra* note 43, at § H.

[267] *All. For Nat. Health U.S.*, 714 F. Supp. 2d at 57 n.16.

[268] *Id.* at 70–71.

cancer."[269] The court held that such a disclaimer effectively negated the claim and as such the reasonable fit test of *Central Hudson* was violated.[270] In doing so, the court discounted the fact that the disclaimer precisely and accurately summarized the evidence per the mandated FDA guidelines noted above. The same may be said of the second case, *Alliance II*, where the court rejected two FDA disclaimers that were similar in detail because the claims failed to satisfy the reasonable fit requirement of the *Central Hudson* test.[271] Again, these disclaimers precisely stated the strengths and weaknesses of the evidence as reviewed by the expertise of the FDA.[272] What better fit could there be than including precisely accurate evidence in a disclaimer? The law should permit the FDA to provide disclaimers that accurately describe the evidence, regardless of whether the manufacturer's claim is negated.

Finally, a district court within the Second Circuit ruled on this issue.[273] Although this court allowed the FDA to accurately summarize the evidence in its disclaimer,[274] the court struck down the disclaimer for other language.[275] This underscores how difficult it has become for the FDA to protect consumers. In addition, since the case was decided in district court, it is of limited precedential value. In this case, a plaintiff posited the claim "that drinking green tea 'may reduce the risk of breast or prostate cancer.' "[276] The FDA evaluated the evidence and found that two of three breast cancer studies showed no link between

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[269] *Id.* at 71.

[270] *Id.*

[271] All. for Nat. Health U.S. v. Sebelius, 786 F. Supp. 2d 1, 24 (D.D.C. 2011).

[272] *Id.* at 11, 23–24. One of the two plaintiffs' health claims that the FDA determined required a disclaimer was: "Vitamin E may reduce the risk of bladder cancer. The scientific evidence for this claim is convincing, but not conclusive." The FDA's disclaimer for this claim stated: "One small study suggests that Vitamin E supplements may reduce the risk of bladder cancer. However, two small studies showed no reduction of risk. Based on these studies, FDA concludes that it is highly unlikely that vitamin E supplements reduce the risk of bladder cancer." *Id.* at 23–24. The other health claim stated that "Vitamin C may reduce the risk of gastric cancer. The scientific evidence supporting this claim is persuasive, but not conclusive." The FDA disclaimer for this claim was: "One weak study and one study with inconsistent results suggest that vitamin C supplements may reduce the risk of gastric cancer. Based on these studies, FDA concludes that it is highly uncertain that vitamin C supplements reduce the risk of gastric cancer." *Id.* at 24.

[273] *See generally* Fleminger, Inc. v. U.S. Dept. of Health and Human Servs., 854 F. Supp. 2d 192 (D. Conn. 2012).

[274] *Id.* at 217.

[275] *Id.*

[276] *Id.* at 195.

green tea and lower breast cancer rates, and a third study found a positive benefit in a very limited population.[277] The FDA found "very limited credible evidence" for the claim in the prostate cancer studies.[278] Thus, the FDA determined that the claim required a disclaimer.[279] Although this court held that the disclaimer language accurately summarized the evidentiary findings, it held that an extra sentence in the disclaimer claiming that the "FDA does not agree that green tea may reduce that risk" was considered to be too restrictive and in violation of the reasonable fit test.[280]

This case should give the FDA hope, however. Just as the judges here turned to other decisions for guidance—up until this case, they were all from courts within the D.C. Circuit—and then reasonably held that it was appropriate for the FDA to provide a precise summary of the evidence in the disclaimer, a court in another jurisdiction could turn to this case for guidance and decide to do the same. Given the confusion over front-of-package labeling schemes that currently exists, how can effective and believable disclaimers be crafted in cases where there is no direct evidence to support the health claims or where disclaimer language is restricted? Will a large number of consumers mistakenly believe that since the FDA has authored a disclaimer—even those disclaimers where the FDA was forced to edit out strong verbiage—it is also endorsing the product?[281] The average consumer may conclude that if the FDA did not believe the claim was properly worded based on the available scientific evidence then it would not have allowed it to appear on the label. Further, the average consumer likely does not know the FDA, which is charged with assuring consumers that we can rely on information contained on our food labels, is required to provide disclaimers against its better judgment, or is required to modify its disclaimer language by using verbiage it disagrees with, based on its expert analysis of the evidence. For these reasons, it is a bad idea to greatly curtail the FDA's ability to ban claims.

Courts have been inconsistent in their treatment of evidence used to prove that speech is potentially misleading. Although mere conjecture by the government will not suffice as evidence,

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[277] *Id.* at 203.
[278] *Id.*
[279] *Id.* at 204.
[280] *Id.* at 217–18.
[281] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 655 (D.C. Cir. 1999).

courts have determined that evidence may consist of references to studies and anecdotes from areas outside the jurisdiction of the court.[282] However, in *Association of National Advertisers, Inc. v. Lungren*, the court needed only two examples of evidence to determine that speech was potentially misleading: (1) a plastic bag labeled "recyclable" but could only be recycled if it was returned to South Carolina; and (2) a disposable diaper labeled "biodegradable" although it would take several hundred years for it to biodegrade.[283] Similarly, in *Friedman v. Rogers*, the Supreme Court noted that the governing body in question was merely familiar with past abuses and that was enough evidence to determine that the speech was misleading.[284] In *Ackerman v. Coca-Cola Co*., the court found evidence of misleading speech in the text of the FDA's existing regulations.[285] It appears that all of these examples belie the tough stand that the D.C. Circuit has taken to repeatedly deny FDA disclaimer language, especially in light of *Central Hudson*. According to the first prong of *Central Hudson*, communication may be banned if it is "more likely to deceive the public than to inform it."[286] A rational analysis would, for instance, allow a claim to be banned if the majority of the evidence is weighed against it. In fact, the court in *Pearson I* stated that such was a possibility.[287] The *Pearson I* court also left open the idea that the government could possibly prove that disclaimers would confuse the public.[288]

The second prong of *Central Hudson*, a substantial government interest, is met in health claims disputes where the government's mission is to protect the "health, safety, and welfare of its citizens" and to protect citizens from misleading advertising.[289]

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[282] City of Renton v. Playtime, Inc., 475 U.S. 41, 50–52 (1986).

[283] Brief of Plaintiffs-Appellants at 33 n.14, Ass'n of Nat'l Advertisers, Inc., v. Lungren, 44 F.3d 726 (9th Cir. 1994) (No. 93-15644).

[284] Friedman v. Rogers, 440 U.S. 1, 13 (1979).

[285] Ackerman v. Coca-Cola, Co., No. CV-09-0395(JG)(RML), 2010 WL 2925955, at *15–16 (E.D.N.Y. 2010).

[286] Cent. Hudson Gas & Elec. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563 (1980).

[287] Pearson v. Shalala (*Pearson I*), 164 F.3d 650, 659 (D.C. Cir. 1999) ("Nor do we rule out the possibility that where evidence in support of a claim is outweighed by evidence against the claim, the FDA could deem it incurable by a disclaimer and ban it outright.").

[288] *Id*. at 659–60.

[289] Rubin v. Coors Brewing Co., 514 U.S. 476, 484–85 (1995) (finding a substantial government interest existed when a statute prohibited beer labels from listing alcohol content because the statute protected the "health, safety, and welfare

The third prong of *Central Hudson*, whether the regulation directly advances the governmental interest asserted, also requires that the government provide evidence. *Lungren* stated that this prong was satisfied if the fit between the government's interest and the restriction is "simply reasonable."[290] In *Lungren*, the court held that the legislature's belief that uniform standards would promote consumer protection was enough to directly advance the governmental interest.[291] Similarly, the *Lungren* trial court cited to the Supreme Court case *Posadas v. Tourism Co. of Puerto Rico* for its acceptance of the legislature's belief regarding casino gambling advertising.[292] Further, the court in *Joseph* accepted the legislative history of the law as evidence that this prong was met.[293]

The court in *Pearson I* held that the fourth prong of *Central Hudson*, whether the fit between the government's ends and the means chosen to accomplish those ends is reasonable, was not met because the use of a disclaimer was a reasonable less-restrictive means than an outright ban of the claims in question.[294]

Notwithstanding the prior analysis of *Pearson I*, which concluded that the FDA should not have had to issue disclaimers in the first place, the court's claim that a less-restrictive means was required is not accurate. Courts have determined that the fourth prong does not require that the government act with the least restrictive means available to it. The *Joseph* court rejected such an argument by the plaintiff in response to a state banning

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of its citizens."); Posadas de P.R. Assocs. v. Tourism Co. of P.R., 478 U.S. 328, 341 (1986) (holding that government restrictions on casino gambling advertisements were a substantial interest because they protected the "health, safety, and welfare of its citizens"); *Pearson I*, 164 F.3d at 655–56 (quoting *Rubin*, 514 U.S. at 485 (finding that an FDA regulation requiring its approval of health claims not meeting the "significant scientific agreement" threshold was considered to be a substantial government interest, in that the regulation was aimed at preventing consumer fraud and "promoting the health, safety, and welfare of its citizens.")); American Acad. of Pain Mgmt. v. Joseph, 353 F.3d 1099, 1108–09 (9th Cir. 2004) (finding the government had substantial interest in protecting members of the public from misleading advertisements); U.S. Food & Drug Admin**.,** *What We Do, About* FDA, https://www.fda.gov/aboutfda/whatwedo/default.htm (last updated Mar. 28, 2018).

[290] Ass'n of Nat'l Advertisers v. Lungren, 44 F.3d 726, 732 (9th Cir. 1994) (citing Ass'n of Nat'l Advertisers v. Lungren, 809 F. Supp. 747, 757 (N.D. Cal. 1992)).

[291] *Id*.

[292] *Id.* at 732–33 (citing *Ass'n of Ntl. Advertisers*, 809 F. Supp. at 757).

[293] *Joseph*, 353 F.3d at 1109–11.

[294] *Pearson I*, 164 F.3d at 657–58.

the phrase "board certified" from physician advertisements.[295] In *Board of Trustees of State University of New York v. Fox*, the government banned Tupperware parties in student dorm rooms because of their commercial element.[296] The Supreme Court noted the least restrictive means of regulating commercial speech need not be chosen, and the government will determine the best method for regulating such speech.[297] In *City of Cincinnati v. Discovery Network, Inc.*, the dissenting justices of the Supreme Court stated the claim that the government was required to choose a less restrictive means of regulating commercial speech had been "discredited," and that the cases which held that the government's restrictions failed the fourth prong of the *Central Hudson* test were "substantially excessive, disregarding far less restrictive and more precise means."[298]

IV. SUGGESTED IMPROVEMENTS

Food laws must be streamlined to become an effective tool for consumer protection. Eliminating unnecessary and confusing laws is directly in line with the current administration's edict to cut bureaucracy.

Many authors have eloquently argued for sundry logical changes to food laws, such as the FDA relying less on guidance documents and more on the notice and comment provision of § 553 of the Administrative Procedure Act.[299] Many other reasonable changes could be made. For example, Winters advocates for state regulation of health claims and the repeal of the health and nutrient content claims provisions of the NLEA, which would save federal money.[300] Mortazavi suggests that allowing individual lawsuits would force change in the industry.[301] Mortazavi illustrates this point by highlighting recent litigation on the use of the term "natural," which convinced companies who were not part of the litigation to voluntarily drop the term from their labels.[302] Mortazavi

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[295] *Joseph*, 353 F.3d at 1111.

[296] Bd. of Trustees of State Univ. of N.Y. v. Fox, 492 U.S. 469, 471–72 (1989).

[297] *Id.* at 480.

[298] City of Cincinnati v. Discovery Network, Inc., 507 U.S. 410, 441 (1993) (Rehnquist, C.J., dissenting) (citing *Fox* at 478–79).

[299] Paben, *supra* note 74, at 212–13.

[300] Diana R. H. Winters, *The Magical Thinking of Food Labeling: The NLEA As A Failed Statute*, 89 TUL. L. REV. 815, 859 (2015).

[301] Mortazavi, *supra* note 86, at 931–32, 969–70.

[302] *Id.* 969–70.

recognized that individual lawsuits allow for public involvement in food law policy, which is necessary for government accountability and also serves as a means of instituting positive change for consumers.[303] Paben suggests that a federal private right of action be added to the FDCA, which would enhance the FDA's control over food laws.[304] Zarski argues that courts should interpret the NLEA preemption provision more narrowly so that a higher number of misleading label claims could be brought in state courts.[305] Zarski notes that 21 U.S.C. § 343(a)(1) bars all false or misleading label claims, thus suggesting that all state law claims for misleading labels should be allowed under existing law.[306]

The sheer number of reasonable solutions that have been posited over the past several years are staggering and there are far too many to implement. There needs to be a workable solution created from the surplus of solutions recently offered. This Article's proposed improvements to food laws will be limited to establishing a simple mandatory front-of-package labeling scheme that will include: (1) eliminating structure/function claims; (2) greatly revising and simplifying nutrition content claims laws; (3) having the FDA issue letter grades for products based on evidence of health claims while allowing agreed-on health claims language to appear on the label; and (4) deferring to the expertise of the FDA in the courts.

Although some of the Article's solutions are not new, the specific combination is unique and will greatly enhance the FDA's ability as a primary consumer advocate organization.

Paben calls for the FDA to change its regulations to ensure better, uniform food laws that are less confusing to consumers.[307] Negowetti suggests that the FDA require the significant scientific agreement standard for all label claims. [308] Thus, we

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[303] *Id.* at 931–32, 975.

[304] Paben, *supra* note 74, at 209–10.

[305] Sylvia Zarski, Comment, *Can You Judge Your Food By Looking At Its Cover? How Courts' Application of Federal Preemption Allows Misleading Food Labeling to Slip Through the Regulatory Cracks*, 64 DEPAUL L. REV. 1119, 1120, 1137 (2015).

[306] *Id*. at 1137.

[307] Paben, *supra* note 74, at 175.

[308] Nicole E. Negowetti, *Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority*, GOVERNANCE STUDIES AT BROOKINGS 2 (June 2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf.

should simply require FDA pre-approval of all label claims.[309] This will serve to eliminate the confusion caused by having multiple claims schemes. The current rules and guidelines for structure/function claims are confusing and rarely complied with.[310] For instance, the statement "improves joint mobility and reduces inflammation" is not allowed because it implies a cure for rheumatoid arthritis, but the statement "improves absentmindedness" is allowed because, although many consumers may equate that statement with a treatment for Alzheimer's disease, absentmindedness is also characteristic of non-disease symptoms.[311] For these reasons, structure/function claims are inherently misleading to consumers. It would be better if such claims were prohibited.

Nutrient content claims allow manufacturers to describe the level of nutrients in a product, on its label, if the FDA defined the level—these are levels such as "low in," "high in," reduced, lite; e.g., "low in fat."[312] The laws regarding nutrient content claims should be greatly streamlined,[313] to comply with a new mandatory front-of-package labeling scheme, which along with restructured health claims laws, described below, make the current nutrition content claims scheme obsolete.

The new nutrition content scheme will eliminate confusion by limiting the number of nutrition content messages that appear on the front of the package and utilizing short, concise statements. Currey proposed that the FDA should mandate front-of-package disclosures for certain potentially harmful ingredients when products contain more than the daily value of those ingredients.[314] Currey argued that sugar and sodium levels

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[309] Matthew W. Lindsey, Comment, *Dietary Supplements and Structure-Function Claims: The Dysfunctional Structure of Current Regulation*, 5 J. FOOD L. & POL'Y 201, 220 (2009) (suggesting pre-market approval for all dietary supplements, not for the claims being made about the supplements and not for food products).

[310] LEVINSON, *supra* note 183, at 16.

[311] U.S. Food & Drug Admin., Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide (Jan 9, 2002), https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm103340.htm.

[312] *Label Claims*, *supra* note 38.

[313] Marion Nestle & David S. Ludwig, *Front-of-Package Food Labels: Public Health or Propaganda?*, 303 J. AM. MED. ASS'N 771, 772 (2010) (although not advocating for a revision of nutrient content claims laws, the authors suggest the elimination of all front-of-package claims should be considered); Winters, *supra* note 300, at 817, 867.

[314] Currey, *supra* note 16, at 1282–83, 1303–05; *see* Szanyi, *supra* note 11, at 181–82 (Syznyi recognized the value on a front-of-package labeling system "from a psychological standpoint." He noted that the objective of front-of-package labeling is

should be required.[315] Along that same line, the Centers for Disease Control and Prevention ("CDC") recognized that front-of-package labeling would be most effective if the information is limited to the most important health-related nutrients, considering the need for more uniformity in front-of-package schemes caused by the many different ways that manufacturers present information.[316] The Institute of Medicine recommends that front of the package labels include unhealthful amounts of calories, sugars, saturated fats, and sodium levels be required if one of these ingredients exceeded the daily value by a certain percentage.[317] Hayes suggests only having a requirement for nutrition claims for offending ingredients, and not allowing beneficial claims at all.[318] This is in line with Kozup's experiments which concluded the Nutrition Facts panel, on the back of the product, is the best place for positive product information to appear.[319] Since a front-of-package labeling scheme must include just a few ingredients, the FDA should not allow the inclusion of beneficial claims, such as "low in sodium." Only negative nutrition claims (or more accurately, negative nutrition disclaimers) for a few important ingredients should be required on the label. It is sufficient to flag sugars, saturated fats, sodium levels, and calories that are well above the recommended daily value established by the Institute of Medicine. Doing so quickly alerts those consumers who must watch their food intake of the risks involved with eating certain foods. Health-conscious consumers will already scour the Nutrition Facts panel on the back of the product for healthful

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to provide a small amount of information in one prominent place, which "squares with what we know about the limits of human attention.").

[315] Currey, *supra* note 16, at 1308–10. Currey states that if at least 20% of the total carbohydrates in a product come from sugars, then the disclaimer "High in Sugar" must be used on the label. Currey also stated that trans fats should be identified too, but these have subsequently been banned by the FDA. *Id*.

[316] INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PHASE I REPORT 1, 1–3 (Ellen A. Wartella, et al., eds., 2010), https://www.nap.edu/read/12957/chapter/1#x.

[317] INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PROMOTING HEALTHIER CHOICES 4 (ELLEN A. WARTELLA, ET AL., eds., 2012), https://www.nap.edu/download/13221. The report also calls for a listing for trans fats, which have subsequently been banned by the FDA. *Id.*

[318] Kathryn E. Hayes, Note, *Front-of-Package Nutrition Claims: Trustworthy Facts or Deceptive Marketing? Closing the Loopholes in Labeling*, 19 CARDOZO J.L. & GENDER 545, 573–75 (2013).

[319] Kozup et al., *supra* note 148.

information. But those who are not necessarily healthy eaters likely will not view the Nutrition Facts panel and therefore would find the negative information on the front useful. This scheme clearly places consumers on alert for critical negative ingredient information while still providing a means of identifying positive product attributes by viewing the Nutrition Facts panel on the back of the product. By expanding on Currey's scheme, the current practice of selectively including only favorable information on the front of the package will be eliminated.[320] Not only would these ingredient listings be the most helpful information to consumers, but limiting the list to just a few ingredients would minimize or eliminate confusion.

Mandatory nutrition content disclosures would replace the currently allowed claims. They would be worded more directly than the "See nutrition information for _____ content" disclosure that is currently required if a product contains more than a certain level of fat, cholesterol, or sodium.[321] The current disclosure language leaves the burden of discovering nutrient deficiencies on the reader who has to think to check the Supplement Facts label on the back of the product. Front-of-package disclosures should be direct statements that leave no doubt of the nutrient deficiency. Research concluded that short claims are more effective than long claims.[322] For products that contain levels of the above-mentioned ingredients higher than the daily value, Currey suggests that the mandatory disclosure language should simply be "High in _____,"[323] with the offending ingredient in the blank space. The FDA should consider using two categories here—"high" and "very high." The FDA has already established a baseline of 20 percent above the daily value as being "high"[324] and there is no reason to discard that definition. I suggest that a second category of "very high" should also be used, leaving the FDA to define the term. This would incentivize manufactures to lower the level of harmful ingredients in their products.

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[320] Currey, *supra* note 16, at 1302–04.

[321] 21 C.F.R. § 101.13 (h)(1) (2016).

[322] Wansink et al., *supra* note 181, at 10–11.

[323] Currey, *supra* note 16, at 1308.

[324] U.S. Food & Drug Admin., A Food Labeling Guide. Guidance For Industry 91 app'x B, https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatory information/ucm2006828.htm (last updated Jan. 2013).

As others note, the health claims scheme also requires modification.[325] The introduction of a simple letter grade system for health claims would help eliminate the confusion caused by structure/function claims and nutrition content claims. Because consumers are familiar with letter grades, the FDA should assign a letter grade to *every* health claim based on the level of evidence that exists in support or opposition to the health claim. The letter grades would be prominently placed on the front label of the product, next to the health claim. In 2009, the FDA experimented with a grading scheme in which unqualified health claims received an A grade since they were supported by significant scientific agreement, and qualified claims received grades from B through D, with a brief statement that the FDA had assigned the grade based on the evidence.[326] The letter grade experiment showed some success.[327] Evidence from an earlier FDA report card experiment suggested that having fewer letter grades would help consumers properly identify the strength of evidence in support of a claim[328] and it would be up to the FDA to consider such a modified grading scheme. Additionally, a grading scheme, which incentivizes manufacturers to achieve a high grade, places the burden and cost of testing on the manufacturers who see 50% profit margins on supplements.[329]

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[325] Winters, *supra* note 300, at 859, 861, 867 (suggesting to eliminate NLEA's health and nutrition content claims provisions); Pomeranz, *supra* note 87, at 646 (suggesting that congress require preauthorization for claims and that the FDA work together with the food industry to develop a claims database); David C. Vladeck, *Devaluing Truth: Unverified Health Claims in the Aftermath of* Pearson v. Shalala, 54 FOOD & DRUG L.J. 535, 542–52 (1999) ("Unverified [h]ealth [c]laims [i]nherently [a]re [m]isleading."); Monika Jankowska, *U.S. Food Labelling Regulations vs. Freedom of Speech – Creation of "Qualified Health Claims,"* 12 EUR. FOOD & FEED L. REV. 142, 150 (2017) ("[F]reedom of expression should not be used to protect bad science.").

[326] Conrad J. Choinière & Linda Verrill, *Experimental Study of Qualified Health Claims: Consumer Inferences about Monounsaturated Fatty Acids from Olive Oil, EPA and DHA Omega-3 Fatty Acids, and Green Tea: Executive Summary*, U.S. FOOD AND DRUG ADMIN., https://www.fda.gov/Food/LabelingNutrition/ucm207699.htm (last updated Jan. 3, 2018). This grading scheme was one of three schemes evaluated in the study to determine the effectiveness of conveying the scientific evidence supporting health claims. *Id.*; Derby & Levy, *supra* note 182, at 36 (suggesting giving products with unqualified health claims an A grade).

[327] Choinière & Verrill, *supra* note 326.

[328] *2004 Qualified Health Claims Research Executive Summary*, FOODINSIGHT.ORG (Apr. 25, 2010), http://www.foodinsight.org/2004_Qualified_Health_Claims_Research_Executive_Summary.

[329] *See* Dickens, *supra* note 9, at 592–93, 595–96 (discussing how the European Union requires manufacturers to adequately prove that their products are safe); *see*

Using a well-recognized grading scheme will provide certainty to the consumer in two meaningful ways. First, only one entity would assign the grade, not manufacturers or trade associations. Second, the governing agency tasked with consumer protection, not the manufacturer,[330] assigns the grade. However, the grading scheme may run afoul of commercial speech laws that recently arose when the FDA attempted to deny qualified health claims, as discussed in Part IV.C. Therefore, health claims should be allowed on the label—except if a total ban is appropriate— subject to disclaimer modifications by the FDA. In addition, the courts should give the FDA strong agency deference in analyzing its evidence, as per *Auer v. Robbins*.[331] In that way, letter grades would not replace the text of health claims, and the FDA would be allowed to signal to consumers the strength of the claim by way of a simple format that is supported by the FDA's evidentiary standards.

The use of this new health claims scheme would require the FDA to spot test products that are on the market, which would require additional funding. To the extent that this would require additional resources and staffing, Dickens has several suggestions that would help. She suggests the FDA could reward states if they assist in its regulatory efforts, for instance providing product-testing facilities for the FDA to use.[332] Dickens also suggests that tax incentives could encourage relevant state and federal agencies to "pool their budgets to help test dietary supplements."[333]

The FDA should also focus efforts on approving qualified health claims as another means of streamlining the process.[334] Under the new scheme, all products with qualified health claims would automatically receive an A letter grade. In those instances, there is no lengthy, complicated FDA process to navigate or the possibility of ensuing lawsuits over claim denials because of weight of evidence issues.

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also Lindsey, *supra* note 309, at 220 (assuring supplement safety via premarket approval would be the financial burden of manufacturers).

[330] Derby & Levy, *supra* note 182, at 38 (noting that consumers considered health claims and strength of science disclaimers to be part of the products marketing).

[331] Auer v. Robbins, 519 U.S. 452, 461 (1997).

[332] Dickens, *supra* note 9, at 594.

[333] *Id*.

[334] Pomeranz, *supra* note 87, at 646–47 (suggesting that the FDA should work with the food industry to develop a claims database).

Finally, courts have misinterpreted First Amendment commercial speech laws relating to health claims. Courts have misinterpreted the law by holding that FDA disclaimers are too strongly worded and wholly negate the health claim of the plaintiffs—even with accurate and precise language based on an expert summary of the evidence. Courts challenged the expertise of the FDA in denying its decision to disallow a claim when it was not supported by credible evidence. Courts have misapplied the FDA's evidentiary standard. Admittedly, these limiting cases are all from one jurisdiction (courts within the D.C. Circuit), but a promising case having been decided in a court within the Second Circuit. Nonetheless, the FDA must be allowed to properly protect the public from misleading health claims by exercising the highest degree of administrative deference as recognized for administrative agencies in *Auer v. Robbins*.[335] The Article's proposed improvements to food laws will have a profound positive effect on the convoluted, detailed, and crazy maze of food label and claims laws that currently exist. By establishing a simple mandatory front-of-package labeling scheme that will include: (1) eliminating structure/function claims; (2) greatly revising and simplifying nutrition content claims laws; (3) having the FDA issue letter grades for products based on evidence of health claims while allowing agreed-on health claims language to appear on the label; and (4) deferring to the expertise of the FDA in the courts, consumer protection will be greatly enhanced.

CONCLUSION

The FDA has the burdensome but crucial task of ensuring that our food is safe and adequately represented in the marketplace. Currently, food laws are ineffective and strip the FDA of the clout it needs to be a proper watchdog agency. As a result, the FDA is far less effective. By improving food laws and prioritizing FDA actions, a more consumer-oriented agency will emerge to provide adequate protections for unsuspecting consumers. Our nation is fortunate enough to have the resources to make this critical change a reality. The question is whether we have the ability to transcend political and industry forces to make it a priority.

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[335] 519 U.S. at 461.