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Misleading Food Labels: How Current Litigation Trends Are Exposing a Gap in Consumer Protection Enforcement

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I. Introduction

People have worried about misleading and false food claims since at least medieval times.[1] At present, most people choose to buy their food, rather than grow it themselves.[2] Moreover, people choose to consume an increasing amount of processed food.[3] Before modern day food labeling regulations, it was nearly impossible for people to know what they were putting in their bodies.[4] Muckraker journalists and scientists uncovered some unsettling revelations about the creation and marketing of processed

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[1] *See* Mario Moore, Third Year Paper, *Food Labeling Regulation: A Historical and Comparative Survey*, HARV. L. SCH. STUDENT PAPERS 3, 4 (2001), http://nrs.harvard.edu/urn-3:HUL.InstRepos:8965597 [https://perma.cc/WY22-L3WB] (describing early food labeling regulation). "In medieval and early modern Europe, many types of food were identified by origin, grade, and regulatory marks." *Id.* at 4. Early food labeling regulations and practices can be traced to breadmaking, where early bakers would imprint a mark on their loaves of bread to indicate quality. *Id. See also* Claudia Kreklau, *"Death in the Pot": The Long History of Food Adulteration*, ST. ANDREWS SCH. OF HIST., (Feb. 11, 2019), https://standrewsschoolofhistory.wordpress.com/2019/02/11/death-in-the-pot-the-long-history-of-food-adulteration/ [https://perma.cc/FP8W-XG7J]. When societies transitioned from agrarian to industrial, people began outsourcing their food production, giving rise to food adulteration in favor of profits and the need for regulation. *Id.*

[2] *See* Joyce H. Lee et al., *United States Dietary Trends Since 1800: Lack of Association Between Saturated Fatty Acid Consumption and Non-communicable Diseases*, FRONTIERS IN NUTRITION, (Jan. 13, 2022), https://www.frontiersin.org/articles/10.3389/fnut.2021.748847/full [https://perma.cc/V43X-FE5A] (describing a trend of increased processed food consumption). "The American diet changed radically since 1800 due to industrial and technological advances, geographic spread, urbanization, wars, cultural changes, as well as food industry conglomerates and globalization." *Id.*; Kreklau, *supra* note 1. Increasingly urban populations began to rely on food vendors and industrial producers to supply their meals. *Id.* Without oversight or regulation, food producers began to value profit over quality, substituting genuine ingredients for cheaper additives. *Id.* Such practices gave rise to a widespread understanding of the idea of food adulteration. *Id.*

[3] *See* Joyce H. Lee et al., *supra* note 2. Between 1800 and 2019, processed and ultra-processed food consumption increased from less than <5% to greater than >60%. *Id.*

[4] *See* Ramunas Kondratas, *Images from the History of the Public Health Service; A Photographic Exhibit*, U.S. NAT'L LIBR. OF MED. (Jul. 29, 2013), https://www.nlm.nih.gov/exhibition/phs_history/foodanddrugs.html [https://perma.cc/26VN-DLGT]. Although food adulteration was generally forbidden by law in the late 19th century, there existed few ways to ensure compliance. *Id.* It was incredibly common for labels to state unfounded health claims without listing ingredients or warnings. *Id.*

foods and began to lobby heavily for labeling regulations.[5] Congress eventually took action, leading to the modern food laws that we have today.[6]

Despite the regulations established by the Food and Drug Administration (hereinafter *FDA*) and the Federal Trade Commission (hereinafter *FTC*), misleading food label lawsuits have faced an uptick in recent years.[7] Class action litigation against food and drug companies more than doubled from just a decade ago, reaching a recent high.[8] Many of the lawsuits concern whether a product label is describing a flavor or if the label is misleading when referring to the presence of an ingredient that may not actually be contained in the product.[9] Advocates continue to search for more stringent federal

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[5] *See id.* Upton Sinclair's novel, The Jungle, was successful in raising public alarm over the appalling conditions of Chicago's meat-packing plants. *Id.* In 1902, Dr. Harvey W. Wiley successfully brought the adverse effects of unregulated preservatives in food to the public's attention. Kondratas, *supra* note 4. Other "muckrakers" utilized national magazines such as Ladies Home Journal and Good Housekeeping to warn the public of false medicines and food in order to raise support for federal regulation. *Id. See generally* UPTON SINCLAIR, THE JUNGLE (Seawolf Press 2020) (1906) (portraying working conditions in Chicago meat-packing industry during early 20th century).

[6] *See* Kundratas, *supra* note 4. In 1937, a tragedy that resulted in over 100 people dying due to a poisonous solvent contained in a "wonder drug" elixir finally convinced lawmakers to broaden existing legislation in an attempt to offer more consumer protection. *Id.*; Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG. (Jun. 1981), https://www.fda.gov/about-fda/histories-product-regulation/sulfanilamide-disaster [https://perma.cc/GBH6-MF5X] (recounting devastating aftermath and legislative reaction to 1937 elixir sulfanilamide incident). "At the time the food and drugs law did not require that safety studies be done on new drugs. Selling toxic drugs was, undoubtedly, bad for business and could damage a firm's reputation, but it was not illegal." *Id.* "The charge was misbranding. "Elixir," FDA said, implied the product was an alcoholic solution whereas it was, in fact, a diethylene glycol solution and contained no alcohol. If the product had been called a "solution" instead on an "elixir," no charge of violating the law could have been made." *Id. See also* Moore, *supra* note 1, at 19, 22.

[7] *See* John Zabriskie et al., *Parsing the Recent Surge in Midwest Food Labeling Litigation*, LAW 360 (Feb. 24, 2022), https://www.law360.com/articles/1462282 [https://perma.cc/FKB8-GS9M] (examining recent increase in food label litigation in Midwestern states). These lawsuits focus primarily on mislabeled food, specifically regarding whether a label is referring to a flavoring, or to an ingredient not actually contained in the product. *Id. See also* Andrew Jacobs, *Lawsuits Over 'Misleading' Food Labels Surge as Groups Cite Lax U.S. Oversight*, N.Y. TIMES (Sept. 7, 2021), https://nyti.ms/3jOS2d9 [https://perma.cc/PVD6-3NG6]. Descriptions on the upswing in litigation have varied, with some describing the lawsuits as outlandish and a means of extortion, while others celebrate the lawsuits as a form of legal activism. *Id.*; Jane Caldwell, *Food Labels Are Constant Targets of Litigation,* AM. COUNS. ON SCI. AND HEALTH (Apr. 4, 2022), https://www.acsh.org/news/2022/04/04/food-labels-are-constant-targets-litigation- [https://perma.cc/8AZ4-23MA].

[8] *See* Jacobs, *supra* note 7 (noting that in 2020, two hundred lawsuits were filed, compared to forty-five the decade prior).

[9] *See* John Zabriskie et al., *supra* note 7. There were at least four food label lawsuits from 2021 that challenged the use of the word "strawberry," coupled with an image of a strawberry, as misleading when the product contained no strawberries. *Id.* Other litigation involved use of the words "chocolate," "honey," "fudge," and "butter." *Id. See generally* Zahora v. Orgain L.L.C., No. 21 C705, 2021 WL 5140504, at *1 (N.D. Ill. Nov. 4, 2021) (alleging protein shake label portraying authentic vanilla misleading because flavoring came from synthetic); Tropp v. Prairie Farms Dairy, Inc., No. 20-cv-1035-jdp, 2021 WL 5416639, at *1 (W.D. Wis. Nov. 19, 2021) (claiming

oversight.[10] Indeed, for each class action suit that makes its way to court, dozens are dismissed and settled.[11] Food producers have no guidance for appropriate label marketing practices, and consumers lack an effective remedy for holding processed food producers accountable for misleading tactics.[12]

II. History

A. Pre FDA/FTC

The concept of food adulteration and misbranding has existed since people began to buy and sell food.[13] Some of the earliest regulations on food labeling stem from English common law which standardized the sale of loaves of bread.[14] Initially, these standards did not identify ingredients and instead were used to identify the baker, which allowed consumers to trace loaves with misrepresented quality back to the source.[15] Colonial

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deceptive practice because ice cream flavored with artificial flavor rather than vanilla beans); Gierwatowski v. Trader Joe's Co., No. 21-cv-1119, 2021 WL 2660760, at *1 (N.D. Ill. Jun. 29, 2021) (alleging misleading portrayal of vanilla on granola label); Karlinski v. Costco Wholesale Corp., No. 1:21-cv-03813, 2022 WL 2867383, at *1 (N.D. Ill. Jul. 21, 2022) (alleging ice cream bar label misled consumers about amount of cacao in chocolate coating); Cruz v. D.F. Stauffer Biscuit Co., No. 20-CV-2402 (PGG) (JLC), 2021U.S. Dist. LEXIS 213641, at *1 (S.D.N.Y. Nov. 4, 2021) (claiming lemon imagery misled consumers to think flavor came from only lemons).

[10] *See* Jacobs, *supra* note 7. Advocacy groups attribute the rise of food label litigation to a surge in deceptive practices by food producers, coupled with a lack of government oversight. *Id.*

[11] *See id.; see also* John Zabriskie, *supra* note 7 (urging manufacturers to consider whether to file motion to dismiss before settling).

[12] *See* Jacobs, *supra* note 7. Federal regulators have yet to specifically define commonly used terms like "healthy" and "whole grain." *Id.* The lack of clarity surrounding definitions of commonly used terms has led food producers to go with wording that they know will most resonate with consumers. *Id.*

[13] *See* Kondratas, *supra* note 4 (highlighting public concern about food and drug adulteration throughout human history); *see also* Moore, *supra* note 1, at 3-4. Complex and specific rules governing the sale of food has existed at least since Roman times. *Id.* Although labels as we think of them today were not widely used until the industrialization of food production, early civilizations imposed other rules to ensure transparency and indicate quality, like requiring bread to be sold publicly rather than in secret and assigning specific city steps for the sale of different grades of bread. *Id.*

[14] *See* Moore, *supra* note 1, at 5. "In London of the fourteenth and fifteenth centuries, each baker was required to have his own seal, and each loaf of bread was required to be labeled using the seal so that its baker could be identified." *Id.* Regulation of bread labeling in England can be traced back to 1203, when the Assize of Bread was enacted by King John. *Id.* at 4. Wine was also one of the earliest food products subject to label regulations in England, with regulations dating back as far as a 1311 ordinance requiring label markings on the front of wine bottles. *Id.* at 5-6. Wine was especially susceptible to adulteration because it was one of the earliest articles of commerce and often created far from where it was sold. *Id.* at 5. Additionally, butter was one of the most commonly adulterated foods in English history, prompting regulations which imposed specific labeling requirements on butter packers in the 17th century. *Id.* at 6.

[15] *See* Moore, *supra* note 1, at 4 (describing labeling requirements for bread in 13th century England). Medieval regulators had an interest in regulating bread quality and pricing to maintain support from a population that was largely dependent on bread as a food source, along with sustaining an effective tax base because bread was an important article of commerce. *Id.* In medieval England, common law standards for weight and measure were well- known and most misbranding was achieved through false weights or verbally presenting an inferior product as a

America adopted English bread regulations, requiring that every baker have a distinct mark for their bread.[16] In the eighteenth century, America expanded the regulatory scheme to other foods, such as flour and pork.[17]

Industrialized agriculture began in the second half of the nineteenth century.[18] The advancement of railroads and the modernization of preservation practices, like canning and refrigeration, made it easier to ship food to distant places.[19] Food producers were able to sell in mass to distant consumers for the first time.[20] As the distance between consumers and food producers widened, consumers started to associate their foods with labels and branding, rather than individual producers.[21] The depersonalization of the food industry resulted in an abundance of fraudulent practices, like food adulteration and unsubstantiated claims.[22]

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superior one. *Id.* at 7. Food vendors who utilizing utilized verbal misrepresentations, false weights, and measures could be more easily held accountable when their products could be traced directly back to the maker. *Id.*

[16] *See* Moore *supra* note 1, at 9. The first recorded regulation was recorded in 1646 by the General Court of Massachusetts Bay Colony and was almost an exact copy of the British Assize of Bread enacted by King John. *Id.*

[17] *See id.* at 9-10. Flour and Pork were commonly expected to be inspected and marked before sale to indicate quality control. *Id.* Massachusetts was the first state to enact a broad food adulteration state statute meant to be applicable to all food products. *Id.* at 10.

[18] *See* Moore, *supra* note 1, at 10 (identifying trends contributing to rise of industrialized agriculture). "In the US, the West was settled, farm mechanization began, the rise of mass transportation, the increasing specialization of farming, the drastic decline of self-sufficient farms, expansion into new markets, and the rise of educational opportunities that allows the dissemination of knowledge about science and technology." *Id.* Notably, the advancement of food preservation technology paired with the rise of mass transportation made it more profitable for farmers to focus on growing fewer crop varieties. *Id.* at 11. *See also* Joyce H. Lee et al*., supra* note 2 (attributing drastic change in American diet since 1800 to food industry conglomerates).

[19] *See* Moore, *supra* note 1, at 11. This rise in food preservation technology made it cheaper to buy canned or frozen food from the grocery store than for farmers to grow greater varieties of produce on their farms. *Id.*

[20] *See* Moore, *supra* note 1, at 11. As a result, a notable disassociation developed between consumers and food producers. *Id.* Consumers no longer had any way of knowing where their food came from or how it was processed. *Id.* The lack of transparency over food production methods created an imbalance of power between consumers and producers. *Id.* Food producers began to undercut competitor prices by altering the quality and ingredients of their products, resulting in rampant adulteration and misbranding. *Id.*

[21] *See* Moore, *supra* note 1, at 13 (describing reinvention of consumer/producer relationship through branding). Branding gave consumers means of assessing quality without having personal relationships with producers. *Id.* In the late 19th century, mass food producers began to brand their products and engage in aggressive marketing tactics. *Id.* at 14.

[22] *See* Kondratas, *supra* note 4 (providing examples of early food adulteration and elixirs). Adulteration and false claims took many forms, including: adulterated milk composed of water and various chemicals, "soothing syrups" for babies containing morphine, heroin, opium, or laudanum, which led to physical addiction symptoms in babies, and unsanitary conditions for unprocessed foods like oysters, poultry and eggs. *Id. See also* Kreklau, *supra* note 1 (describing publication outlining food adulteration in 19th century Britain). Some outlined adulterations include: cheese containing lead, flour cut with alum, and tea containing cherry leaves, which is a very strong laxative. *Id.*

B. FDA History

Before governmental advertising regulations existed in the early twentieth century, food, drinks, and drugs were sold to anyone, without restriction.[23] During the last quarter of the nineteenth century, many groups attempted to enact national food and drug laws to no avail.[24] Pressure from a coalition of food processors, farmers, state officials, physicians, and muckraking journalists, combined with public alarm over revelations uncovered in Upton Sinclair's novel, "The Jungle," finally pushed Congress to enact the Food and Drugs Act of 1906 (hereinafter *1906 Act*).[25]

The 1906 Act was the beginning of the FDA's modern regulatory function.[26] The 1906 Act generally prohibits manufacturers from using false or misleading food labels that misstate the nature or identity of the product.[27] The definition of "misleading" was very

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[23] *See* Kondratas, *supra* note 4 (explaining medicine, food, and drink abuses). Misbranded, unregulated food and drug products would contain ingredients ranging from harmless additives to narcotic drugs and alcohol. *Id.* As chemicals were being invented and added to food products, nothing prevented manufacturers from testing these new additives on consumers in the general market. *Id.*

[24] *See id.*; Nicole Gerhart, *The FDA & The FTC: An Alphabet Soup Regulating The Misbranding Of Food*, LEDA AT HARV. L. SCH. (Apr. 30, 2002), https://dash.harvard.edu/bitstream/handle/1/8965563/Gerhart.html?sequence=2&isAllowed=y [https://perma.cc/Z5H9-HZBR]. "Between 1879 and 1906, more than 100 Congressional bills had been introduced that attempted general legislation, yet none were enacted." *Id.*; *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN. (Apr. 24, 2019), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement [https://perma.cc/VUJ3-SSEQ]; *see also* Moore, *supra* note 1, at 17-19. Before national regulations existed, many individual states had adopted anti-adulteration statutes, but the state regulations were generally inadequate because states could not effectively regulate food transported across state lines. *Id.* Concerns about federal regulations interfering with state and local matters was a major hurtle preventing national legislation. *Id.*

[25] *See* Moore, *supra* note 1, at 21. Upton Sinclair's novel, The Jungle, raised significant public alarm over the unhygienic conditions in the meat-packing plants of Chicago. *Id.*; *Part I: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 24 (explaining Sinclair's impact on Food and Drugs Act). *See also* Moore, *supra* note 1, at 17-19 (describing lobbying efforts by certain food producers in favor of national misbranding statute). Notable proponents of national legislation included H.J. Heinz of Heinze Ketchup, and Frederick Pabst of a major beer brewing company. *Id.* at 17. Food producers in support of national regulations saw it as a means of gaining consumer trust and preventing unfair competition practices. *Id.* at 17-18; Federal Food and Drugs Act of 1906, ch. 3915, §3, 34 Stat. 768 (1906) (repealed 1938); *see generally* SINCLAIR, *supra* note 5 (giving graphic account of working conditions in meat-packing industry of early 20th century).

[26] *See FDA History*, U.S. FOOD & DRUG ADMIN. (June 29, 2018), https://www.fda.gov/about-fda/fda-history [https://perma.cc/KC2A-CG4C]. "Although it was not known by its present name until 1930, FDA's modern regulatory functions began with the passage of the 1906 Pure Food and Drugs Act, a law a quarter-century in the making that prohibited interstate commerce in adulterated and misbranded food and drugs." *Id.; see also* Moore, *supra* note 1 (describing standards imposed by the 1906 Act); Gerhart, *supra* note 24 (discussing early implementation of the 1906 Act); Kondratas, *supra* note 4.

[27] *See* Moore, *supra* note 1, at 19-20. "The Act's only regulation of labeling was the prohibition of false or misleading statements on food labels." *Id.* at 19; *FDA History*, *supra* note 26; Gerhart, *supra* note 24. "The Act declared it unlawful to manufacture and transport any food or drug that is adulterated or misbranded." *Id.* The law focused primarily on the regulation of product

vague, which granted courts broad discretion to interpret and apply its meaning.[28] Such broad discretion resulted in courts reaching inconsistent conclusions regarding what constituted a violation.[29] The 1096 Act became increasingly limited as courts made determinations that imposed requirements like seller intent, among others.[30]

Thirty years after the 1906 Act took effect, a poisonous solvent killed over 100 people and greatly dramatized the need to broaden existing product safety legislation.[31]

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labeling, rather than pre-market approval of products. *Id.*; Moore, *supra* note 1, at 19-20. "The Act's only regulation of labeling was the prohibition of false or misleading statements on food labels." *Id.* *See also* Kondratas, *supra* note 4. Although the 1906 Act prohibited food adulteration and misbranding of food labels on products in interstate commerce, the Act contained few requirements to ensure compliance. *Id.*; Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768.

[28] *See* Gerhart, *supra* note 24 (highlighting responsibility of courts to interpret and apply 1906 Act); Moore, *supra* note 1, at 20. Generally, courts interpreted a label based on how they thought an ordinary English-speaking person of average intelligence and familiarity with the product would understand it. *Id.; see also Part I: The 1906 Food and Drugs Act and Its Enforcement*, *supra* note 24 (pointing out differing opinions in courts on how standards would apply). *See generally* United States v. Scanlon, 180 F. 485, 487 (N.D. Ohio 1908) (interpreting label as misleading based on standard of average customer's cursory glance); United States v. Seventy-Five Boxes of Alleged Pepper, 198 F. 934, 938 (D.N.J. 1912) (holding labels should be interpreted according to their ordinary, rather than technical, meaning); United States v. One Hundred and Fifty Cases of Fruit Puddine, 211 F. 360, 364 (D. Mass. 1914) (holding use of words "fruit flavored" misleading when product contained no fruit); United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar, 265 U.S. 438, 443 (1924) (declaring literally true or not technically false statements as still having ability to deceive); United States v. Five Cases of Champagne, 205 F. 817, 820 (N.D.N.Y 1913) (focusing on seller's intent to deceive and Congressional intent); United States v. Johnson, 221 U.S. 488, 498 (1911) (holding 1906 Act only applies to statements determining identity of product); United States v. Am. Druggists' Syndicate, 186 F. 387, 391 (C.C.E.D.N.Y. 1911) (holding advertisement enclosed within carton was not within scope of Act); Hall-Baker Grain Co. v. United States, 198 F. 614, 616 (8th Cir. 1912) (including intent as necessary component for misbranding claim).

[29] *See* Gerhart, *supra* note 24. Some judges focused on the intent of the producer to deceive, while others instead focused on the perspective of the consumer. *Id.* Furthermore, courts had differing opinions as to the definition of "misleading" and whether to distinguish the words "false" and "misleading" stated in the statute. *Id.* Some courts judged whether a label is misleading based on a "cursory glance," while other courts differed in application. *Id. See generally Hall-Baker Grain Co.*, 198 F. at 614 (holding intent necessary for misbranding claim); *Five Cases of Champagne*, 205 F. 817 (focusing on intent of the seller); *Scanlon*, 180 F. 485 (using "cursory glance" of consumer standard); *Seventy-Five Boxes of Alleged Pepper*, 198 F. at 934 (focusing on consumer perspective); *One Hundred and Fifty Cases of Fruit Puddine*, 211 F. at 360 (weighing consumer perspective in determination); *Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. at 438 (holding packaging can be misleading even if technically true).

[30] *See* Gerhart, *supra* note 24. *See generally* United States v. Am. Druggists' Syndicate, 186 F. at 387 (holding advertisement contained within product not in scope of 1906 Act); *Johnson*, 221 U.S. at 488 (limiting scope of 1906 Act to statements about product identity); *Hall-Baker Grain Co.*, 198 F. 614, 618 (holding seller intent as necessary to find misbranding).

[31] *See* Ballentine, *supra* note 6 (describing Elixir Sulfanilamide incident's harrowing effect on those involved). The tragedy was a direct result of unregulated dissemination of drugs containing chemicals not tested for safety. *Id.* The company that created the drug only tested for appearance, flavor, and fragrance before sending shipments for sale all over the country. *Id.* At the time, no law prohibited the sale of dangerous or untested drugs, so the FDA brought the charge of misbranding against the producer. *Id.* If the company had called their drug a "solution" instead of an "elixir" no charge would have been possible. Ballentine, *supra* note 6.

President Franklin D. Roosevelt enacted the Federal Food, Drug, and Cosmetic Act of 1938 (hereinafter *FDCA*) the following year, which, with some major amendments, contains the basic law of the land today.[32] The FDCA's prohibition of misbranding and food adulteration is consistent with the 1906 Act.[33] Under the FDCA, the FDA's authority is expanded and misbranding is expressly prohibited.[34] Misbranding includes both false claims and misleading claims.[35]

While the FDA publicly advocated for strict enforcement of the FDCA, it was clear by the 1990's that the FDA lacked enforcement policies.[36] In response to criticism, Congress enacted the Nutrition and Labeling Education Act (hereinafter *NLEA*) in 1990, requiring all packaged foods to bear a standard nutrition label.[37] Despite new nutrition

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Without the misbranding charge, the FDA would have had no authority to ensure the recovery of the drug. *Id.; see also* Kondratas, *supra* note 4 (noting tragedy dramatized need for more legislation to ensure product safety).

[32] *See* Ballentine, *supra* note 6; Kondratas, *supra* note 4; Gerhart, *supra* note 24 (emphasizing high standard of consumer protection pursued by FDA under FDCA); Moore, *supra* note 1. "The Act's requirements became the standard for food labeling regulation, and even most current food labeling statutes have done little to exceed the regulatory scope of the 1938 Act." *Id.* at 22. The FDCA was far more comprehensive than the 1906 Act and expanded the authority of the FDA. *Id. See generally* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399 (describing current FDA authority).

[33] *See* Gerhart, *supra* note 24. "The FDCA as enacted, in terms of misbranding, is almost the same today as in 1938." *Id.*; Food and Drugs Act of 1906, ch. 3915, § 403(a), 34 Stat. 768 § 403(a). "A food shall be deemed to be misbranded if its labeling is false or misleading in any particular." *Id.*; Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(b). "The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce." *Id. See also* Moore, *supra* note 1, at 22. "It is designed to apply to all misrepresentations of whatever kind, whether of origin, identity, quality, effect, or other description or property; whether made as averments of fact or statements of opinion; whether conveyed directly, or by implication." *Id.*

[34] *See* Gerhart, *supra* note 24. "Specifically, in regards to labeling, the 1938 Act removed the burden from the FDA of proving knowledge or intent in misbranding cases." *Id. Compare* Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, (describing FDA authority on regulation of misbranding and adulteration pre-FDCA), *with* 21 U.S.C. §§ 301-399 (prescribing current FDA authority to regulate misbranding and adulteration). *See generally* Moore, *supra* note 1, at 21-24 (describing comprehensive nature of FDCA).

[35] *See* Gerhart, *supra* note 24; *see also* V.E. Irons, Inc. v. United States, 244 F.2d 34, 42 (1st Cir. 1957) (citing Congressional intent for FDCA to include false and misleading claims). "Bearing in mind the broadly remedial purposes of the Act in preventing deception, the Congress must be taken to have meant to strike not only at palpably false claims but also at clever indirection and ambiguity in the creation of misleading impressions." *Id.* The courts still play a role in interpreting the FDCA in its application to determine whether a label should be considered misbranded or misleading. *See generally id.* If a claim is ambiguous, it may still be misleading even if it is not blatantly false. *Id.* at 42.

[36] *See* Gerhart, *supra* note 24. Food producers began to ignore threats of seizure from the FDA because the most common response to the violations were sending regulatory letters, rather than implementing enforcement actions. *Id.* Furthermore, advances in food science and technology, paired with evolving consumer interests in healthy and diet-oriented foods made it increasingly difficult for the FDA to define adulterated foods and enforce misbranded labeling. *Id.*

[37] *See* Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 301 (1990) (requiring nutrition information on back of food labels); *see also* Gerhart, *supra* note 24. The NLEA created stricter regulations for nutrient content claims and a uniform label format for nutrition labeling. Gerhart*, supra* note 24. The goal of Congress was to promote accurate information to provide

label requirements, food producers used front-of-package labels to make claims inconsistent with nutrition labels.[38]

C. FTC History

Working in conjunction with the FDA's mission to protect consumers, the FTC's mission is protecting the public from deceptive or unfair business practices.[39] In 1914, Congress created the FTC to prevent unfair competition methods in commerce, thus scrutinizing monopolies of the time more extensively.[40] The Supreme Court later clarified that FTC authority was limited in scope to the protection of competition, not consumers.[41] Following this clarification, FTC authority was limited to circumstances where harm to a competitor could be shown to have resulted from an offending practice.[42] Congress expanded the powers of the FTC in 1938 to include regulating unfair and

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consumers the chance to make more informed decisions. *Id.*; Moore, *supra* note 1, at 26. All foods other than raw produce are subject to the regulations. *Id. See generally Nutrition Labeling and Education Act (NLEA) Requirements – Attachment 1*, U.S. FOOD & DRUG ADMIN. (Nov. 24, 2014), https://www.fda.gov/nutrition-labeling-and-education-act-nlea-requirements-attachment-1 [https://perma.cc/44ZR-Q2TP] (outlining required formatting and definitions for nutrient content claims).

[38] *See Food Marketing and Labeling*, JOHNS HOPKINS CTR. FOR A LIVABLE FUTURE, https://www.foodsystemprimer.org/food-and-nutrition/food-marketing-and-labeling/ [https://perma.cc/GZX5-YWK4]. "Studies suggest shoppers frequently trust front-of-package claims instead of reading the Nutrition Facts panel." *Id.* Food producers often make front-of-package claims that are misleading when taken with the information on the Nutrition Label by highlighting a very narrow health claim of an otherwise unhealthy product. *Id.* For example, the front packaging may promote a product as being "antioxidant rich" while the back nutrition label reveals an overall unhealthy product. *Id.*

[39] *See* Judith A. McMeekin, *Foreword 2022*, U.S. FOOD & DRUG ADMIN. (2022), https://www.fda.gov/media/83196/download#:~:text=Protect%20consumers%2Fpatients%20and%20enhance,%2C%20quality%20FDA%2Dregulated%20products [https://perma.cc/2YRH-6GBM]. "Protect consumers/patients and enhance public health by ensuring timely access to safe, quality FDA-regulated products." *Id.*; *Mission*, FED. TRADE COMM'N., https://www.ftc.gov/about-ftc/mission [https://perma.cc/U5HU-JL2W]. "The FTC's mission is protecting the public from deceptive or unfair business practices and from unfair methods of competition through law enforcement, advocacy, research, and education." *Id.*

[40] *See generally* Marc Winerman, *The Origins of the FTC: Concentration, Cooperation, Control, and Competition*, 71 ANTITRUST L. J. 1, 2 (2003) (describing arduous process of garnering necessary support for creation of FTC). Confronted with an unprecedent explosion of business in the late 19th and early 20th century, President Woodrow Wilson dedicated much of his political career advocating for the regulation of monopolies and anti-competitive business practices, culminating with the signing of the Federal Trade Commission Act. *Id.*

[41] *See* Gerhart, *supra* note 24. The FTC could protect consumers only by indirect means of protecting competitive business practices, which was seen as good for consumers. *Id.* Interpretation of FTC authority and practices was generally left up to case law. *Id.*; F.T.C. v. Raladam Co., 283 U.S. 643, 654 (1931) (holding existence of competition as necessary to support FTC jurisdiction). The court went on to clarify that the FTC could not assume the existence of competition to give itself jurisdiction but must prove the existence of competition to survive a jurisdictional inquiry. *Id.*

[42] *See* Gerhart, *supra* note 24. *See generally Raladam Co.*, 283 U.S. at 643 (lacking evidence of competitor harm led to dismissal for lack of jurisdiction). "None of the supposed competitors appeared or was called upon to show what, if any, effect the misleading advertisements had, or were likely to have, upon his business." *Id.* at 653.

deceptive acts and practices in commerce.[43] As a result, the FTC may now protect competition practices along with the interests of consumers.[44]

Despite expanded power, the FTC focuses on primarily on deceptive advertising and not food labels.[45] The Fair Packaging and Labeling Act of 1967 granted the FTC authority to regulate deceptive food labels, thus creating concurrent jurisdiction with the FDA.[46] However, the FTC has declined to exercise authority over misleading food labels and has explicitly left enforcement to the FDA.[47]

III. Facts

A. Current Regulations

The FDA and FTC have a longstanding Memorandum of Understanding between the agencies regarding food advertising practices.[48] The FDA exercises

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[43] *See* Gerhart, *supra* note 24. Under the amendment, false advertising, in connection with the sale and purchase of food and drugs was defined as an unfair or deceptive practice within the prohibition of the FTC Act. *Id.*

[44] *See* Gerhart, *supra* note 24. Whereas before the amendment, the FTC could only protect consumer interests indirectly through the regulation of competition, the FTC can now protect consumers more directly by regulating "unfair or deceptive acts or practices." *Id.*; *Mission*, *supra* note 39 (emphasizing protection of public interest).

[45] *See* Gerhart, *supra* note 24. The Second Circuit has specifically ruled that the regulation of food labels falls within the scope of FTC authority and not exclusively with the FDA. *Id.*; *see also* Fresh Grown Preserve Corp. v. F.T.C., 125 F.2d 917, 919 (1st Cir. 1942) (finding FTC authority over claims stemming solely from food label violations).

[46] *See Fair Packaging and Labeling Act: Regulations Under Section 4 of the Fair Packaging and Labeling Act*, FED. TRADE COMM'N., https://www.ftc.gov/legal-library/browse/rules/fair-packaging-labeling-act-regulations-under-section-4-fair-packaging-labeling-act [https://perma.cc/2TH2-SN3G] [hereinafter *Fair Packaging and Labeling Act*] (authorizing FDA and FTC to enact labeling regulations to prevent consumer deception). The FDA administers the FPLA with respect to food, drugs, cosmetics and medical devices and the FTC with respect to other consumer commodities. *Id.*; Gerhart, *supra* note 24. Labeling is defined as writing, prints or graphics upon any article, container, or wrapper seen to accompany such article, and advertising is seen as everything else. *Id.*

[47] *See Fair Packaging and Labeling Act, supra* note 46*;* Gerhart, *supra* note 24. Due to an overlap in jurisdiction, the two agencies have been operating under a Memorandum of Understanding since. *Id.*

[48] *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration*, FED. TRADE COMM'N (May 1971), https://www.ftc.gov/legal-library/browse/cooperation-agreements/memorandum-understanding-between-federal-trade-commission-food-drug-administration [https://perma.cc/JN3G-M9QW] (describing online material with print characteristics); Nicole E. Negowetti*, Food Labeling Litigation: Exposing Gaps in the FDA's Resources and Regulatory Authority,* BROOKINGS (2014), https://www.brookings.edu/wp-content/uploads/2016/06/Negowetti_Food-Labeling-Litigation.pdf [https://perma.cc/HB25-DBUR]. The FDA is allocated authority over food labels, whereas the FTC is allocated authority over general food advertising. *Id.* at 1; Kathryn B. Armstrong & Jennifer A. Staman, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues,* CONG. RSCH. SERV. (Feb. 9, 2018), https://sgp.fas.org/crs/misc/R43609.pdf [https://perma.cc/T7F2-XPJX] (acknowledging concurrent FTC and FDA jurisdiction and need for Memorandum of Understanding); Gerhart, *supra* note 24 (referencing Memorandum of Understanding). The memorandum is an informal

responsibility for regulating labels on the physical food packaging, while the FTC takes responsibility for other aspects of food product advertisement.[49] The FDCA expressly prohibits the misbranding of food and prohibits labeling that is "false or misleading in any particular."[50] The FDA considers a "false and misleading" label as one that fails to reveal material facts in light of the representations made, or a term that characterizes the level of nutrients in a food not already defined by the FDA.[51] The FDA has formally defined many foods and certain nutrient content terms, like "healthy," to provide guidance for producers.[52] Other terms, like "natural" and "whole grain" have no official definition.[53]

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allocation meant to reduce duplicative regulation and conserve agency resources by eliminating confusion. *Id.*; *see also Fair Packaging and Labeling Act, supra* note 46.

[49] *See* Negowetti, *supra* note 48, at 3. "Under this agreement, the FDA exercises primary responsibility for regulating food labeling, while the FTC assumes primary responsibility for ensuring that advertising of food products is truthful and not misleading." *Id. See also* Armstrong, *supra* note 48, at 5 (describing allocation of authority over certain FDCA regulated products); Gerhart, *supra* note 24.

[50] *See* 21 U.S.C. § 343(a); Negowetti, *supra* note 48, at 3; Gerhart, *supra* note 24; Moore, *supra* note 1, at 22.

[51] *See* Food Labeling: Nutrient Content Claims; Definition of the Term "Healthy," Fed. Reg. (proposed Sept. 29, 2022) (to be codified at 21 C.F.R. pt. 101) https://www.federalregister.gov/documents/2022/09/29/2022-20975/food-labeling-nutrient-content-claims-definition-of-term-healthy [https://perma.cc/VU3T-KACN] (proposing updated definition for claim "healthy" consistent with FDA regulatory authority under FDCA). The FDA was seeking public input for the purpose of updating the definition the term "healthy" as it is used as a health claim on food packaging and identified its authority to define such a term as stemming from explicit FDA authority to adopt regulations that prohibit misleading labeling. *Id.* An updated definition has yet to be released as of the date of this publication. *Id.; see also* 21 U.S.C. §§ 201(n), 403(a), 403(r), 701(a) (authorizing FDA to adopt regulations regarding misleading labeling and nutrient specific terms); Armstrong, *supra* note 48, at 2-3 (elaborating on definitions of "adulteration" and "misbranding" under FDCA).

[52] *See* Negowetti, *supra* note 48, at 5. "A nutrient content claim, which is the claim most frequently used on food products, directly or implicitly characterizes the level of a nutrient in the food, using terms such as, 'low,' 'high,' 'free,' 'reduced,' or 'light.'" *Id. See also Food Labeling: Nutrient Content Claims; Definition of the Term "Healthy", supra* note 51 (attempting to update the term "healthy"). Public and scientific definitions of terms like "healthy" change over time, prompting the FDA to periodically seek public input regarding the definitions of specific terms. *Id. See generally* 21 C.F.R. §§ 101.54-101.95 (outlining specific requirements for nutrient content, health, and descriptive claims on food packaging); *Standards of Identity for Food*, U.S. FOOD & DRUG ADMIN., (Dec. 14, 2022), https://www.fda.gov/food/food-labeling-nutrition/standards-identity-food [https://perma.cc/X5EG-HHXN] (describing FDA regulation of standards of identity for certain foods). The FDA prescribes standards of identity for more than 250 products, including milk, bread, ketchup, and peanut butter. *Id.* Standards of identity outline what certain products must contain to meet their respective definitions, along with descriptions of ingredient proportions and methods of production. *Id.*

[53] *See* Caldwell, *supra* note 7 (describing lack of legal definitions for certain terms as source of current legal disputes); *Use of the Term Natural on Food Labeling,* ,U.S. FOOD & DRUG ADMIN., (Oct. 22, 2018), https://www.fda.gov/food/food-labeling-nutrition/use-term-natural-food-labeling [https://perma.cc/RDN4-928D] (acknowledging public desire for FDA to establish definition for term "natural" on food labels). The FDA has acknowledged several Citizen Petitions and requests from the Federal courts for a formal definition of the term "natural," but no such definition has materialized. *Id.* "Although the FDA has not engaged in rulemaking to establish a formal definition for the term 'natural,' we do have a longstanding policy concerning the use of 'natural' in human food labeling." *Id. See generally Draft Guidance for Industry and FDA*

B. Identifying Violations and Warning Letters

The FDA does not require any review of food labels before they go to market.[54] Instead, the FDA relies on voluntary compliance and tips from consumers and product competitors to identify violations.[55] When the FDA identifies a violation, the agency may issue a Warning Letter to notify the manufacturer and encourage voluntary compliance.[56] Warning Letters are not enforcement actions and do not commit the FDA to taking further action.[57] Furthermore, the FDA does not have independent litigating authority;

Staff: Whole Grain Label Statements, U.S. FOOD & DRUG ADMIN. (Feb. 2006), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-and-fda-staff-whole-grain-label-statements [https://perma.cc/SE4J-W2TT] (establishing FDA thinking regarding the use of "whole grain" on food labels). "The FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities." *Id.* Draft guidance is meant to provide industry guidance on what the FDA would consider a proper use of certain commonly used food terms but does not establish legally binding definitions. *Id.*

[54] *See Guidance for Industry: Food Labeling Guide*, U.S. FOOD & DRUG ADMIN., (Sept. 16, 2018), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-food-labeling-guide [https://perma.cc/96FQ-42L3YJ7F-LMWP]. "Under FDA's laws and regulations, FDA does not pre-approve labels for food products." *Id.*; Negowetti, *supra* note 48, at 9 (quoting FDA commissioner speaking on enforcement challenges because of lack of pre-market approval process). *See also* James Kincheloe, *Weekly Topic: Editorial - Misleading Food Labeling*, UNIV. OF MINN., (Aug. 2, 2018) https://cahfs.umn.edu/news/weekly-topic-editorial-misleading-food-labeling [https://perma.cc/U2VQ-DCMC]. "Unlike the USDA, which reviews all labels before allowing them to be published, the FDA is structured on voluntary compliance." *Id.*; Patrick Meyer, *The Crazy Maze of Food Labeling and Food Claim Laws*, 92 ST. JOHN'S L. REV. 233, 239 (2018). The FDA relies on spot-checking for violations rather than a pre-market approval process. *Id.*

[55] *See* Meyer, *supra* note 54, at 239. "The FDA also does not pre-approve food labels for nutritional content accuracy. Instead, the FDA spot checks manufacturers after consumer complaints are lodged." *Id. See also* Kincheloe, *supra* note 54; Negowetti, *supra* note 48, at 9.

[56] *See* Negowetti, *supra* note 48, at 3. "When the FDA determines that a manufacturer has violated a labeling regulation, the agency's principal enforcement tool is to issue a Warning Letter to notify the manufacturer." *Id.* Warning Letters are used in an attempt to achieve voluntary compliance and to establish proof of manufacturer notice of the violation should the agency pursue further action. *Id. See also* Kincheloe, *supra* note 54. When there is a violation that does not present a public safety concern, the FDA can only issue a Warning Letter. *Id.;* Armstrong & Staman, *supra* note 48, at 9-10. Warning Letters are used to request corrective action from violators with the expectation that most recipients will choose to voluntarily comply with the law. *Id. See generally Understanding Front-of-Package Violations: Why Warning Letters Are Sent to Industry,* U.S. FOOD & DRUG ADMIN., (Jul. 15, 2014), http://wayback.archiveit.org/7993/20170406011341/https://www.fda.gov/Food/ComplianceEnforcement/WarningLetters/ucm202784.htm [https://perma.cc/U6CF-YKU4] (archiving reasons behind issuance of FDA Warning Letters).

[57] *See* Joshua Kipnees, *How Much Is Too Much Deference to FDA Warning Letters in Consumer Class Actions?,* MISBRANDED (Jun. 3, 2019), https://www.pbwt.com/misbranded/how-much-is-too-much-deference-to-fda-warning-letters-in-consumer-class-actions [https://perma.cc/69L3-5JYL]. "The FDA may ultimately take no further action, even if the manufacturer's response to the warning letter is deficient; in fact, according to a 2013 analysis of the FDA's enforcement activity, warning letters rarely precipitate further action on the FDA's part." *Id. See also* Negowetti, *supra* note 48, at 3 (describing Warning Letters as a voluntary compliance

thus it must coordinate with the Department of Justice (hereinafter *DOJ*) when pursuing a violation further.[58]

C. FDA & DOJ – Civil and Criminal Enforcement

Generally, the FDA does not seek enforcement action beyond issuing a Warning Letter unless the FDA believes that the misbranded article presents a threat to consumer safety.[59] When the FDA seeks formal enforcement action, it must coordinate with the DOJ to institute injunctions, seizures, civil penalties, or criminal prosecutions.[60] The FDA may only recall a food product if significant consumer safety issues are discovered.[61] Alternatively, an injunction can be imposed to stem the flow of non-complying goods into the marketplace, allowing companies a chance to correct the violation.[62] Criminal prosecutions for violations of the FDCA are infrequent because the FDA usually allows companies an opportunity to voluntarily comply before initiating a prosecution.[63] Furthermore, the FDA primarily issues Warning Letters for deceptive food packaging violations because the standard for pursuing formal enforcement action is high, and requires cooperation with the DOJ and ongoing threat to consumer safety.[64]

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mechanism); Armstrong & Staman, *supra* note 48, at 10. The FDA has maintained that Warning Letters are informal and advisory in nature and do not constitute "final agency action." *Id.*

[58] *See* Armstrong & Staman, *supra* note 48, at 4 (describing FDA and DOJ coordination in pursuit of criminal and civil remedies for violations).

[59] *See* Kipnees, *supra* note 57; Negowetti, *supra* note 48, at 4. Enforcement actions like injunctions and criminal prosecutions are seldom used for purely misleading food labels because the FDCA provides that such enforcement actions should not be initiated for violations that do not pose a threat to public health or safety. *Id.*; Negowetti, *supra* note 48, at 4. The FDA relies primarily on voluntary compliance from food companies when products are purely misleading. *Id.*; Kincheloe, *supra* note 54. "Mindbogglingly, the FDA as structured has no ability to leverage fines or recall food products for false claims that companies put out, only for food safety issues." *Id.*

[60] *See* Kipnees, *supra* note 57 (identifying Warning Letters as primary enforcement tool); Negowetti, *supra* note 48, at 4 (noting inadequacy of enforcement authority by the FDA).

[61] *See* Armstrong, *supra* note 48, at 12. "FDA can *request* a recall when it determines that a regulated product in distribution presents a 'risk of illness, injury, or gross consumer deception' that necessitates agency action to protect public health." *Id.*

[62] *See* Armstrong, *supra* note 48, at 16. "According to FDA guidance, an injunction 'may be considered for any significant out-of-compliance circumstance, but particularly when a health hazard has been identified.'" *Id.* The FDA will choose to issue an injunction when there is either (1) an imminent and definitive health hazard, or gross consumer deception and seizure is also impractical, (2) a voluntary recall was refused or insufficient for public protection and seizure of the product is considered impractical, or (3) practices that have not caused a public health hazard or consumer fraud have been long standing and have not been corrected through a voluntary approach. *Id.* *See also* Negowetti, *supra* note 48 (describing FDA injunction procedures).

[63] *See* Negowetti, *supra* note 48 (describing the FDA as relying primarily on voluntary compliance); *see also* Armstrong, *supra* note 48, at 17 (outlining FDA criminal enforcement procedures). To impose a criminal conviction under the FDCA, there are three required elements that must be proven: (1) the article in violation must fall under the scope of the FDCA, (2) the article must be considered adulterated or misbranded, (3) the article must have been introduced to interstate commerce. *Id.* Notably, the FDCA does not include a mens rea requirement and defendants are instead held to a strict liability standard, meaning no proof of intent is required. *Id.*

[64] *See* Armstrong, *supra* note 48 (outlining FDA enforcement procedures); Negowetti, *supra* note 48; Kincheloe, *supra* note 54 (describing Warning Letter as only compliance tool absent risk to public health).

D. FDA Discretion

The Supreme Court has consistently held that the FDA has "absolute discretion" in deciding whether to enforce FDCA violations.[65] The FDA has used its discretion to issue Warning Letters almost exclusively for violations involving nutritional and health claims.[66] The focus on nutrition specific violations leaves a gap in misleading food packaging enforcement that marketing teams have taken advantage of.[67] More than ever, consumers are looking for a higher standard of transparency regarding the ingredients of processed foods.[68]

E. Exclusive Enforcement and Consumer Protection Statutes

Unfortunately for consumers seeking enforcement action for violations of FDCA label regulations, the FDCA contains an exclusive enforcement provision, prohibiting a private right of action.[69] Furthermore, in accordance with the Supremacy Clause of the

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[65] *See* Armstrong, *supra* note 48 (noting FDA discretion regarding pursuit of enforcement procedures); Heckler v. Chaney, 470 U.S. 821, 831 (1985) (holding FDA has absolute discretion over pursuit of enforcement). "This Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Id.* at 831.

[66] *See* Negowetti, *supra* note 48. *See generally* Armstrong, *supra* note 48 (outlining FDA enforcement standards and procedures); *Attorney General Says FDA Will Be Powerful Enforcement Partner In Fighting False Food Labels,* CONN. ATT'Y GEN. OFF. (Oct. 20, 2009), https://portal.ct.gov/AG/Press-Releases-Archived/2009-Press-Releases/Attorney-General-Says-FDA-Will-Be-Powerful-Enforcement-Partner-In-Fighting-False-Food-Labels [https://perma.cc/TAF3-UASS]; *Front-of-Package Labeling Initiative,* U.S. FOOD & DRUG ADMIN. (Oct. 20, 2015), http://wayback.archive-it.org/7993/20170404162741/https://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202726.htm [https://perma.cc/T8JQ-TX35].

[67] *See* Negowetti, *supra* note 48, at 9. The FDA has publicly acknowledged the futility of pursuing every purely misleading food label claim because of their resource restraints and the sheer magnitude of existing marketing claims. *Id. See also* Kincheloe, *supra* note 54; Pierre Chandon, *Food Packaging Claims Mislead Consumers With Ideas of Health,* EUREKALERT! AAAS (Apr. 29, 2019), https://www.eurekalert.org/news-releases/905548 [https://perma.cc/U8GQ-B5Y3] (providing examples of marketing deception practices).

[68] *See* Negowetti, *supra* note 48. "Although the Food and Drug Administration (FDA) is charged with regulating food labeling, plaintiffs' attorneys are seeking to fill a void in the FDA's regulatory authority and enforcement of food labeling laws." *Id.*; Jacobs, *supra* note 7 (noting the need for systematic change in food label regulation); Cary Silverman & James Muehlberger, *The Food Court: Trends in Food and Beverage Class Action Litigation,* INST. FOR LEGAL REFORM, (Feb. 2017), https://instituteforlegalreform.com/wp-content/uploads/2020/10/TheFoodCourtPaper_Pages.pdf [https://perma.cc/V8VA-MDAC]; Richard Dahl, *Food Companies Face Heightened Scrutiny Over Labels*, FINDLAW (Oct. 27, 2021), https://www.findlaw.com/legalblogs/courtside/food-companies-face-heightened-scrutiny-over-labels/ [https://perma.cc/BM3S-VBD8]; Robert Guite, et al., *Food & Beverage Industry's 2022 Litigation Outlook,* FOOD MANUFACTURING (Jan. 5, 2022), https://www.foodmanufacturing.com/labeling/article/21977542/food-beverage-industrys-2022-litigation-outlook [https://perma.cc/GR53-SK6M]; Zabriskie*, supra* note 7.

[69] *See* Christopher Fitzgerald, *Increased Litigation Regarding Food and Beverage Product Labeling Creates Risk for Manufacturers,* JDSUPRA, (June 7, 2022), https://www.jdsupra.com/legalnews/increased-litigation-regarding-food-and-2164638/ [https://perma.cc/5EXW-RHQ6]; Negowetti, *supra* note

US Constitution, state laws are invalid when they contradict federal statutes.[70] Private consumers may take action against a company for misleading food packaging by relying on a state's consumer protection statute, if it has one.[71] As a result, certain jurisdictions have become especially popular for food label litigation, usually in the form of a class action suit.[72]

F. Food Litigation Trends

Misleading food label litigation has been rising for the better part of two decades, coinciding with a decline in FDA oversight.[73] Recent claims have focused on the presence

48, at 10 (noting lack of private right of action under FDCA). Neither the FDCA, nor the FCT Act provide a private right of action for consumers to privately enforce regulations. *Id.* Private litigants may not bring a cause of action that relies solely on the violation of the FTC Act or FDCA regulations. *Id. See also* Celia Choy, *FDCA's Exclusive Enforcement Provision Reigns Supreme Over State Laws,* LAW.COM, (Oct. 28, 2022), https://onpractice.law.com/4057521/fdcas-exclusive-enforcement-provision-reigns-supreme-laws [https://perma.cc/B7FQ-VK3U] (explaining preemption regarding FDCA enforcement and state laws).

[70] *See Supremacy Clause,* CORNELL L. SCH., (June 2017), https://www.law.cornell.edu/wex/supremacy_clause#:~:text=Article%20VI%2C%20Paragraph%202%20of,laws%2C%20and%20even%20state%20constitutions [https://perma.cc/4FNT-QSMK]. "Article VI, Paragraph 2 of the U.S. Constitution is commonly referred to as the Supremacy Clause. It establishes that the federal constitution, and federal law generally, take precedence over state laws, and even state constitutions." *Id.*

[71] *See* Fitzgerald, *supra* note 69, at 1. The First Circuit and Massachusetts federal courts suggests that plaintiffs utilize state law to bypass FDCA preemption provision. *Id.*; Negowetti, *supra* note 48, at 11. "[S]tates may permit causes of action based on violations of state laws that mirror the federal requirements." *Id.* "Therefore, the food labeling lawsuits have been predicated upon violations of state statutes on false advertising, unfair trade practices, consumer protection, fraud, and breach of warranty." *Id.*

[72] *See* Cary Silverman & James Muehlberger*, supra* note 68; Guite, *supra* note 68; Zabriskie*, supra* note 7.

[73] *See* Negowetti, *supra* note 48, at 1 (discussing reason for rise in consumer litigation over misleading food labels). Plaintiffs' have filed over 150 food labeling class action lawsuits against food and beverage producers since 2011. *Id.* These class actions have grown exponentially from 2008 to 2012, from 19 cases to more than 102 respectively. *Id.* "As claims on food labels were used more frequently, the FDA's oversight of claims was declining." *Id.* at 7. *See also* Fitzgerald, *supra* note 69. "According to one report, as of November 2021, class-action lawsuits against food and beverage manufacturers had increased by over one thousand percent since 2008." *Id.;* Jacobs, *supra* note 7 (talking about recent rise in food label litigation); Charles Piller, *Exclusive: FDA Enforcement Actions Plummet Under Trump,* AM. ASS'N FOR THE ADV. OF SCI. (July 2, 2019), https://www.science.org/content/article/exclusive-fda-enforcement-actions-plummet-under-trump [https://perma.cc/NWA6-C8BG]. "The agency's 'warning letters'—a key tool for keeping dangerous or ineffective drugs and devices and tainted foods off the market—have fallen by one-third, for example." *Id.;* Jennifer L. Bragg, et al., *Will FDA and DOJ Reassert Their Enforcement Muscle With Life Sciences in 2022?,* SKADDEN, ARPS, SLATE, MEAGHER & FOLM LLP AND AFFILIATES (Jan. 19, 2022), https://www.skadden.com/insights/publications/2022/01/2022-insights/regulation-enforcement-and-investigations/will-fda-and-doj-reassert-their-enforcement-muscle [https://perma.cc/PY53-G5C6]. Overall FDA inspection and enforcement activity dropped from 2020-2021, with the FDA issuing 56% fewer warning letters, bringing 60% fewer injunctions, and imposing 27% fewer product recalls. *Id.* Notably, the numbers indicate a drop from the year 2020, which itself was a significantly low year due to the COVID-19 pandemic. *Id.;*

or omission of specific ingredients, source of origin representation, implied health benefits, and representations of sustainable or ethical production practices.[74] Many of the claims end up dismissed or settled, and the settlements can be sizable.[75] Although there is not a determinative legal standard for misleading food labels, courts have generally upheld a "reasonable consumer" standard.[76] Experts question whether these class action lawsuits are the appropriate avenue to enforce consumer protection.[77] Many believe that Congress should grant the FDA more resources to implement the protection that consumers are seeking via litigation.[78]

G. Proposed Legislation

Lawmakers have recognized the need for more stringent regulations to address concerns of the public and confusion of food producers over food packaging standards.[79]

Silverman & Muehlberger, *supra* note 68; Guite, *supra* note 68; Zabriskie*, supra* note 7; Dahl, *supra* note 68.

[74] *See* Guite, *supra* note 68. *See generally* Cary Silverman & James Muehlberger*, supra* note 68 (outlining recent food litigation trends); Negowetti, *supra* note 48 (examining reasons for recent rise in food litigation).

[75] *See* Guite, *supra* note 68. Class settlements can be extremely costly as evidenced by a recent $2.6 million payout by Blue Diamond to resolve claims involving vanilla flavoring in its almond milk and yogurt products. *Id.* A $13 million settlement by Kellogg focused on a claim that the company falsely advertises its cereals as healthy when they contain sugar. *Id.* Similarly, Post Foods settled a claim for $15 million and further agreed to stop depicting certain products as "healthy" if more than 10% of the advertised product's calories are derived from sugar. *Id.* More recently, Whole Foods was granted a motion to dismiss in an action claiming that the representations of "low fat" and "organic" misleads consumers to think that its oatmeal product does not contain sugar. *Id.*

[76] *See* Fitzgerald, *supra* note 69; *see also* Dahl, *supra* note 68 (providing examples of courts using "reasonable consumer" standard); Cary Silverman & James Muehlberger*, supra* note 68, at 32 (describing court implementation of "reasonable consumer" standard); Guite, *supra* note 68 (providing examples of courts using "reasonable consumer" standard). Courts are consistently applying a "reasonable consumer" standard to claims involving misleading food labels. *Id.* In the application of a "reasonable consumer" standard, cases are likely to be dismissed when an individual plaintiff has atypical, subjective expectations. *Id.* For example, a recent case was dismissed upon the plaintiff's unreasonable expectation that an "All Butter Loaf Cake" would contain only butter as an ingredient. *Id. See generally* Meyer at 235, *supra* note 54 (noting confusion surrounding label claim standards). "Having varying rules and term definitions makes for conflicting laws and consumer confusion." *Id.* at 235.

[77] *See generally* Cary Silverman & James Muehlberger*, supra* note 68 (arguing current food litigation trends have gotten out of control); Caldwell, *supra* note 7 (questioning efficacy of regulation through litigation).

[78] *See* Kincheloe, *supra* note 54; Negowetti, *supra* note 48; Caldwell, *supra* note 7.

[79] *See* Letter from Cory A. Booker, U.S. Sen., to Susan Rice, Dir. of Dom. Pol'y Council (Aug. 31, 2022), https://www.booker.senate.gov/imo/media/doc/letter_highlighting_sen_bookers_priorities_for_white_house_conference_on_hunger_nutrition_and_health.pdf [https://perma.cc/L3QJ-PS9L] (supporting federal reforms regarding food and health); Zoe Richards, *Biden Admin to Propose Nutrition Labels on Front of Food Packaging in Push to Improve Health*, NBC NEWS (Sept. 27, 2022), https://www.nbcnews.com/politics/white-house/biden-administration-propose-nutrition-labels-front-food-packaging-pus-rcna49529 [https://perma.cc/H57X-Y24J]. However, industry interests and powerful lobbying tend to affect lawmaker decision-making. *Id.*; *Industry Profile: Food & Beverage*, OPEN SECRETS (Oct. 24, 2022), https://www.opensecrets.org/federal-

The Food Labeling Modernization Act of 2021 (hereinafter *2021 Bill*) was introduced to Congress in August 2021 to address some of these concerns.[80] The 2021 Bill proposes to amend the FDCA and create new requirements for nutrition food labels.[81] As a result, the FDA would be directed to define certain terms that were previously left in ambiguity.[82] The most noticeable change would require the relocation of the nutrition facts panel to the "principal display panel," or front, of packaging.[83]

IV. Analysis

A. Problems with Proposed Legislation

Although some lawmakers hope that the 2021 Bill will become law, many remain skeptical of its viability.[84] Previous versions of the 2021 Bill have been unsuccessful because some lawmakers are reluctant to impose additional regulations on food producers.[85] The robust lobbying of large, processed food producers contributed more

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lobbying/industries/summary?cycle=2022&id=N01 [https://perma.cc/ZC54-Q7QV]. *See also* Lawrence O. Gostin, *"Big Food" Is Making America Sick*, NAT'L LIBR. MED. (Sept. 13, 2016), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5020160/ [https://perma.cc/Y5ZY-E9QN].

[80] *See* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to the Senate, Aug. 3, 2021); *see also* Jessica L. Griswold, *U.S. Lawmakers Introduce the Food Labeling Modernization Act of 2021 in the House and Senate: Can the Industry Adjust to a New Natural?*, DOWNS, RACHLIN, MARTIN (Aug. 3, 2021), https://www.drm.com/resources/fblb/u-s-lawmakers-introduce-the-food-labeling-modernization-act-of-2021-in-the-house-and-senate-can-the-industry-adjust-to-a-new-natural/ [https://perma.cc/D6C8-CFWZ] (describing contents of 2021 Bill); *see also The Food Labeling Modernization Act Introduced in Congress (Again)*, COVINGTON (Aug. 6, 2021), https://www.cov.com/en/news-and-insights/insights/2021/08/the-food-labeling-modernization-act-introduced-in-congress-again [https://perma.cc/9GDR-QJU7] (describing what lawmakers are hoping to accomplish with the 2021 Bill).

[81] *See* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to Senate, Aug. 3, 2021); Richards, *supra* note 79; Kathleen M. Sanzo & Maria Kalousi-Tatum, *Food Labeling Modernization Act Reintroduced in Congress*, MORGAN LEWIS (Sept. 14, 2021), https://www.morganlewis.com/blogs/welldone/2021/09/food-labeling-modernization-act-reintroduced-in-congress [https://perma.cc/74SM-WL5B].

[82] *See* Richards, *supra* note 79; Sanzo, *supra* note 81. *See generally* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to the Senate, Aug. 3, 2021).

[83] *See* Richards, *supra* note 79; Sanzo, *supra* note 81. *See generally* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to Senate, Aug. 3, 2021).

[84] *See* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to Senate, Aug. 3, 2021); *see also Food Labeling Modernization Act Reintroduced in Congress*, *supra* note 81 (remarking on failure of previous versions of 2021 Bill); Jacobs, *supra* note 7 (describing industry opposition as likely to complicate passage of the 2021 Bill); COVINGTON, *supra* note 80 (expressing doubt regarding 2021 Bill's passage and whether FDA would prioritize enforcement). *See generally Industry Profile: Food & Beverage*, *supra* note 79 (demonstrating prevalence of food industry lobbying in politics).

[85] *See* Kathleen M. Sanzo & Maria Kalousi-Tatum, *supra* note 81. "If passed, the 2021 Bill would require significant changes to most food labels, imposing significant requirements on both FDA and food manufacturers/importers." *Id. See also* COVINGTON, *supra* note 80 (describing significant changes to food labels should 2021 Bill pass). *See generally* Food Labeling Modernization Act of 2021, S. 2594, 117th Cong. (as introduced to Senate, Aug. 3, 2021); Food Labeling Modernization Act of 2018, H.R. 5425, 115th Cong.

than $20 million to political campaigns in 2022 alone.[86] These groups tend to favor politicians with anti-regulatory proclivities and power in the processed food regulatory space.[87]

If the 2021 Bill is to become law, it is unlikely that the FDA will alter its tendency to prioritize safety over purely misleading violations.[88] Furthermore, imposing additional obligations without increasing funding will only exacerbate the imbalance of obligations and resources of the FDA.[89] Imposing new regulations will not institute effective change if the agency charged with enforcement lacks the resources necessary to ensure compliance.[90]

B. Problems with FDA Enforcement

The FDA lacks the resources to provide consistent guidance to food manufacturers and the authority to enforce regulations already in place.[91] Warning Letters

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[86] *See Industry Profile: Food & Beverage*, *supra* note 79 (showing statistics on food industry lobbying). Coca-Cola Co. contributed the most to food and beverage lobbying efforts in 2022, contributing over $4.5 million. *Id.* *See also* Gostin, *supra* note 79 (emphasizing power of food lobbyists). "Big Food is relentless in litigating against any law that is likely to be effective in curbing unhealthy eating." *Id.*

[87] *See generally* Gostin, *supra* note 79. Food industry lobbyists not only donate large sums of money to political campaigns, but also fund scientific studies to downplay the adverse health effects of unhealthy ingredients and engage in litigation to oppose laws that would more strictly regulate the industry. *Id.* An estimated $6 million was contributed directly by food lobbyists in 2013-2014 to lawmakers responsible for food regulation. *Id.*

[88] *See* COVINGTON, *supra* note 80 (remarking that FDA seems more inclined to focus on food safety issues). "While sponsors believe these changes are necessary to ensure consumers have the information needed to make healthier and more informed purchasing decisions, we believe, at present, such changes are not among FDA's priorities." *Id.* *See also* Meyer, *supra* note 54, at 245 (citing a lack of FDA resources). The FDA has limited resources to pursue all regulatory violations and must prioritize which complaints they pursue. *Id.*; Negowetti, *supra* note 48, at 13 (citing lack of FDA resource and need for prioritization). Due to a lack of resources, the FDA has repeatedly expressed a need to prioritize its regulatory authority in order to focus on safety and nutritional issues. *Id.*

[89] *See* Meyer, *supra* note 54, at 234. "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." *Id.* *See also* Negowetti, *supra* note 48, at 9 (quoting FDA deputy commissioner of foods regarding priorities of FDA). The FDA is forced to allocate its resources toward nutrition initiatives rather than purely misleading marketing tactics. *Id.*

[90] *See* Negowetti, *supra* note 48, at 12. The FDA has declined to define the word "natural" even though both the courts and the public have urged the agency to do so. *Id.* The FDA came out with a statement explaining that the agency had other priorities to focus on and furthermore lacked the resources to properly define the term. *Id.* *See also* COVINGTON, *supra* note 80 (doubting whether FDA has resources to enforce 2021 Bill). *See generally* Meyer, *supra* note 54, at 234 (pointing to lack of resources as main hurdle of effective FDA regulation).

[91] *See generally* Meyer, *supra* note 54, at 234 (describing FDA hurdles in successfully fulfilling its mission); *see generally* Negowetti, *supra* note 48 (stating need for FDA guidance to ensure consistency and avoid industry confusion). "Ultimately, litigation should be unnecessary if the FDA is funded and properly staffed to fulfill its regulatory mission – to protect consumers from misleading claims on food labels." *Id.* at 23. The FDA lacks the funding necessary to impose clear and consistent regulations regarding misleading food labels. *Id.* As a result, the FDA has been forced to prioritize its regulatory actions and focus strictly on violations that pose

come with virtually no legal repercussions, considering the FDA's tendency to forgo investigations into whether voluntary compliance was achieved.[92] Furthermore, Warning Letters do little to discourage similar misleading practices because they are inconsistently issued with the FDA's sole discretion on a case-by-case basis.[93] The FDA may choose to impose civil monetary fines without DOJ cooperation, but the fines are insignificant relative to the overall profits companies gain as a result of misleading food labels.[94] If the FDA wishes to instill harsher penalties, significant public health risks and coordination with the DOJ is necessary.[95] Thus, companies lack sufficient incentives to avoid misleading food label practices absent an overt risk to public health.[96]

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significant risk to public health. *Id.* at 9. *See generally* Gerhart, *supra* note 24. Differing definitions between the FDA and FTC of what exactly constitutes "misleading," or "misbranding" has led to industry confusion. *Id.* The differences in definitions can be attributed to differences in the respective missions of the two agencies, as well as their differing sources of authority (FDCA and FTC Act). *Id.* The FDA alone lacks the authority to establish a consistent definition of "misleading" across all food advertising. *Id.*

[92] *See* Kipnees, *supra* note 57 (arguing relevance of Warning Letters as evidence in litigation). The FDA has recognized the informal and advisory nature of Warning Letters in their own guidelines. *Id.* A Warning Letter in no way obligates the FDA to take further action, even if no voluntary compliance is achieved as a result of the letter's issuance. *Id.* It is rare that the FDA will take further enforcement action after a Warning Letter is issued. *Id. See also* Armstrong, *supra* note 48, at 10. Warning Letters are considered so informal that most courts do not consider them a sufficient basis to file suit in opposition to the FDA. *Id.;* Negowetti, *supra* note 48, at 3 (identifying Warning Letters as FDA's principal enforcement tool). "As the food labeling lawsuits demonstrate, these Warning Letters provide little incentive or threat for companies to avoid or discontinue use of misleading claims on food labels." *Id.* at 4.

[93] *See* Meyer at 239, *supra* note 54. The FDA waits for consumer complaints to be lodged before utilizing their discretion to spot check manufacturers for violations. *Id. See also* Armstrong, *supra* note 48 (describing discretion afforded to FDA in regulatory enforcement). "Supreme Court precedent recognizes that FDA enjoys significant discretion over enforcement of most FD&C Act provisions." *Id. See generally* Negowetti, *supra* note 48 (describing impossibility of pursuing every misleading label claim due to creative marketing and restricted resources).

[94] *See* Meyer, *supra* note 54, at 241. "The potential profits incentivize companies to keep marketing their products in the same way and treat government fines as the 'cost of doing business.'" *Id. See also* Armstrong, *supra* note 48, at 19 (describing fines that may be imposed for violations of FDCA); Negowetti, *supra* note 48, at 4. The FDA may choose to impose civil monetary fines when the misbranding or adulteration violation will result in serious adverse health consequences or death. *Id.* The requirement of adverse public health effects to impose fines has limited FDA enforcement actions to simple Warning Letters with the hope of voluntary compliance for violations resulting from simply misleading practices. *Id.*

[95] *See* Negowetti, *supra* note 48, at 4. The FDA will only impose fines or a recall order when the misbranded product poses serious public health risks. *Id.* Furthermore, the FDA may only seize misbranded foods after the company has received notice of the violation, has had an opportunity to cure, and there exists probable cause to believe substantial injury to consumers will occur. *Id. See also* Armstrong, *supra* note 48 (outlining FDA and DOJ coordination for imposing civil and criminal penalties). "Because FDA, like most executive agencies, does not have independent litigating authority, it must coordinate with the Department of Justice (DOJ) to pursue criminal or civil remedies." *Id.* Food manufacturers are held to a "strict liability" standard for criminal enforcement, forgoing the typical "mens rea" requirement typically seen in criminal law. *Id.* at 17. *See generally* Kincheloe, *supra* note 54 (pointing out FDA enforcement limitation to instances of public safety).

[96] *See* Meyer, *supra* note 54, at 234 (pointing out reluctance of FDA to investigate claims until existence of widespread health concern); *see also* Negowetti, *supra* note 48, at 3. "Although the

The lack of FDA authority to impose penalties, combined with its refusal to define common terms, has given rise to misleading food labeling practices and industry confusion.[97] The FDA has declined to produce enforceable definitions for ambiguous terms, like "natural" and "wholesome," that are commonly used to mislead consumers.[98] FDA-issued guidance documents provide some insight into the administration's standards but are non-binding and do not establish legally enforceable responsibilities.[99] Pre-market approval is not required for food labels, forcing FDA inspectors to rely on spot checking

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FDA is responsible for enforcing labeling regulations, it lacks the enforcement authority to effectively deter food companies from making misleading claims." *Id.* The FDA reserves more stringent measures for instances where there is a serious risk to public safety because imposing more drastic sanctions requires both a significant allocation of resources and cooperation with the DOJ. *Id.* at 3, 5, 9. *See also* COVINGTON, *supra* note 80 (discussing FDA inclination to prioritize food safety issues over pure labeling issues).

[97] *See* Negowetti, *supra* note 48, at 20-21 (advising FDA to rethink approach to health claims and terminology on food packaging). Research has shown that consumers are routinely confused about the validity of health claims made on food packaging. *Id.* at 21. Food processing has advanced in such a way that the average consumer cannot be expected to accurately evaluate how healthy or natural a given food product is without the help of label indications. *Id.* at 20. Consumers should be able to rely on an agency with their interests in mind to ensure consistency about how terms and food descriptions may be used on food packaging. *Id. See* Kincheloe, *supra* note 54 (noting confusion over definitions in food industry and need to change FDA power and enforcement); Caldwell, *supra* note 7 (identifying common terms as the focus of rising food label litigation). *See generally* Gerhart, *supra* note 24 (pointing out consumer and industry confusion surrounding FDA/FTC jurisdiction and authority); Kipnees, *supra* note 57 (remarking on inconsistencies in court opinions regarding relevancy of Warning Letters). Warning Letters are used by some courts to gain insight on FDA opinions regarding the implementation of FDA rules and regulations. *Id.* However, courts are split as to how much weight of authority to give these letters in court, because a Warning Letter is not considered to be a formal enforcement action by the agency. *Id.* Some courts question whether the issuance of a Warning Letter preempts citizens from taking private action against food producers, while other courts allow plaintiffs to utilize Warning Letters as evidence of misbranding for claims under state consumer protection statutes. *Id. See generally Use of the Term Natural on Food Labeling, supra* note 53 (stating FDA policy concerning the term "natural"); *Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements, supra* note 53 (non-binding statement to provide industry guidance for the use of "whole grain").

[98] *See Use of the Term Natural on Food Labeling, supra* note 53 (admitting lack of formal definition); *see also Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements, supra* note 53 (providing industry guidance, but no formal definition). *See generally* Negowetti, *supra* note 48 at 2, 15 (suggesting FDA define terms such as "natural" and pointing out litigation over unregulated term "wholesome"). Caldwell, *supra* note 7 (noting failure of FDA to produce legal definition of "healthy" in 2016).

[99] *See Guidance for Industry: Food Labeling Guide Draft, supra* note 54 (clarifying guidance as a purely non-binding recommendation); *see also Guidance for Industry and FDA Staff: Whole Grain Label Statements, supra* note 53. "This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public." *Id. See also* Negowetti, *supra* note 48, at 16-17 (characterizing Draft Guidance as not legally enforceable).

and consumer complaints.[100] Moreover, the FDA lacks enough trained inspectors to effectively and efficiently assess whether food labels are misleading.[101]

The FDA lacks the adequate staff and funding necessary to effectively regulate the enormous number of products on the market today.[102] Deficiency in funding and resources has led the administration to prioritize critical health and safety concerns, allowing purely misleading food label practices to continue with minimal repercussions.[103] The FDA has previously acknowledged a sense of futility in enforcing violations of misleading food labels, attributed to the never-ending creativity of food marketing teams and the substantial resources required to enforce existing regulations.[104] Beyond enforcement, the FDA has referenced a lack of funding and resources as the rationale for

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[100] *See Guidance for Industry: Food Labeling Guide Draft, supra* note 54. "Under FDA's laws and regulations, FDA does not pre-approve labels for food products." *Id.* *See* Kincheloe, *supra* note 54. "Unlike the USDA, which reviews all labels before allowing them to be published, the FDA is structured on voluntary compliance." *Id.* *See* Meyer, *supra* note 54, at 239. "The FDA also does not pre-approve food labels for nutritional content accuracy. Instead, the FDA spot-checks manufacturers after consumer complaints are lodged." *Id.* For the FDA to warrant an investigation, a certain amount of consumer complaints of serious adverse events must be lodged. *Id.* at 238. However, studies have shown that few adverse events even get reported, raising the question of how effective the current system is at identifying public health risks. *See* Meyer, *supra* note 54, at 239; *see also* Negowetti, *supra* note 48, at 9 (quoting FDA commissioner speaking on enforcement challenges being due to lack of pre-market approval process). *See generally* Armstrong, *supra* note 48 (regarding FDA violation identification and enforcement process).

[101] *See* Meyer, *supra* note 54, at 234 (citing lack of FDA resources in relation to enforcement responsibilities). The FDA lacks both the staff and the funding to properly enforce current regulations and keep up with an evolving marketplace. *Id.* *See also* Negowetti, *supra* note 48, at 23 (recommending improvements for inspector training). Current FDA inspector instructions do not provide guidelines to help inspectors identify potentially false or misleading food labels. *Id.*

[102] *See* Meyer, *supra* note 54, at 234. "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." *Id.*; see *also* Negowetti, *supra* note 48, at 9, 13 (identifying lack of FDA resources to effectively enforce all regulations). The FDA has repeatedly acknowledged resource limitations as a reason for not pursuing misleading food label violations or clarifying definitions of common packaging terms. *Id.* at 9, 12-13. *See also* Gerhart, *supra* note 24 (suggesting FTC enforcement capabilities as necessary to supplement FDA enforcement). Due to constrained resources causing a decrease in FDA enforcement, the FDA has downplayed the prevalence of misleadingly labeled products as a way to justify a focus on purely public health concerns. *Id.* Revising the current Memorandum of Understanding between the FTC and the FDA and embracing FTC enforcement in areas of concurrent jurisdiction may aid in filling current enforcement gaps regarding purely misleading food labels. *Id.*

[103] *See* Negowetti, *supra* note 48, at 13. "Finally, the FDA again noted its lack of resources and identified other priorities, such as regulations implementing the Food Safety Modernization Act of 2011 and nutrition labeling regulations." *Id.* *See also* Kipnees, *supra* note 57 (noting general absence of FDA action after issuing Warning Letter); Kincheloe, *supra* note 54 (stating FDA sanctions reserved for health and safety concerns only); COVINGTON, *supra* note 80 (discussing FDA prioritization of safety and lack of focus on misleading labeling).

[104] *See* Negowetti at 9, *supra* note 48, at 9 (explaining prevalence of potential violations and lack of resources enforcing food label violations). "Going after them one-by-one with the legal and resource constraints we work under is a little like playing Whac-a-Mole, with one hand tied behind your back." *Id.* *See generally* Meyer, *supra* note 54, at 239 (pointing out inadequacy of resources relative to enforcement responsibilities).

the agency's failure to establish legally binding definitions for commonly used terms, like "natural."[105] Limited resources combined with complete enforcement discretion has led the FDA to prioritize public health concerns over purely misleading labels.[106] The decision to prioritize health and safety over violations that are purely misleading is understandable due, but creates a notable gap in regulatory enforcement.[107]

C. Problems With FDA/FTC Concurrent Jurisdiction

The concurrent jurisdiction shared by the FDA and FTC in regulating misleading food labels is defined by a Memorandum of Understanding between the two organizations.[108] The Memorandum of Understanding allocates the responsibility for regulating food labeling practices to the FDA, leaving the regulation of misleading advertisements to the FTC.[109] Despite its existence since the 1970's, the Understanding

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[105] *See* Negowetti, *supra* note 48, at 13 (refusing to define "natural" upon judiciary request of FDA); *see also Use of the Term Natural on Food Labeling, supra* note 53 (requesting public comment on use of term "natural" on food labels). The FDA acknowledged that the current, longstanding policy concerning the use of the word "natural" was outdated because it does not address food production methods or the use of "natural" in the context of nutrition or health claims. *Id.* The comment period closed in May of 2016, and no updated guidance has since been released. *Id.*

[106] *See* Negowetti, *supra* note 48, at 12 (lacking FDA resources forces prioritization of regulation responsibilities); Meyer, *supra* note 54 (noting inadequate FDA relative to regulation responsibilities); Gerhart, *supra* note 24 (noting FDA ineffective because of depletion of resources); *see also* Armstrong, *supra* note 48, at 3 (describing FDA discretion over enforcement). The FDA has declared safety as a priority over other responsibilities. *Id.* at 9. *See generally* COVINGTON, *supra* note 80 (highlighting FDA priority of nutrition and health concerns over food label regulation); *see generally* Heckler v. Chaney, 470 U.S. 821, 831 (1985) (holding FDA enjoys significant discretion whether to pursue enforcement proceedings).

[107] *See* Negowetti, *supra* note 48, at 11 (recognizing that defining the term "natural could prevent confusion). Inadequate resources have prompted the FDA to neglect its regulatory responsibilities of enforcing misleading food label violations and enacting new regulations to dispel consumer and industry confusion regarding food label practices. *Id.* at 9, 13. The regulatory gap is evident from the rise in consumer litigation over misleading food labels, because the consumer litigation is centered around issues that fall within the scope of FDA regulatory responsibilities. *Id.* at 2. *See generally* Gerhart, *supra* note 24 (suggesting regulatory gap left by ineffective FDA enforcement could be filled by FTC); Meyer, *supra* note 54 (pointing out inadequate FDA resources in relation to regulatory responsibilities); Jacobs, *supra* note 7 (arguing systematic change needed to stem consumer food label litigation); Kincheloe, *supra* note 54 (arguing FDA is currently ineffective at regulating food labels); Silverman & Mueblberger, *supra* note 68, at 48 (citing regulatory gaps as reason for rise in food label litigation trends).

[108] *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, supra* note 48 (allocating responsibility for misleading label regulation to FDA); *see also* Gerhart, *supra* note 24; *see also* Negowetti, *supra* note 48 (highlighting different responsibilities of FTC and FDA). Pursuant to the memorandum, the FTC assumes primary responsibility for food advertisements, while the FDA focuses on the regulation of food labels. *Id.* at 3. *See generally* Armstrong, *supra* note 48, at 5 (clarifying objective of The Memorandum of Understanding). The Memorandum of Understanding was entered into because of the concurrent jurisdiction shared by the FDA and FTC over the regulation of misleading labels. *Id.*

[109] *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, supra* note 48 (illustrating different duties of FDC and FTC). "With exception of drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of food, drugs, devices, and cosmetics." *Id.* "In the absence of express agreement between the two agencies to the contrary, the Food

can be revoked by either agency with 30 days' notice, allowing the FTC to potentially assert authority over labeling practices.[110]

The FDA and FTC have two distinct standards to determine when something is considered misbranded or deceptive.[111] The FDA requires only that a label be "false or misleading in any particular," while the FTC must show that a statement is misleading in a material way.[112] Food producers aiming to comply with the law must educate themselves on the regulatory divisions and enforcement standards of both organizations.[113] The interlacing of advertising and labeling often leads people to view them as the same script in a different medium.[114]

Identical messaging across advertisements and labels provides insight into the inconsistent standards and discretionary enforcement practices between the two agencies.[115] The FTC has to meet a higher burden of proof when enforcing misleading

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and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of food, drugs, devices, and cosmetics." *Id.* *See also* Gerhart, *supra* note 24; Negowetti, *supra* note 48, at 3; Armstrong, *supra* note 48, at 5.

[110] *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, supra* note 48 (describing termination clause and period of agreement). "This agreement, when accepted by both parties, covers an indefinite period of time and may be modified by mutual consent of both parties or terminated by either party upon thirty (30) days advance written notice." *Id.* *See also* Gerhart, *supra* note 24.

[111] *See* Negowetti, *supra* note 48, at 3 (describing FDA and FCT standards for misleading); *see also* Gerhart, *supra* note 24 (comparing misbranding standards under FTC Act and FDCA). Statutory intent indicates that the two sections that define misleading advertising and misleading labeling, in the FCT Act and FDCA respectively, were intended to have the same applied meaning. *Id.* However, the level of proof needed to show that a label or advertising is misleading differs across the two statutes. *Id.* The distinctive standards between the FDA and FCT on what constitutes as "misleading" is due in part to differing views on statutory purpose, with the FDA focusing on public health and consumer protection, compared to the FTC's focus on accurate information. *Id.*

[112] *See* Negowetti, *supra* note 48, at 3; *see also* Gerhart, *supra* note 24. Misbranding under the FDA is typically easier to prove because the FDA does not require the statement to be materially misleading like the FTC. *Id.* Additionally, unlike the FDA, the FTC considers material to be misleading only if a reasonable consumer, under the circumstances, would likely have been misled. *Id.*

[113] *See* Gerhart, *supra* note 24, at 3-4. Manufacturers must spend time and resources to anticipate both the FDA's and FTC's reactions to marketing materials. *Id.* However, the FDA and FTC choose to focus their efforts in different ways, with the FTC focusing on adjudication and the FTC primarily focusing on rulemaking, rather than enforcement. *Id.* *See generally* Negowetti, *supra* note 48 (describing differing standards of FCT Act and FDCA resulting in inconsistent outcomes); Meyer, *supra* note 54, at 235 (describing consumer confusion stemming from multiple agencies responsible for food regulation).

[114] *See* Gerhart, *supra* note 24, at 16 (describing interconnectedness of advertising and labeling). The FDA and FTC must often communicate and work together regarding misleading advertising and labeling regulations because advertising and labeling do not function independently of one another. *Id.* *See* Negowetti at 22, *supra* note 48 (suggesting FDA and FTC work more closely to monitor misleading claims). Eliminating a misleading label alone may not fully address the misleading claims of food manufacturers because a single company can make misleading claims spanning many mediums like food labels, television, print, and the internet. *Id.*

[115] *See generally* Negowetti, *supra* note 48, at 17-18 (providing examples of FCT enforcement of misleading advertisement with no concurrent FDA label enforcement). Dean Foods' Horizon

advertising practices, while the FDA uses its enforcement discretion to focus primarily on misleading labels that pose public health and safety risks.[116] Discrepancies between enforcement practices can result in companies facing enforcement actions from one agency but not the other.[117] In these instances, the FTC compels a company to alter misleading advertising, but the food labels containing the same misleading language may remain unaltered.[118] This inconsistency has caused industry confusion and has raised questions over the practicality of having separate jurisdictions for advertising and packaging.[119]

D. Problems with Private Action

Private actions concerning misleading food labels have increased exponentially in recent years, mostly in the form of class action lawsuits.[120] Consumer advocate groups

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Organic Milk made false claims on their labels and across general advertising that their milk supported brain health. *Id.* An FTC investigation found that the company did not have any evidence to support the representation, and the company subsequently modified its radio, print, online, and television advertisements accordingly. *Id.* Yet, the company did not alter the claim on its product labels or packaging. *Id. See generally* Gerhart, *supra* note 24 (emphasizing interconnectedness of advertisements and product labeling).

[116] *See generally* Negowetti, *supra* note 48 (describing FDA/FTC standards for "misleading" and FDA prioritization of safety because of inadequate resources); Gerhart, *supra* note 24; Armstrong, *supra* note 48; Meyer at 234, *supra* note 54 at 234 (remarking on FDA prioritization of health and safety due to inadequate resources). "Therefore, the FDA does not investigate safety issues until becoming aware of a widespread health concern." *Id.* at 234.

[117] *See* Negowetti, *supra* note 48, at 18 (providing example of enforcement action by FTC, but not FDA). "Although the company modified its radio, television, print and online advertisements following an FTC investigation of the 'DHA Omega-3 Supports Brain Health' claim, Dean Foods has not changed product labels and packaging." *Id. See generally* Gerhart, *supra* note 24 (explaining differing views of statutory purpose by FDA/FCT as roadblock for cohesive regulatory enforcement); Meyer at 235, *supra* note 54, at 235 (showing multiple agencies for food regulation makes for conflicting and confusing laws). *But see* Gerhart, *supra* note 24 (emphasizing collaboration and communication between the FDA and FTC). "At times the FTC adopts the findings of the FDA to reach its own finding that an ad was false or deceptive." *Id.* at 35.

[118] *See* Negowetti, *supra* note 48, at 18 (explaining FTC amendments still allow misleading food labels).

[119] *See* Meyer, *supra* note 54, at 235 (having multiple agencies for food regulation makes for conflicting and confusing laws); *see also* Gerhart, *supra* note 24 (questioning efficacy of Memorandum of Understanding). The regulatory responsibilities allocated under the Memorandum of Understanding are not so easily separated, as evidenced by ongoing informal contacts between the FDA and FTC. *See* Gerhart, *supra* note 24. Not only are advertisements and food labels inherently interconnected, but the two agencies also find themselves sharing resources, like specialists, to help analyze the truthfulness of marketing claims. *Id. See also* Negowetti, *supra* note 48, at 22 (suggesting FDA work more closely with FTC to monitor false claims). The FDA and FTC could work together to investigate false or misleading claims because the consistent misleading claims are often used both on a food's packaging and across general advertising. *Id.* Thus, consolidating investigatory work could save both agencies time and resources. *Id.*

[120] *See* Fitzgerald, *supra* note 69. Class action lawsuits regarding food labeling increased as much as one thousand percent between 2008 and 2021, according to one report. *Id. See* Silverman & Mueblberger, *supra* note 68, at 5 (noting rise in food label litigation with no indication of slowing); Dahl, *supra* note 68 (expressing lawsuits over labeling are surging because plaintiffs desire increased federal oversight of food supplies); Guite, *supra* note 68 (predicting continued

celebrate the rise of litigation in the hope that it will compensate for the current lack of federal oversight and encourage more transparent practices among food producers.[121] Others, however, are concerned that such litigation encourages predatory legal practices in the form of frivolous and "cut and paste" lawsuits.[122] The majority of misleading food label lawsuits result in settlement, leaving the litigated food label intact and on the market.[123] Moreover, some question whether private actions are an appropriate means for enforcing food label regulations because of the inevitable inconsistencies across jurisdictions.[124] Regardless of the efficacy in using litigation to hold food producers accountable, consumers and lawyers alike are attempting to use the regulatory enforcement gap to their respective advantages.[125]

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increase in class actions against food and beverage manufacturers); Negowetti, *supra* note 48, at 7 (attributing surge in food label litigation to lack of FDA oversight); Jacobs, *supra* note 7; *see also* Zabriskie*, supra* note 7 (examining recent significant increase of food label litigation in Midwestern states).

[121] *See* Jacobs, *supra* note 7. Environmental and animal welfare groups are using food label litigation as a tool to encourage corporate transparency and more sustainable production practices. *Id.* Advocates say that most of the current litigation could be avoided by a systematic change to federal oversight. *Id. See also* Dahl, *supra* note 68 (indicating advocate groups seek more accountability from food producers). The advocate groups seeking more accountability from large food producers believe that even if the lawsuits do nothing more than attract attention, it will encourage Congress to take action. *Id.*

[122] *See* Silverman & Mueblberger*, supra* note 68, at 4, 7 (claiming lawyers, rather than consumers primarily benefit from class-action settlements). A small number of law firms are responsible for bringing a majority of food label class-action suits, with some firms specializing in particular types of claims, called cut-and-paste complaints. *Id.* Upon receiving a letter threatening to file suit, many food and beverage producers decide to settle to avoid litigation and bad publicity. *Id.* However, about half of the settlement money from a certified class action often goes to the lawyers, typically leaving the consumers with a nominal cash payout or product voucher. *Id. See also* Jacobs, *supra* note 7 (referencing four dozen cut-and-paste lawsuits regarding vanilla flavoring filed in 2020); Caldwell, *supra* note 7 (questioning whether food label class-actions are becoming the norm for opportunistic attorneys).

[123] *See* Silverman & Mueblberger*, supra* note 68, at 38. "Many of these settlements essentially pay the lawyers to go away, providing little or no benefit to consumers." *Id. See also* Jacobs, *supra* note 7 (interviewing Ivan Wasserman, a food lawyer in D.C.). "For every case that makes its way to court, he said dozens of others are quietly settled with monetary compensation – often without making changes to the contested label." *Id. See also* Caldwell, *supra* note 7 (stating companies commonly settle to avoid high legal fees and bad publicity generated by litigation).

[124] *See* Negowetti, *supra* note 48, at 21 (arguing regulation by way of litigation is costly, slow, and ineffective). The rise in food label litigation can be attributed to an absence of effective regulatory enforcement, due in part to underfunding and understaffing of the FDA. *Id. See also* Caldwell, *supra* note 7 (questioning whether consumer interests are served by suing companies into submission); Kipnees, *supra* note 57 (identifying inconsistent court treatment of Warning Letters as evidence of misleading messaging in private actions); Fitzgerald, *supra* note 69 (commenting on inconsistent decisions and approaches to food label litigation by the courts). Recent decisions by some courts, including the federal district court in Massachusetts, have indicated a certain skepticism for misleading food label claims, while other courts, including the First Circuit, have shown a willingness to give plaintiffs their day in court. *Id. See generally* Silverman & Mueblberger*, supra* note 68 (urging courts, lawmakers, and regulatory agencies to take action to reduce food label litigation).

[125] *See The* Silverman & Mueblberger*, supra* note 68, at 14 (describing money-making practices of lawyers engaging in food label class actions). "[T]he food litigation is driven by lawyers as a money-making enterprise; it does not respond to consumer concerns." *Id.* Some lawyers have

Even though the FDA does not afford consumers a private right of action, consumers can bring claims under individual states' consumer protection statutes.[126] Consumer protection statutes may allow consumers a private right of action if they do not contradict FDA regulations.[127] Variations in statutes exist between states, with some jurisdictions affording more opportunities for plaintiffs than others.[128] As a result, certain states have been identified as "food courts," amassing many misleading label claims.[129]

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benefited from food litigation trends by developing lists of potential cases and finding suitable plaintiffs after the fact, with the hopes that most cases will result in a settlement, for the benefit of the lawyer. *Id.* *See also* Caldwell, *supra* note 7 (questioning motives of opportunistic lawyers and acknowledging perceived consumer benefit). Consumer advocates insist that these lawsuits are necessary to protect consumer interests against those of large food producers because government oversight of food label claims has been lacking. *Id.* *See also* Jacobs, *supra* note 7 (noting advocacy groups' interest in legal activism is to call out large food producers). *See generally* Negowetti, *supra* note 48 (identifying regulatory enforcement gap as reason for food label litigation). Consumers are attempting to protect their interests in food label transparency and fill a regulatory enforcement gap concerning the regulation of misleading food labels by engaging in private litigation. *Id.*

[126] *See* Negowetti, *supra* note 48, at 10-11 (describing state statutes as basis for misleading food label litigation). State statutes on consumer protection, false advertising, unfair trade, fraud, and breach of warranty can support claims for a plaintiff seeking relief for misleading food label practices. *Id.* *See also* Fitzgerald, *supra* note 69 (notwithstanding FDCA preemption, courts have allowed plaintiffs to pursue remedies under state consumer protection statutes). The First Circuit in particular has suggested that state consumer protection statutes may support a claim regarding misleading food labels, even with the FDCA's express preemption provision and a lack of private right of action for FDA regulation violations. *Id.* *See also* Silverman & Mueblberger, *supra* note 68, at 14 (identifying popular "food courts" resulting from favorable consumer protection laws); Kipnees, *supra* note 57 (describing how plaintiffs use FDA guidance, statements, and rules as evidence in claims). Plaintiffs often use FDA guidance, statements, and rules regarding labeling regulations as evidence in claims brought under state consumer protection statutes. *Id.*

[127] *See* Kipnees, *supra* note 57. Consumers do not have a private right of action under the FDCA but may still bring claims over misleading food labels under state law if the state law does not interfere with the FDA's regulatory regime. *Id.* The Ninth Circuit has noted that state claims seemingly used to impose FDCA regulations may still be allowed to go forward if they rely on traditional tort law duties. *Id.* *See also* Choy, *supra* note 69 (discussing preemption doctrine as it relates to FDCA).

[128] *See* Silverman & Mueblberger, *supra* note 68, at 8 (identifying states that are food litigation friendly). In 2015, just four states were responsible for hosting three-quarters of all food class actions. *Id.* Jurisdictions with expansive consumer protection laws and class-action friendly judges tend to be popular for food label litigation. *Id.* at 9. *See* Jacobs, *supra* note 7 (describing California as popular food litigation state because of stringent consumer protection regulations).

[129] *See* Silverman & Mueblberger, *supra* note 68, at 8. U.S. district courts in New York, California, Florida, and Illinois hosted more than three-quarters of food class action lawsuits in 2015. *Id.* *See also* Negowetti, *supra* note 48, at 1 (identifying U.S. District Court for Northern District of California as "food court"); *see also* Guite, *supra* note 68 (identifying Northern District of California as country's "food court"). The Southern and Central Districts of California, along with federal courts in New York, Florida, Illinois, and Missouri are also known for their sizeable number of food label class actions. *Id.* *See generally Parsing the Recent Surge in Midwest Food Labeling Litigation*, *supra* note 7 (mentioning traditional food litigation hotbeds of California and New York). Notably, 2021 also saw an increase in food label litigation in Midwestern states. *Id.*

Most of these lawsuits are based on violations of state laws regarding unfair trade practices, consumer protection, false advertising, breach of warranties, and fraud.[130]

Misleading food label lawsuits are treated very differently across jurisdictions.[131] Some courts have indicated willingness to hear such litigation, while others tend to defer to the FDA.[132] When deferring to the FDA, the judge often cites concern about undermining the FDA's authority or contradicting legislative intent.[133] Jurisdictions also vary in how they regard previously-issued FDA Warning Letters in actions brought under state statutes.[134] The courts generally treat Warning Letters in one of three ways: (1) as irrelevant, (2) as evidence that the FDA found the label misleading, or (3) if the FDA did not pursue further action; as evidence that the FDA approves of the label, and therefore the private suit should be preempted because a negative ruling would violate the Supremacy Clause.[135]

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[130] *See* Negowetti, *supra* note 48, at 11 (describing state statutes as basis for misleading food label litigation); *see also* Fitzgerald, *supra* note 69 (noting courts have allowed plaintiffs to pursue remedies under state consumer protection statutes); *see also* Silverman & Mueblberger, *supra* note 68, at 14 (identifying states with favorable consumer protection laws); *see also* Choy, *supra* note 69 (explaining relationship of FDCA preemption and state laws). The Ninth Circuit has noted that certain state law claims relating to the FDCA are allowed to persist as long as the basis of the claim relies on tort law duties, rather than noncompliance with FDA requirements. *Id.*

[131] *See* Kipnees, *supra* note 57 (examining inconsistent treatment by courts of Warning Letters as evidence in food label litigation); *see also* Fitzgerald, *supra* note 69 (observing differing views of misleading food label claims between Massachusetts District Court and First Circuit); *see also Parsing the Recent Surge in Midwest Food Labeling Litigation, supra* note 7 (noting Midwestern food label litigation decisions were mixed bag at district court level). *See generally* Silverman & Mueblberger, *supra* note 68 (providing examples of inconsistent rulings).

[132] *See* Negowetti, *supra* note 48, at 12 (providing example of courts deferring to FDA). Litigation over use of the term "natural" in lawsuits alleging deceptive use of the term have prompted several judges to hold that the FDA, not the courts, should be responsible for defining the term. *Id.* The FDA ultimately responded to the courts in a letter by the FDA Commissioner for Policy, declining to formally define the term "natural," in part because the FDA lacked the resources to properly define the term. *Id.*

[133] *Id.* Courts have reasoned that the purpose of the FDCA is to establish a uniform food regulatory scheme, but consistency and uniformity requires the expertise of the FDA. *See* Negowetti, *supra* note 48, at 12. Courts are reluctant to usurp the FDA's regulatory authority over food labeling and risk undermining FDA judgments through private litigation. *Id.*

[134] *See* Kipnees, *supra* note 57 (examining differences in courts' treatment of FDA Warning Letters as evidence). Several courts see Warning Letters as an indication of FDA intent to regulate a particular labeling practice, and therefore supports a defense based on preemption or primary jurisdiction. *Id.* Other courts have regarded Warning Letters as the FDA interpreting its own rules, and therefore defer to the interpretation stated in the Warning Letter unless it is clearly erroneous. *Id.* Another subset of courts has declined to infer that a labeling practice is unlawful simply because a Warning Letter has been issued, stating that Warning Letters are too informal and are not considered to be an official statement by the agency. *Id.* Indeed, the FDA has clearly stated that Warning Letters are not to be considered formal enforcement action, and by affording too much weight to the relevance of a Warning Letter, a Warning Letter in court has the potential of imposing a formal position on the FDA that it had no intention to assume. *See* Kipnees, *supra* note 57.

[135] *Id.*

Another major concern with the rise in food label litigation is the potential for predatory legal practices.[136] Some experts believe that lawyers are driving the onslaught of litigation rather than consumer advocate groups, as shown by the rise in "cut and paste" lawsuits cropping up en masse.[137] As soon as a new form of misleading food label claim is brought in one jurisdiction, others of an identical nature are brought across other jurisdictions.[138] Some lawyers are even drafting complaints before seeking a potential plaintiff.[139]

Some lawyers are making a reputation for themselves by bringing frivolous lawsuits.[140] One such lawyer has been dubbed the "Vanilla Vigilante" because he brought an excess of unsuccessful cases in rapid succession, all claiming that consumers were misled to think that the word "vanilla" on a product label came from vanilla beans or vanilla extract, rather than artificial sources.[141]

Lawyers are incentivized to bring such dubious claims because many misleading food label claims end up settling, resulting in a large payout for the plaintiff's lawyer.[142]

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[136] *See* Silverman & Mueblberger*, supra* note 68, at 14, 38-45 (identifying ways lawyers use food class actions as money making enterprises). The fact that some lawyers will typically draft complaints before finding a suitable client shows that some food litigation is lawyer driven. *Id.* at 14. When a class action lawsuit settles, the plaintiff's lawyer will take a large payout for attorney's fees, as opposed to consumers, who generally receive a nominal benefit or nothing at all. *Id.* at 44. *See also* Caldwell, *supra* note 7 (identifying creativity of opportunistic attorneys in scrutinizing labels for potential lawsuits).

[137] *See generally* Silverman & Mueblberger*, supra* note 68, at 2 (observing food litigation trends and lawyer motivations). *See also* Caldwell, *supra* note 7 (identifying a certain lawyer's "unrelenting cascade" of lawsuits). A specific New York attorney has made a reputation for himself as the "Vanilla Vigilante" by saturating the courts with lawsuits targeting vanilla flavorings. *Id.*

[138] *See* Silverman & Mueblberger, *supra* note 68, at 13.

[139] *See* Silverman & Mueblberger, *supra* note 68, at 14 (explaining food label class action practices by lawyers). Sometimes lawyers will name family members, employees, or friends as plaintiffs in food class actions. *Id.* at 14. It is not uncommon for lawyers to keep a list of drafted complaints and only after seeking out a suitable client, file the lawsuit. *Id.* Affiliations of lawyers have been discovered who help each other identify companies to sue and find suitable plaintiffs. *Id.*

[140] *See* Caldwell, *supra* note 7 (identifying lawyer with nickname "Vanilla Vigilante"); *see also* Jacobs, *supra* note 7 (noting four dozen cut-and-paste lawsuits dismissed in 2020 over vanilla flavoring). The vanilla flavoring lawsuits claimed that customers were misled into thinking that a food product labeled with the term "vanilla" contained real vanilla beans or extract, rather than vanilla flavoring. *Id.* Companies will often point to excessive and frivolous cut-and-paste lawsuits like the dismissed cases over vanilla flavoring as evidence that food label complaints are mostly meritless. *See also* Jacobs, *supra* note 7.

[141] *See* Caldwell, *supra* note 7 (identifying "Vanilla Vigilante"); *see also* Jacobs, *supra* note 7 (noting cut-and-paste lawsuits over vanilla flavoring). Most of the claims over vanilla flavoring were dismissed. *Id.*

[142] *See* Silverman & Mueblberger, *supra* note 68, at 38-45 (identifying benefits to lawyers from settling). When a class action lawsuit settles, the plaintiff's lawyer will take a large payout for attorney's fees, as opposed to consumers, who generally receive a nominal benefit or nothing at all. *Id.* at 44. When motions to dismiss a food class action suit fail and the court certifies the class action, a defendant will typically try to settle. *Id.* at 38. Most food producers want to settle to avoid costly litigation, bad publicity, and the risk of an adverse ruling. *Id.* Many settlements are settled privately and never recorded, resulting in payment for the plaintiff and their lawyer, but no benefits for the class or the average consumer. *See* Silverman & Mueblberger, *supra* note

Most settlements do not pass much compensation to the original plaintiff or class claiming injury, because the bulk of the settlement typically lines the pockets of the attorney who brought suit.[143] Moreover, companies are generally willing to settle to avoid negative publicity and the hassle of litigation, even if the claim seems frivolous.[144] Unfortunately for consumer advocate groups championing food label litigation, a settlement usually means that the alleged misleading label will not change and stay on the market.[145]

Additionally, industry food producers and some food litigation lawyers believe that the litigation trend has gone too far.[146] Companies are uncertain if a label will be construed as misleading and worried about becoming the next target of a misleading food label lawsuit.[147] Some lawyers have expressed concern that the uptick in litigation will have a chilling effect on free speech, thus limiting companies' ability describe products

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68, at 38-39. *See generally* Jacobs, *supra* note 7 (stating settling generally results in offending label remaining unchanged).

[143] *See generally* Silverman & Mueblberger, *supra* note 68, at 38-45 (providing examples of settlement compensation for plaintiffs' lawyers, classes, and consumers, respectively). A 2013 class action lawsuit in New Jersey against Subway, claiming some of their Footlong sandwiches measured only 11 inches, resulted in a $525,000 total settlement, with $520,000 going to the plaintiffs' lawyers and $500 each going to the class representatives. *Id.* at 39-40. A 2013 class action against StarKist accused the company of under-filling their tuna cans, resulting in a $12 million settlement, with $3,755,800 going to plaintiffs' lawyers, $5,000 going to each of the class representatives, and $4.43 tuna vouchers to consumers. *Id.* at 40. A 2013 class action against Red Bull alleged that the slogan "Red Bull gives you wings" misled consumers into believing that Red Bull provided added benefits over coffee. *Id.* at 41. The parties reached a settlement totaling $13 million, with $3,493,448 going to plaintiffs' attorneys, $5,000 going to each class representative, and $10 cash or two free Red Bull products to consumers. *See generally* Silverman & Mueblberger, *supra* note 68, at 41.

[144] *See* Silverman & Mueblberger, *supra* note 68, at 38 (threatening class action lawsuit incentivizes settlement). The Supreme Court has recognized that a certification of a class action pressures a defendant to settle, because settling outweighs the risk of enormous loss should the defendant lose in court. *Id.*; *see also* Caldwell, *supra* note 7 (settling is means to avoid legal fees and negative publicity).

[145] *See* Jacobs, *supra* note 7 (noting settlements usually result in contested label remaining unchanged). Advocates are celebrating food label litigation as legal advocacy, serving to fill regulatory gaps and bring attention to the unsavory practices of food manufacturers. *Id. See generally* Negowetti, *supra* note 48 (concluding regulation by litigation is generally ineffective); s*ee also* Caldwell, *supra* note 7 (questioning efficacy of litigation as means to protect consumers).

[146] *See* Jacobs, *supra* note 7 (quoting food lawyers on negative aspects of rise in food label litigation). Ivan Wasserman, a food lawyer in Washington D.C., is worried that the cases will have a chilling effect on free speech. *Id.* Companies often point to meritless claims like the two-dozen dismissed claims surrounding vanilla flavorings. *Id. See* Caldwell, *supra* note 7. The dramatic rise in food label litigation has some food producers worried that the threat of court costs and legal fees is only a means to extort monetary settlements. *Id. See generally* Silverman & Mueblberger, *supra* note 68 (criticizing recent rise in food label class actions).

[147] *See* Jacobs, *supra* note 7. If companies constantly fear potential litigation, they may worry that even truthful and accurate information could leave them vulnerable. *Id. See also* Caldwell, *supra* note 7 (quoting Ivan Wasserman food litigation's potential to chill free speech); *see also* Negowetti, *supra* note 48, at 23 (noting food producer confusion regarding food label standards); *see also* Fitzgerald, *supra* note 69 (suggesting compliance with federal regulations not enough to avoid litigation).

effectively via packaging.[148] Moreover, the rise in litigation adversely effects small, independently owned businesses that are targeted and lack the resources of larger corporations.[149] Litigation is an expensive and time-consuming process that is unlikely to inspire the widespread, consistent change necessary to fill the gap in enforcement of misleading food label violations.[150]

E. Proposed Solutions

The significant rise in food label litigation has revealed a stark gap in the regulatory enforcement of purely misleading food label practices.[151] Food label regulations should be consistent, easy to understand, and straightforward to implement.[152] A government entity with proper authority should define and enforce misleading food label regulations rather than the courts, because of the severely inconsistent treatment of food label litigation across jurisdictions.[153] The FDA and the FTC are in the best position

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[148] *See* Jacobs, *supra* note 7 (quoting food lawyers on negative aspects of rise in food label litigation). Ivan Wasserman, a food lawyer in Washington D.C., is worried that the cases will have a chilling effect on free speech. *Id. See also* Caldwell, *supra* note 7 (quoting Ivan Wasserman on food litigation's potential to chill free speech).

[149] *See* Silverman & Mueblberger*, supra* note 68, at 15-16 (describing adverse effect of food label litigation on small businesses). The cost of initiating a cut-and-paste complaint is nominal, but hiring a lawyer to respond to a lawsuit by way of litigation or settlement can have a huge impact on a small business. *Id.* at 16.

[150] *See* Negowetti, *supra* note 48, at 23. Ideally, litigation should be unnecessary if the FDA is able to fulfill its regulatory mission and responsibilities. *Id. See also* Caldwell, *supra* note 7 (arguing in favor of legislative regulation over regulation by litigation). *See generally* Meyer, *supra* note 54 (identifying regulatory gap left by FDA); Gerhart, *supra* note 24 (identifying gap in misleading food label enforcement); Silverman & Mueblberger*, supra* note 68 (describing lawyer exploitation of current regulatory gap).

[151] *See* Negowetti, *supra* note 48, at 1. The FDA lacks the resources and authority to effectively regulate the misleading labeling practices which are the focal point of the recent rise in food label litigation. *Id.* at 2. *See also* Kincheloe, *supra* note 54 (calling labeling litigation evidence of ineffective regulatory system). Consumers are trying to enforce regulations in court, while the offending products often remain on the shelves. *Id. See also* Caldwell, *supra* note 7 (attributing litigation by consumer advocates to weak government oversight); Dahl, *supra* note 68 (attributing surge in litigation to frustration over current regulations). *See generally* Silverman & Mueblberger*, supra* note 68 (describing food litigation as an exploitation of current regulatory gap).

[152] *See* Silverman & Mueblberger*, supra* note 68 (suggesting federal agencies close regulatory gaps and provide uniform labeling definitions); Meyer, *supra* note 54 (suggesting implementation of new simple, easy to understand labeling system); Gerhart, *supra* note 24 (suggesting some consolidation of FDA/FTC resources to simplify enforcement processes and regulations). *See generally* Negowetti, *supra* note 48 (suggesting improvements to current regulatory standards).

[153] *See* Negowetti, *supra* note 48, at 23. Regulation through litigation is slow, costly, generally ineffective at bringing forth change. *Id.* Additionally, leaving the enforcement of food label regulation to the judiciary is contrary to the legislative purpose of both the FDCA and NLEA in establishing uniform labeling laws. *Id. See also* Gerhart, *supra* note 24 (arguing in favor of consolidating FDA and FTC). Many benefits would come from a consolidation of FDA and FTC resources and enforcement powers, including enforcement consistency and conservation of agency resources. *Id.* Kipnees, *supra* note 57 (examining courts' inconsistent treatment of Warning Letters as evidence in food label litigation); Fitzgerald, *supra* note 69 (observing differing views of misleading food label claims between Massachusetts District Court and First Circuit). The Federal District Court in Massachusetts seems to view misleading food label claims with skepticism, showing an inclination for dismissals. *Id.* Conversely, the First Circuit has shown

to enforce misleading food label regulations because of the existing concurrent jurisdiction over misbranding practices of food labeling and advertisements.[154]

To eliminate inconsistencies and confusion, the FDA and FTC should amend their existing Memorandum of Understanding to allow for active collaboration between the two agencies.[155] Creating a more integrated and collaborative system would encourage utilizing resources from both organizations to identify misleading advertising and food labeling concurrently.[156] Working together to monitor intertwined misleading advertisements and food labels would promote consistent standards for identifying

more of a willingness to give plaintiffs their day in court. *Id.* *See also* Zabriskie, *supra* note 7 (noting Midwestern food label litigation decisions were mixed bag at district court level). Midwestern courts have come to differing conclusions in cases involving claims about food products being free of artificial ingredients or preservatives. *Id.* *See generally* Silverman & Mueblberger, *supra* note 68 (providing examples of inconsistent rulings); Meyer, *supra* note 54 (arguing in favor of expanded FDA authority).

[154] *See Fair Packaging and Labeling Act: Regulations Under Section 4 of the Fair Packaging and Labeling Act*, *supra* note 46 (authorizing FDA and FTC to enact labeling regulations to prevent consumer deception); *see also Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, supra* note 48 (allocating responsibility for misleading label regulation to FDA); Armstrong, *supra* note 48, at 5. The Memorandum of Understanding was entered into because of the concurrent jurisdiction shared by the FDA and FTC over the regulation of misleading labels. *Id.* Gerhart, *supra* note 24 (describing necessity of FDA/FTC cooperation). Advertisements and food labels are so closely related that the FDA and FTC often must communicate and cooperate when dealing with misleading claims. *Id.* Negowetti, *supra* note 48, at 3 (describing FDA and FTC concurrent jurisdiction). Because of the close relationship between food labels and advertising, the FTC and the FDA are often monitoring the same claims made by the same companies, but across different forms of media. *Id.* at 22.

[155] *See Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration, supra* note 48. "With exception of drugs, the Federal Trade Commission has primary responsibility with respect to the regulation of the truth or falsity of all advertising (other than labeling) of food, drugs, devices, and cosmetics." *Id.* "In the absence of express agreement between the two agencies to the contrary, the Food and Drug Administration will exercise primary jurisdiction over all matters regulating the labeling of food, drugs, devices, and cosmetics." *Id.* *See also* Gerhart, *supra* note 24 (noting ease of amending Memorandum). The Memorandum of Understanding allows for either party to revoke the Understanding with as little as thirty days' notice. *Id.* Currently, the FTC and FDA hold the term "misleading" to two different standards, which results in industry confusion. *Id.* *See generally* Negowetti, *supra* note 48, at 18 (providing example of FCT enforcement of misleading advertisement with no concurrent FDA label enforcement); Meyer, *supra* note 54 (having multiple agencies regulating same area results in confusion and conflicting laws).

[156] *See* Negowetti, *supra* note 48, at 22 (suggesting FDA work more closely with FTC to monitor misleading claims). The line between labeling and advertising is so blurred that the two agencies are likely investigating the same claims only across different mediums. *Id.* at 22. Combining the two organizations would also help establish more consistent requirements for claims made in food marketing. *Id.* *See also* Gerhart, *supra* note 24 (emphasizing need for FTC to compensate for depleted FDA capabilities due to underfunding).

misleading practices and imposing disciplinary enforcement.[157] Merging FDA and FTC standards would eliminate existing industry and consumer confusion.[158]

The FDA should also create legally enforceable definitions for commonly litigated terms in misleading food label claims.[159] Clarifying commonly used food packaging terminology would provide actionable guidance to food producers and eliminate one of the most popular subjects in misleading food label litigation.[160] Limiting health and function assertions on the front of food packaging would also eliminate much of the ongoing and prospective food label litigation.[161] Resolving commonly litigated

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[157] *See* Negowetti, *supra* note 48, at 22. Closer FDA and FTC collaboration would eliminate instances of inconsistent enforcement because either agency could pursue all of the misleading content, rather than only the portion within their jurisdiction. *Id.* at 18. *See also* Gerhart, *supra* note 24 (noting FDA and FTC progress towards cohesive regulation). Eliminating the Memorandum of Understanding would allow the agencies to work more closely, allowing for more increased flexibility in the allocation of enforcement responsibilities and resources, and encourage progress towards more unified regulatory standards. *Id.*

[158] *See* Meyer, *supra* note 54, at 242. Multiple regulatory agencies overseeing the same things inherently leads to consumer and industry confusion. *Id. See also* Gerhart, *supra* note 24 (outlining conflicting FDA/FTC standards for "misleading"). It is easier to define a message as misleading under the FDA standard, as opposed to the FTC's standard used by the FTC. *Id.* The two different standards for "misleading" used by the FDA and FTC have led to industry confusion among food producers. *Id. See generally* Negowetti, *supra* note 48 (attributing industry and consumer confusion to differing agency standards).

[159] *See* Negowetti, *supra* note 48, at 20-21 (advising FDA to rethink approach to health claims and terminology on food packaging). Research has shown that consumers are routinely confused about the validity of health claims made on food packaging. *Id.* at 21. Food processing has advanced in such a way that the average consumer cannot be expected to accurately evaluate how healthy or natural a given food product is without the help of label indications. *Id.* at 20. Consumers should be able to rely on an agency with their interests in mind to ensure consistency about how terms and food descriptions may be used on food packaging. *Id. See* Kincheloe, *supra* note 54 (noting confusion over definitions in food industry); *see* Caldwell, *supra* note 7 (identifying common terms as focus of rising food label litigation). *See generally Use of the Term Natural on Food Labeling, supra* note 53 (stating FDA policy concerning the term "natural"); *see generally Draft Guidance for Industry and FDA Staff: Whole Grain Label Statements, supra* note 53 (containing non-binding statement to provide industry guidance for using "whole grain").

[160] *See* Silverman & Muehlberger*, supra* note 68, at 48 (suggesting creating uniform definitions for common labeling terms). The FDA should use current litigation trends to identify terms in need of defining and provide uniform definitions to prevent the need for litigation. *Id. See also* Negowetti, *supra* note 48, at 20 (urging FDA to define commonly used terms to achieve uniformity and consistency); s*ee also* Caldwell, *supra* note 7 (identifying common terms as focus of rising food label litigation).

[161] *See generally* Negowetti, *supra* note 48 (noting consumer confusion over health and function claims on packaging). A function claim is defined as a claim that describes the effect that a particular substance has on the function of the body, like "calcium builds strong bones." *Id.* at 5. Studies have indicated that consumers equate function claims with health claims made about the food products to which they are attached. *Id.* at 21. However, the FDA does not currently indicate the level of scientific support needed for a function claim to survive a misleading food label challenge, nor does the FDA pre-approve function claims made on food packaging. *Id.* at 22. Eliminating health and function claims from the front of food packaging would help protect consumers from deceptive practices. *See* Negowetti, *supra* note 48. *See generally* Meyer, *supra* note 54 (arguing for prohibition of function claims). Function claims are susceptible to misleading practices because they do not require pre-approval by the FDA and do not actually assert proven

issues would result in a decline in litigation and significantly reduce the regulatory gap that current litigation is attempting to fill.[162]

Additionally, a nutrition grading system that is easy to understand and affixed to the front of food labels, would install a reliable health signifier for consumers.[163] Such a system should be implemented by the FDA, and would provide consistent information to replace the current hodge-podge of misleading health identifiers presented by food manufacturers.[164] An FDA-imposed system would decrease misleading practices by allowing an organization motivated by consumer protection to assign grades, rather than profit-motivated manufacturers.[165]

The FDA can also reduce misleading food label litigation by imposing a pre-market approval process for food labels, thus eliminating reliance on voluntary compliance, spot-checking, and consumer reporting.[166] Other agencies, like the USDA, have successfully implemented a pre-market approval process, reducing the risk of misleading food labels making it onto shelves.[167] To effectively implement a pre-market approval process, the FDA should focus on inspector training to ensure that misleading packaging can be identified efficiently and consistently.[168] Checking each proposed food

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nutritional benefits relating to the product they are attached to. *Id.* at 277. So as not to infringe upon the right to free speech, health claims should be held to a pre-approval process and subject to disclaimer modifications as the FDA deems appropriate. *Id.* at 281. *See generally* Silverman & Muehlberger, *supra* note 68 (listing health claim disputes as one of the most common food litigation claims).

[162] *See* Kincheloe, *supra* note 54 (calling labeling litigation evidence of ineffective regulatory system); *see also* Caldwell, *supra* note 7 (attributing litigation by consumer advocates to weak government oversight); *see also* Dahl, *supra* note 68 (attributing surge in litigation to frustration over current regulations). *See generally* Negowetti, *supra* note 48 (describing litigation disputing misleading health and function claims); Meyer, *supra* note 54 (noting lack of FDA regulation over health and function claims).

[163] *See* Meyer, *supra* note 54, at 280; *see also* Sanzo*, supra* note 81 (summarizing proposed legislation to implement symbol system to indicate food health value).

[164] *See* Meyer, *supra* note 54, at 281 (proposing stream-lined grading system to indicate food health value); *see also* Sanzo*, supra* note 81 (summarizing proposed legislation implementing symbol system to indicate food health value). The 2021 Bill would establish a symbol system to alert consumers to unhealthy foods, as well as a front of package grading system to rank foods in accordance with their health value. *Id. See also* COVINGTON*, supra* note 80 (proclaiming success of other countries implementing systems similar to proposed in 2021 Bill).

[165] *See generally* Meyer, *supra* note 54 (describing benefits of package labeling system controlled by FDA). Consumers would benefit from an FDA-imposed system because the primary purpose of the FDA is to protect consumer interests, unlike profit-driven food producers. *Id.* at 281. Having a single regulatory agency make clear rules and regulations regarding front of package food labels would eliminate industry confusion and promote consistency. *Id.* at 235.

[166] *See* Kincheloe, *supra* note 54 (urging FDA to switch to pre-approval process for food label regulation). Both the EU and the USDA utilize pre-market approval processes without issue. *Id. See also* Negowetti, *supra* note 48, at 22 (arguing pre-approval requirement would help protect consumers from deceptive practices). *See generally* Meyer, *supra* note 54 (identifying lack of pre-approval requirement as pitfall of FDA enforcement).

[167] *See* Kincheloe, *supra* note 54. *See generally* Meyer, *supra* note 54 (describing inefficiency of current FDA reliance on spot-checking for label violations).

[168] *See generally* Negowetti, *supra* note 48 (recommending better training for FDA inspectors). Inspectors should receive more thorough training to help them effectively identify misleading

label would decrease misleading labels in the marketplace and reduce potential litigation.[169] Finally, the FDA should monitor ongoing food label litigation trends to identify and address regulatory gaps.[170]

Congress should also widen FDA authority to impose sanctions against violations.[171] The DOJ cooperation requirement prevents the FDA from imposing sanctions freely.[172] Congress should encourage the FDA to use its authority to fine corporations found to consistently skirt regulations.[173] Regulations will be taken more seriously if the FDA can impose fines significant enough to impact company profits.[174] Congress should also empower the FDA to request substantiation for claims made on food packaging so that questionable assertions can be verified.[175]

None of the above recommendations are actionable unless the FDA sees a substantial increase in funding and resources.[176] Unfortunately, the current political

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food labels. *Id.* at 23. The current inspector guidance manual lacks instructions to aid inspectors in identifying false and misleading claims. *Id. See generally* Meyer, *supra* note 54 (pointing out understaffing problems within FDA); *see generally* Kincheloe, *supra* note 54 (urging FDA switch to a pre-approval process for food label regulation).

[169] *See generally* Negowetti, *supra* note 48 (arguing food label pre-approval procedure will effectively protect consumers from deception); *see also* Meyer, *supra* note 54 (describing spot-checking process as ineffective to stop deceptive labeling practices). A pre-approval process would more efficiently identify potential violations and largely eliminate the need for consumer litigation. *Id.*

[170] *See* Silverman & Mueblberger, *supra* note 68, at 48. Food label litigation exposes regulatory and enforcement gaps in food label regulations. *Id.*

[171] *See* Kincheloe, *supra* note 54. Congress should restructure the FDA to allow the imposition of sanctions more easily for food label violations because companies have realized that there is little danger in utilizing misleading practices. *Id. See also* Meyer, *supra* note 54, at 241 (observing companies' treatment of government fines as cost of doing business). Large food manufacturers generate so much profit that FDA imposed fines have no effect on their bottom line. *Id. See generally* Negowetti, *supra* note 48 (describing insufficient FDA enforcement authority to impose sanctions for purely misleading label practices); Armstrong, *supra* note 48 (describing FDA need to coordinate with DOJ for most enforcement actions). Because of a lack of independent litigation authority, the FDA must coordinate with the DOJ if it wishes to impose more serious sanctions for misconduct. *Id.*

[172] *See* Armstrong, *supra* note 48 (describing FDA cooperation with DOJ in enforcement actions).

[173] *See* Kincheloe, *supra* note 54. *See generally* Meyer at 241, *supra* note 54, at 241 (questioning efficacy of FDA authority to impose fines). More frequent imposition of fines by the FDA would likely do more to encourage compliance than Warning Letters, because companies are motivated by their bottom line. *Id.*

[174] *See generally* Meyer at 241, *supra* note 54, at 241 (arguing current fines are not enough to warrant attention or reaction from companies).

[175] *See* Negowetti, *supra* note 48, at 22. Without the authority to require companies to substantiate claims made on food packaging, establishing whether a claim is supported by scientific evidence will prove very costly and time consumer for the FDA. *Id.* Another solution would be for the FDA to utilize resources from the FTC by working more closely with the agency to monitor advertising and labeling claims concurrently. *Id.*

[176] *See* Negowetti, *supra* note 48, at 22 (stating increased budget for FDA is necessary to implement change). "To properly fulfill its statutory mission, the FDA will require an increased budget and the political will to monitor the marketplace." *Id.* The FDA has repeatedly acknowledged that resource limitations are a reason for not pursuing purely misleading label violations or defining commonly used package terms. *Id.* at 9, 12-13. *See generally* Gerhart, *supra*

system allows "Big Food" lobbyists to assert powerful influence over the regulatory leanings of political leaders.[177] Skepticism therefore surrounds the probability of substantive regulatory change because lawmakers may be unwilling to broaden proposals to the extent suggested above.[178] However, significant systematic change is necessary to successfully fill the regulatory gap identified by the recent increase in food label litigation.[179]

V. Conclusion

Congress created the FDA to function as a consumer protection agency against deceptive, misleading, and unsafe industry practices. However, recent litigation over misleading food labels has exposed gaps in the FDA's regulatory and enforcement abilities. The FDA can fill these gaps by imposing formal definitions for commonly used food packaging terms, eliminating front of package health and function claims, and implementing a grading system to indicate food health value. Moreover, the FDA can prevent future claims by subjecting food labels to a pre-market approval process. Regulatory compliance can be assured by substantially increasing the FDA's budget, enforcement capabilities, and collaboration with the FTC. A well-funded agency with adequate authority is needed to protect consumers from predatory food label marketing; that agency is the FDA.

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note 24 (pointing out depleted FDA resources). The FDA has downplayed the prevalence of misleading label violations because it lacks the resources to pursue such claims. *Id. See generally* Meyer, *supra* note 54 (listing lack of FDA resources as reason for prioritization of responsibilities). The FDA has too many regulatory responsibilities for the number of resources at its disposal. *Id.*

[177] *See generally* Gostin, *supra* note 79 (describing practices of food industry lobbyists). Food lobbyists seek out politicians who have antiregulatory leanings. *Id.* Not only do food lobbyists target lawmakers, but they also focus their funds and efforts on influencing regulatory agencies. *Id. See generally Industry Profile: Food & Beverage, supra* note 79 (showing statistics of political monetary donations to campaigns by food lobbyists).

[178] *See generally* COVINGTON, *supra* note 80 (expressing uncertainty over viability of 2021 Act). Two prior versions of the Bill have failed to pass in recent years and there has been some skepticism about the chances of the 2021 Act passing. *Id. See generally Food Labeling Modernization Act Reintroduced in Congress*, *supra* note 81 (describing extent of the proposed law).

[179] *See* Jacobs, *supra* note 7 (declaring need for drastic systematic change); *see also* Kincheloe, *supra* note 54 (identifying labeling litigation as evidence of ineffective regulatory system). Consumers are trying to enforce regulations in court, while the offending products often remain on the shelves. *Id. See also* Caldwell, *supra* note 7 (attributing litigation by consumer advocates to weak government oversight); Dahl, *supra* note 68 (attributing surge in litigation to frustration over current regulations). *See generally* Silverman & Mueblberger, *supra* note 68 (describing food litigation as exploitation of current regulatory gap); Meyer, *supra* note 54 (proposing systematic changes to FDA regulatory systems and authority to eliminate consumer deception); Negowetti, *supra* note 48 (proposing systematic changes to fill current regulatory gap). The FDA lacks the resources and authority to effectively regulate the misleading labeling practices which are the focal point of the recent rise in food label litigation. *Id.* at 2.