COMMENT

IS THE FDA NUTS? AN OVERVIEW OF THE FDA'S ENDEAVOR TO REDEFINE THE TERM "HEALTHY"*

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I. INTRODUCTION

Food products in the United States have displayed labels for over fifty years, but these labels were generally ignored until recently.[1] Today's supermarkets are crowded with product labeling that boasts a variety of health benefits consumers may reap from eating a particular food.[2] One purpose of these enticing labeling claims on a product's packaging is to accommodate busy Americans who do not have time to digest an entire nutrition label by quickly alerting them to a nutritious food choice.[3] In turn, manufacturers hope that consumers may be more inclined to purchase their products based on the health and nutritive statements that the products promise.[4] Clear health claims have been empirically proven to benefit manufacturers in terms of consumer purchasing decisions, and a recent experiment concluded that consumers were actually willing to pay more for products that bear organized and concise labeling as opposed to chaotic packaging environments that may take too long to comprehend.[5]

Additionally, the Food and Drug Administration (FDA), an agency that is charged with safeguarding the nation's food and drug

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1. *Why Are Food Labels Important*, FOODPACKAGINGLABELS.NET, http://www.foodpackaginglabels.net/food-labels/ [https://perma.cc/G32L-KES9] ("With the rise of problems and diseases associated with poor eating habits, people are increasingly reading the information printed on food packaging labels.").

2. J. Craig Andrews et. al., *Consumer Research Needs from the Food and Drug Administration on Front-of-Package Nutritional Labeling*, 33 J. PUB. POL'Y & MARKETING 1, 10–11 (2014) (noting that some common examples might include structure/function claims (e.g., "helps promote heart health,"); nutrient-content claims and symbols (e.g., "low in saturated fat," with heart images); health claims (e.g., "calcium rich foods such as yogurt may reduce the risk of osteoarthritis"); or dietary guidance statements (e.g., "grain foods may reduce the risk of heart disease.")).

3. *Id*. Other primary roles of food labels include informing consumers of a food's nutritional values and ingredients, its manufacturer, and possible allergens contained in the product. *Why Are Food Labels Important*, FOODPACKAGINGLABELS.NET, http://www.foodpackaginglabels.net/food-labels/ [https://perma.cc/G32L-KES9].

4. *Benefits of Nutrition Information and Food Labels*, CENTRE FOR FOOD SAFETY (Feb. 24, 2010), http://www.cfs.gov.hk/english/programme/programme_nifl/programme_nifl_02.html [https://perma.cc/3KY3-UUBQ].

5. Global Health and Wellness Report, NIELSEN, *We Are What We Eat: Healthy Eating Trends Around the World* (January 2015), https://www.nielsen.com/content/dam/nielsenglobal/eu/nielseninsights/pdfs/Nielsen%20Global%20Health%20and%20Wellness%20Report%20-%20January%202015.pdf [https://perma.cc/D4Q4-EDXR].

supply,[6] considers easy access to reliable information about calories and nutritive content in food products an important objective for the agency.[7] Simply put, food labeling[8] is an important indicator that American consumers rely on in making food product selections, and its regulation is vital to our marketplace.[9]

This comment analyzes the FDA's recent mission to redefine the term "healthy" as it relates to its regulations governing food-labeling claims.[10] Part II discusses the FDA's authority to regulate claims made in food product labeling and accompanying promotional material.[11] Part III highlights the recent controversy that has unfolded relating to the FDA's archaic definition of the word "healthy," which seems to contradict other government agencies' interpretations of the term.[12] This part also highlights one manufacturer's successful initiative to pioneer a reform of the definition.[13] Part IV recalls a similar incident involving outdated government standards and outlines the harsh effects of

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6. 21 C.F.R. § 7.1 (2000); Ann Mileur Boeckman, Comment, *An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco*, 45 CATH. U.L. REV. 991, 991 (1996).

7. Margaret A. Hamburg, Comm'r of the Food and Drug Admin., Remarks at the Nutrition Summit, Events (April 28, 2010) (*available at* http://www.fda.gov/newsevents/speeches/speecharchives/ucm209954.htm) [https://perma.cc/23TT-FGRC].

8. The food industry is not the only realm where Americans rely heavily on labeling claims. For example, the FDA requires full disclosure of ingredients in the labeling of cosmetic products. Scholars have noted that these regulations diminish the hazard to consumers from reactions to unknown ingredients and also afford consumers the opportunity to compare different cosmetic brands to ultimately make a purchasing determination based on the quality of ingredients in relation to the price of a particular cosmetic product. Ronald G. Fischer, *Cosmetic Labeling: The FDA's Response to Consumer Needs*, 14 SANTA CLARA LAW. 542, 553–54 (1974).

9. Christopher Chen, *Food and Drug Administration Food Standards of Identity: Consumer Protection Through the Regulation of Product Information*, 47 FOOD & DRUG L.J. 185, 185–86 (1992) ("Food is among the most basic and valuable commodities known to human society. Thus, it is not surprising that governments for centuries have sought to prohibit fraud in the manufacturing and marketing of food . . .").

10. *See infra* Parts II–VI (explaining the FDA's endeavor to redefine the term "healthy" in light of increased public and industry pressure and inconsistencies between related government agencies).

11. *See infra* Part II (detailing the Federal Food, Drug, and Cosmetic Act (FDCA) as the FDA's enabling statute that grants the agency jurisdictional authority over food labeling, among other products and the Nutrition Labeling and Education Act (NLEA), which clarified the scope FDA's regulatory authority over claims made in a food product's labeling).

12. *See infra* Part III (summarizing the litigation sparked by an FDA warning letter that was recently sent to Kind, LLC, a leading manufacturer of nut-based bars and other nutritious snack products).

13. *See infra* Part III (noting a pending lawsuit initiated by Kind, LLC against the government and the FDA's subsequent announcement of its plans to redefine the regulatory definition of the term "healthy").

overbearing and strictly enforced government regulations.[14] Part V discusses the FDA's response to the recent outcry involving its definition of "healthy."[15] Part VI notes additional concerns that the FDA should be aware of in redefining the term "healthy," including the evolving constitutional boundaries of commercial speech cases and the need to ensure that the new definition allows room for future innovation within the food industry.[16] Part VII concludes by offering some alternative solutions for the FDA to revise and improve its current definition of "healthy" in a manner that accounts for all of the competing interests involved in this controversy.[17]

II. A BRIEF HISTORY OF THE FDA'S AUTHORITY TO REGULATE PRODUCT LABELING

As an executive agency, the FDA receives its authority from Congress.[18] The Federal Food, Drug, and Cosmetic Act (FDCA) authorizes the FDA to exercise jurisdiction over the national regulation of food, drugs, medical devices, and cosmetic products.[19]

A. *The Food and Drug Cosmetic Act*

In 1938, Congress enacted the FDCA to address the public's growing concern for unsafe foods, drugs, and marketing schemes.[20] Among other things, the FDCA charged the FDA with the responsibility to regulate the statements made in a food product's labeling to ensure that the label is not "false or misleading in any

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14. *See infra* Part IV (examining a period of prolonged litigation from the 1920s through the 1980s in response to Congress' Filled Milk Act as an example of the United States government's history of strong food identity standards and discussing the eventual downfall of the Filled Milk Act).

15. *See infra* Part V (analogizing controversies surrounding the FDA's ambiguous definition of the term "natural" in food labeling to the current problem that the FDA is grappling with in its mission to redefine the term "healthy" and the negative impact on public health that would result if the FDA were to exercise its enforcement discretion and decline to assert jurisdiction over food labeling claims entirely).

16. *See infra* Part VI (discussing the constitutional boundaries posed by freedom of speech concerns and the United States Supreme Court's shift in attitude on commercial speech cases as well as other practical implications that a new definition of "healthy" could have on industry innovation and predictability of a regulatory framework).

17. *See infra* Part VII (posing some statutory schemes that are tailored to the particularities of the healthy snack industry by allowing the term "labeling" to be bore by food products on a variety of alternative bases instead of exclusively being measured by fat content).

18. 21 C.F.R. § 7.1 (2000); *See* Boeckman, *supra* note 6, at 991.

19. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 (1938) [hereinafter FDCA].

20. *Id.* The FDCA replaced the Wiley Act of 1906, which only offered modest reforms to the food labeling industry and failed to grant the government any affirmative power to require industry compliance. Caroline Q. Shepard, *"Natural" Food Labeling: False Advertising and the First Amendment*, 16 MARQ. ELDER'S ADVISOR 173, 177–78 (2014).

particular."[21] "Labeling" is statutorily defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying any such article."[22] If a product's labeling is "false or misleading in any particular," the product is misbranded and the FDA may exercise a broad range of enforcement powers against the manufacturer.[23] The FDCA's adulteration provisions also instruct the FDA to promote honesty and fair dealings in the interest of consumers by promulgating reasonable food definitions and standards of identity.[24]

The FDA's authority to deem a food product misbranded is also bolstered by the provisions contained in FDCA § 201(n), which expands the scope of a product's "labeling" subject to the misbranding standard.[25] Under FDCA § 201(n), "labeling" includes any representations made or suggested by a manufacturer's statement, the product's overall design and packaging, and the extent to which a product's label fails to reveal material facts in light of the representations made relative to the consequences that may result from the labeling.[26] Simply put, the intended use of a product may be divined from advertising as well as labeling.[27] Therefore, a significant portion of promotional material may still be within the FDA's purview and could potentially be subject to its enforcement powers.[28] In light of Congress' expansive interpretation of the term "labeling" and the FDA's position on interpreting a product's "intended use," the FDA has broad authority to regulate claims made in a variety of labeling, packaging, and promotional materials.[29]

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21. FDCA § 403(n) (codified as 21 U.S.C. § 343(a) (2012)) ("A food shall be deemed to be misbranded . . . [i]f (1) its labeling is false or misleading in any particular.").

22. FDCA § 201(m) (codified as 21 U.S.C. § 321(m) (2012)).

23. The FDA has many enforcement mechanisms through which it may enforce its authority under the FDCA, including, among others: injunction proceedings, civil money penalties, seizure and condemnation, criminal prosecution, and debarment. FDCA § 403(n) (codified as 21 U.S.C. § 343(a) (2012)); 21 U.S.C. §§ 332–337 (2012).

24. FDCA § 401 (codified as 21 U.S.C. § 341 (2012)) ("Whenever in the judgment of the Secretary, such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container."); *see also* Chen, *supra* note 9, at 191 (noting that FDCA § 401 "gives the FDA broad discretion to determine the precise form and criteria of a standard of identity").

25. FDCA § 201(n) (codified as 21 U.S.C. § 321 (2012)).

26. *Id*.

27. *See* 21 C.F.R. § 201.128 (1994); Hanson v. United States, 417 F. Supp. 30, 35 (D. Minn.) (1976) (noting that it is "well established that the 'intended use' of a product, within the meaning of the [FDCA], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.").

28. Lars Noah & Barbara A. Noah, *Liberating Commercial Speech: Product Labeling Controls and the First Amendment*, 47 FLA. L. REV. 63, 69-70 (1995).

29. *See* FDCA § 201(n) (codified as 21 U.S.C. § 321 (2012)); 21 C.F.R. § 201.128 (1994);

B. *The Nutrition Labeling and Education Act*

The FDA's jurisdiction over food product labeling dramatically increased when Congress passed the Nutrition Labeling and Education Act (NLEA),[30] which amended the FDCA[31] and completely overhauled the existing nutritional labeling requirements.[32] NLEA introduced a number of substantial reforms.[33] Pertinently, NLEA required nutritional claims such as "healthy" to conform to standards[34] promulgated by the FDA in order to appropriately use the phrase on food product packaging and marketing materials.[35] In other words, manufacturers were now subject to strict compliance with the FDA's standards in order to legally keep their products on market shelves.[36] The FDA was also entitled to use its enforcement power against manufacturers for violation of NLEA provisions in the same way that it could proceed against non-compliant manufacturers under the FDCA.[37]

Acting under its new authority from NELA, the FDA began promulgating regulations that set forth specific requirements that

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Hanson, 417 F. Supp. at 35; Noah et al., *supra* note 28, at 70.

30. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990) (codified at 21 U.S.C. § 343(q), (r) (2014))[hereinafter NLEA]. The regulations assisting NLEA are located in 21 C.F.R. § 101.9 (2014). Prior to NLEA, in 1966, Congress passed the Fair Packaging and Labeling Act (FPLA), which also imposed regulations on food products under FDA's jurisdiction, but this Act was unsuccessful because manufacturers were still not required to obtain affirmative FDA approval for product labels advertising food products that would be sold to consumers. 15 U.S.C. § 1451 (2012); Patricia Curtis, *Food Labeling*, GUIDE TO FOOD LAWS AND REGULATIONS 86 (1st ed. 2005).

31. Despite the vast change in regulatory landscape that was provided by NLEA, the FDA Commissioner, Doctor Margaret Hamburg, noted in 2009 that, "the public health importance of food labeling as an essential means of informing consumers about proper nutrition . . . has not been substantially addressed since the FDA implemented the Nutrition Labeling and Education Act." Margaret A. Hamburg, Comm'r of the Food and Drug Admin., Keynote Address at National Food Policy Conference (Sept. 8, 2009), (*available at* http://www.fda.gov/NewsEvents/Speeches/ucm182061.htm, archived at http://perma.cc/VC99-FY9J) (noting food labeling has not changed since NLEA).

32. Holk v. Snapple Beverage Corp., 575 F.3d 329, 332 (3rd Cir. 2009); Julie M. Muller, Note, *Naturally Misleading: FDA's Unwillingness to Define "Natural" and the Quest for GMO Transparency Through State Mandatory Labeling Incentives*, 48 SUFFOLK U.L. REV. 511, 522 (2015).

33. Shepard, *supra* note 20, at 179 (noting several reforming provisions of the NLEA, including: expanded coverage of products under NLEA's purview, changed substance and form of ingredient labels, and standardized definitions of nutrient content claims and serving sizes).

34. *See Holk*, 575 F.3d at 331–32 (describing FDA's function under FDCA and outlining NLEA reforms)*; see also* Erik Benny, *"Natural" Modifications: The FDA's Need to Promulgate an Official Definition of "Natural" that Includes Genetically Modified Organisms*, 80 GEO. WASH. L. REV. 1504, 1509–10 (2012) (explaining purpose of NLEA).

35. *See Holk*, 575 F.3d at 332; Muller, *supra* note 32, at 522.

36. *Holk*, 575 F.3d at 332

37. *See* CURTIS, *supra* note 30, at 96.

had to be satisfied in order for a product to bear nutrient content claims.[38] After these regulations were promulgated, a study of consumer use of the new nutrition label revealed that the regulations did not motivate Americans to significantly alter their consumption habits as the government hoped.[39] Rather, the regulatory scheme that FDA created has been criticized as "highly technical[,] . . . detailed and complex."[40] For example, the FDA's current standards for "healthy" products impose absolute limits on the amounts of fat, saturated fat, and cholesterol that the product bearing the claim may contain.[41] Pursuant to these strict standards, any product that exceeds the regulatory maximum levels of fat, saturated fat, or cholesterol is automatically barred from making any implied nutritive health claim that the product is "healthy," regardless of any other nutritive benefits that a higher fat content food may provide.[42] The ironclad labeling rules also constrained food industry advertising, a realm in which the FDA generally does not have the authority to regulate.[43]

This comment addresses the current controversy surrounding the FDA's regulatory definition of "healthy," revisits a similar historic controversy, analyzes the common problem that the FDA faces in defining inherently subjective terms, discusses important considerations that the FDA should not ignore in redefining the term "healthy," and proposes some alternative, more malleable methods for determining what food products may properly claim to be "healthy."

III. RECENT CONTROVERSY REGARDING "HEALTHY" FOOD PRODUCTS

Recently, the FDA's standards have sparked controversy because the inflexible guidelines fail to accommodate shifting societal views that stray from the pejorative notions that high fat foods once carried.[44] Instead, the FDA's current standards neglect

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38. 21 C.F.R. §§ 101.54–101.69.

39. *See* Jennifer Steinhauer, *Food Plus Facts Does Not Equal Action*, N.Y. TIMES, May 10, 1995, at C1.

40. In re: Kind LLC "Healthy and All Natural" Litigation, No. 1:15-md-02645-WHP, 2016 WL 4727935 at *1 (S.D.N.Y. 2016); *see also* Noah et al., *supra* note 28, at 67 (describing the FDA's prohibition against "false or misleading" statements as "vague").

41. 21 C.F.R. § 101.65(d)(2)(i).

42. *Id*.

43. Noah et al., *supra* note 28, at 69; *see* 21 U.S.C. § 355(n)(1994) (denying the FDA authority to regulate product advertising with the narrow exceptions of prescription drugs and restricted medical devices). The statute also calls for coordination between the FDA and the Federal Trade Commission (FTC) in the regulation of advertising for vitamin and mineral products. 21 U.S.C. § 378.

44. *See, e.g.*, Allison Aubrey, *Why The FDA Is Re-Evaluating The Nutty Definition Of*

growing consumer awareness that foods with a higher fat content might nonetheless still be healthful.[45]

This widespread change in public attitude toward acceptance of foods with a higher fat content was motivated by a recent distinction in the food industry between "good" fats, such as nuts and avocados, and "bad" fats, such as the trans fats contained in french fries.[46] The noteworthy distinction was incorporated into the 2015–2020 Dietary Guidelines, jointly published by the Department of Health and Human Services (HHS) and the Department of Agriculture (USDA).[47] Because the 2015–2020 Dietary Guidelines suggested that it could be healthy to consume higher amounts of certain fats, which stood in stark contrast to the FDA's absolute limits on fat for a product to be labeled "healthy," the conflict among these agencies served as a catalyst for the public demand that the FDA redefine its version of "healthy."[48] The FDA is now under fire.[49]

The pushback against the FDA's stringent "healthy" guidelines erupted on the national news scale when the FDA issued a warning letter to Kind, LLC (Kind), a manufacturer of nut-based, whole grain snack bars.[50] The warning letter declared that Kind's products were misbranded because the labeling impermissibly bore the term "healthy" while the nut-based bars exceeded the regulatory maximum levels of saturated fat.[51] Specifically, the FDA disapproved of Kind's labeling of certain products as "healthy and tasty, convenient and wholesome,"

'Healthy' Food, NPR (May 10, 2016, 5:05 PM), http://www.npr.org/sections/thesalt/2016/05/10/477514200/why-the-fda-is-reevaluating-the-nutty-definition-of-healthy-food.

45. *Id*.

46. *The Truth About Fats: The Good, The Bad, And The Ugly*, HARV. MED. SCH. HEALTH PUBL'NS, (August 7, 2015), http://www.health.harvard.edu/staying-healthy/the-truth-about-fats-bad-and-good [https://perma.cc/5P88-YNMP]

47. United States Department of Agriculture, *A Closer Look Inside Healthy Eating Patterns - 2015–2020 Dietary Guidelines*, (*available at* https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#saturated-fats) [https://perma.cc/R94U-ZZGD].

48. *See id*.

49. *See, e.g.*, Beth Kowitt, *In Reversal, the FDA Says 'Healthy' Can Return to Kind Bar Packaging*, FORTUNE (May 10, 2016), http://fortune.com/2016/05/10/kind-bar-healthy-fda; Ben Popken, *Some Kind Bars Must Drop 'Healthy' Label, FDA Warns*, TODAY (Apr. 15, 2015), http://www.today.com/money/some-kind-bars-arent-healthy-enough-healthy-label-fda-says-t15281 [https://perma.cc/5A3D-HU2R]

50. William A. Correll, Jr., Director of the Center for Food Safety and Applied Nutrition, *Warning Letter to Kind, LLC*, PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION (March 17, 2015), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm440942.htm [https://perma.cc/986H-S3MV]

51. *Id*.

among other health-related claims.[52] Additionally, the FDA's warning letter asserted that Kind's website impermissibly described its products as "pretty much the nirvana of healthful tastiness," and "healthy and satisfying."[53]

In response to the FDA's misbranding allegations that were contrary to recent American health trends and the 2015–2020 Dietary Guidelines, Kind launched a petition to change the FDA's "strict low-fat definition of healthy" to accommodate recent recognition among both the public and government that higher fat content does not automatically render a food unhealthy.[54]

Due largely in part to Kind's petition, the FDA acquiesced and decided that it would redefine "healthy" as "[p]art of an overall plan to provide consumers with information and tools to enable them to easily and quickly make food choices consistent with public health recommendations and to encourage the development of healthier foods by the industry."[55] The FDA cited public perception and the 2015–2020 Dietary Guidelines for Americans as its primary bases for redefining the term and modernizing its standards.[56]

In connection with its efforts to modernize the definition of "healthy," the FDA also issued a guidance document stating that the agency will not enforce[57] the existing regulatory requirements for products that use the term "healthy" if the product is not low in total fat, but has a fat profile composition that consists predominantly of mono and polyunsaturated fats.[58] The new guidance shielded Kind's nut-based bars from misbranding violations, and the FDA subsequently confirmed that Kind had satisfactorily addressed the violations alleged in the initial warning letter.[59]

Now, the FDA is seeking public input on how its new

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52. Other health-related claims included on Kind's products include: "good source of fiber," "very low sodium," and "no trans fats." *Id*.

53. *Id*.

54. Aubrey, *supra* note 44.

55. *See* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *FDA to Redefine "Healthy" Claim for Food Labeling* (2016) (*available at* https://www.fda.gov/food/newsevents/constituentupdates/ucm520703.htm) [https://perma.cc/GHE6-HRNU].

56. *Id*.

57. As an executive agency, the FDA has the authority to exercise enforcement discretion—the authority to turn a blind eye to legal violations—in deciding whether to pursue manufacturers for violations of FDCA provisions. *See* U.S. CONST. art. II, cl. 3; Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 VAND. L. REV. 671, 682-83 (2014).

58. U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *supra* note 55.

59. *See id*.

definition should operate within the existing regulatory landscape in light of shifting societal views that recognize the potential benefits of some fats.[60] In addition, the FDA has also scheduled public forums to solicit a variety of public input on the issue.[61] The central debate relates to what criteria the agency should use to promote its interests in preserving uniformity and ensuring quality among the industry's understanding of the word "healthy," while still balancing the public's interest by accounting for a varied consumer base that values the healthiness or unhealthiness of a particular product in distinct, varied ways.[62] The FDA has encountered this problem before.

IV. FILLED MILK ACT & THE FDA'S HISTORY OF STRONG FOOD STANDARDS

The FDA's promulgation of food identity standards is analogous to its prescription of guidelines for manufacturers to make proper nutritive health claims. For example, in the same way that a nut-based bar must have a low saturated fat content to bear a nutritive health claim of "healthy," peanut butter must comply with the FDA's food identity standards concerning the percentage of peanuts that it contains, type of peanuts, and amount of water among other standards.[63] Both the "healthy" claim requirements and the peanut butter food identity standards are aimed to preserve uniformity by delineating specific requirements in order to categorize a product in a way that both the manufacturer desires and the consumer will recognize.[64]

A. *Filled Milk Act and* Carolene Products

Much like the controversy that the FDA's "healthy" standards are currently facing, food identity standards previously came under fire in the 1920s when Congress passed the Filled Milk Act, which summarily banned the interstate shipment of filled milk "in imitation or semblance of milk, cream, or skimmed milk."[65] The Filled Milk Act was "based on the Congressional finding that 'filled

60. *Id*.

61. *See id*.

62. *Id*.

63. 21 C.F.R. § 164.150.

64. *See* Shepard, *supra* note 20, at 179 (noting that the standardization of labeling claims allows companies to make credible and consistent marketing claims and also educates consumers on how a particular food product fits into their unique dietary habits).

65. 21 U.S.C. §§ 61(c), 62 (declared unconstitutional in Milnot Co. v. Richardson, 350 F. Supp. 221, 226 (S.D. Ill. 1972)).

milk[66] . . . is an adulterated article of food, injurious to the public health, and its sale constitutes fraud on the public.'"[67] The purpose of the Filled Milk Act was to prevent confusion among consumers in the marketplace because the government was fearful that manufacturers were adding milk substitutes in place of natural milk fat; a substitution which the government deemed fraudulent by making milk less wholesome.[68]

Initially, the constitutionality of this statute was unsuccessfully challenged in *Carolene Products* when a manufacturer of Milnut, a compound condensed skim milk that substituted coconut oil for some milk fat, argued that the Filled Milk Act violated the Equal Protection Clause by singling out its product and banning it from interstate commerce simply because it did not comply with the Filled Milk Act's strict food identity standards.[69]

Because the Court ruled in favor of the government, and not the manufacturer, this case symbolized the Supreme Court's acceptance of the government's broad power to define, regulate, and enforce food identity standards.[70] The court accepted that the danger of confusion to the public was a sufficient rational basis to justify Congress' exclusion of certain filled milk products from interstate commerce.[71]

After *Carolene Products*, the cultural backdrop that initially justified the government's interest in banning filled milk from market shelves began to dismantle.[72] Public attitudes changed and people wanted to consume less milk fat, which lead to increased development of more milk substitute products.[73] Suddenly, a food product like milk, which used to be much simpler, was now subject to rapid innovation and became exponentially more complex to meet the public's new demands.[74]

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66. "'Filled milk' means any milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated, to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is an imitation or semblance of milk, cream, or skimmed milk, whether or not condensed, evaporated, concentrated, powdered, dried, or desiccated . . ." 21 U.S.C. § 61(c).

67. Stephen A. Weitzman, *Comment on the Filled Milk Act – District Court Overrules Supreme Court Case*, 27 FOOD DRUG COSM. L.J. 785, 785 (1972) (quoting 21 U.S.C. § 62).

68. U.S. v. Carolene Prod. Co., 304 U.S. 144, 148-49 (1938).

69. *Id*. at 146.

70. NEAL D. FORTIN, FOOD AND REGULATION: LAW, SCIENCE, POLICY, AND PRACTICE 136 (2d ed. 2017).

71. *Id*. at 138.

72. *Id*. at 147.

73. *Id*.

74. *Id*.

B. *Milnot v. Richardson*

Finally, in *Milnot v. Richardson*, a district court decided that the government needed to accommodate these developments and, in doing so, struck down the Filled Milk Act as an unconstitutional deprivation of equal protection—invalidating the law on the same grounds that initially failed in *Carolene Products*.[75] The plaintiff in this case was the Milnot Company, a successor to the Carolene Products Company which had previously litigated—and lost—the question of the constitutionality of the statute.[76]

The basis for the district court's decision in *Milnot* was that the Due Process Clause of the United States Constitution—which prohibits economic discrimination—had been violated because other imitation milk and dairy products—in this case an evaporated milk product—so similar to the product in question in composition, appearance, and use were permitted to be marketed in interstate commerce.[77] According to the court, the possibility of confusion in the marketplace that initially justified the legislation could no longer be rationally used as a constitutional prop to prevent the interstate shipment of Milnot and other similarly situated products.[78] Simply put, because other imitation milk and dairy products had emerged on the market in response to increased consumer awareness about the negative effects of milk fat, it was no longer constitutional to single out Milnot's filled milk product and ban it from the interstate market under the weak justification that some consumers may mistake Milnot for a traditional version of milk.[79]

In striking down the Filled Milk Act, the district court also referenced the societal change in attitudes on multiple occasions. The court found that if there had been any "dangers of confusion which led to the passage and judicial upholding of the Filled Milk Act many years ago . . . this court finds that the latter have long since ceased to exist," as evidenced by the fact that eleven states had already discarded their Filled Milk Acts—"five by repeal and six by court action"—and that the majority of states now permit sale of such products so long as they remain wholesome and properly labeled.[80]

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75. Milnot Co. v. Richardson, 350 F. Supp. 221 (S.D. Ill. 1972).

76. *See* Weitzman, *supra* note 67, at 785.

77. *Id*. at 786.

78. *Milnot Co.*, 350 F. Supp. at 225 ("Prevention of confusion in the market, however valid in 1944, is no longer a valid basis to sustain the Filled Milk Act, and thus to prevent only the interstate shipment of Milnot (or any other product of milk which is exactly like it).").

79. *Id*.

80. *Id*. at 224-25 n.1.

Furthermore, the court also made the following statements, which may have been of great significance in justifying its decision: "It is worth noting, also, that when the Federal Filled Milk Act was passed by Congress and upheld by the Supreme Court, the presently accepted dangers of 'cholesterol' in animal fat were almost unknown."[81] The FDA and United States Department of Justice chose not to appeal the case and the FDA instead proposed and promulgated standards for filled milk products.[82]

V. "HEALTHY" CONTROVERSY REVIVES A FAMILIAR PROBLEM: *MILNOT* HAS RE-EMERGED

The underlying problem that the government faced in connection with the Filled Milk Act has resurfaced in light of the new controversy over the FDA's definition of the word "healthy" being used as an implied nutritive health claim.[83] Specifically, the government must again grapple with the question as to what extent it can—and should—prescribe food standards that are definite enough to be enforceable while still leaving room in the standards for industry innovation and consumers who use different scales in determining whether particular foods are "healthy."[84]

While the FDA's rigid, numerically-based guidelines are certainly effective in ensuring consistency among food products, there are also some serious costs that result from this method in terms of lacking the flexibility to adapt to consumers' personal choices, being unable to accommodate new scientific conclusions that spark changes in overall societal preferences, and having no mechanisms to account for innovative products that are developed as a result of an ever-changing consumer base.

A noteworthy amount of public comments submitted in response to the FDA's solicitation of consumer input in redefining "healthy" suggested that the government simply remove itself from this conversation and abandon its regulation over "healthy" claims.[85] However, this could be a costly solution for two important reasons: (1) it could open up the opportunity for manufacturers to

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81. *Id*. at 225.

82. *See* Weitzman, *supra* note 67, at 786.

83. Aubrey, *supra* note 44.

84. *See* U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, GUIDANCE FOR INDUSTRY: USE OF THE TERM "HEALTHY" IN THE LABELING OF HUMAN FOOD PRODUCTS (Sept. 2016).

85. *See, e.g.*, Laure Chipmn, *Comment on FDA Proposed Rule: Use of the Term "Healthy" in the Labeling of Human Food Products; Request for Information and Comments*, REGULATIONS.GOV (Oct 18, 2016), https://www.regulations.gov/document?D=FDA-2016-D-2335-0011 [https://perma.cc/X4E8-9ZMR]

commit food fraud, and (2) it would fuel litigation between consumers and manufacturers. Previous case law suggests that manufacturers would certainly benefit from the FDA's abandonment of defining the term "healthy" because, if no regulatory definition of the term "healthy" existed, there could be no federal restrictions preventing products from bearing the term.[86]

Regarding food fraud, it is undisputed that the consistency requirements in the FDA's regulation of food standards are necessary to ensure that consumers are able to make informed purchasing decisions without the fear of fraud and deception.[87] Thus, economic adulteration has historically been a key concern that the FDA has sought to address through its stringent food standard requirements, and advances in food product technology have only exacerbated the opportunity for producers to commit fraud on the public.[88]

The FDA's modern food standardization techniques are helpful in that they increase the information value of product names, reduce consumer research costs, and create incentives for new products to make their way onto market shelves.[89] The goal of the government's current system is to help consumers make informed purchasing decisions without fear of fraud and deception, and according to some scholars, this goal is so important that it outweighs any societal costs of overly restrictive food standards.[90]

However, even today it is not conclusively known how widespread food-related fraud is in the United States or worldwide.[91] "Food fraud" is defined as "the act of defrauding buyers of food or ingredients for economic gain—whether they be consumers or food manufacturers, retailers, and importers . . . ."[92]

Incidents of fraud are incredibly difficult to detect and

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86. *See, e.g.*, Astania v. Hain Celestial Grp., Inc., 905 F. Supp. 2d 1013, 1016 (N.D. Cal. 2012) (involving a First Amendment claim by a manufacturer whose product labeling bore the term "natural").

87. Chen, *supra* note 9, at 186 ("The inherent characteristics of food products ensure that, in the absence of some standards restricting product attribute claims, there will be incentives for many producers to engage in fraud for at least some of their products at the expense of consumers."); Caroline Q. Shepard, *"Natural" Food Labeling: False Advertising and the First Amendment*, 16 MARQ. BENEFITS & SOC. WELFARE L. REV. 173, 179 (2014–2015) (noting that NLEA created consistency among products offered by different manufacturers).

88. Chen, *supra* note 9, at 192–93.

89. Chen, *supra* note 9, at 199–201.

90. *Id*. at 186

91. Renee Johnson, *Food Fraud and "Economically Motivated Adulteration" of Food and Food Ingredients*, CONG. RES. SERV. 1, 3 (2014), http://foodfraud.msu.edu/wp-content/uploads/2014/01/CRS-Food-Fraud-and-EMA-2014-R43358.pdf [https://perma.cc/MDV7-T2TL].

92. *Id*. at 1, 5–6.

quantify as it is no surprise that those who commit fraud will go through great lengths to avoid detection.[93] This begs the question as to whether the government's fear of economic adulteration—a fear that simply cannot be quantified—may continue to serve as its rational basis for harsh, non-malleable food standards or whether that concern has simply become too antiquated to support these extensive regulations in modern times.

Accordingly, the conversation begins to sound eerily similar to the *Milnot* court when it invalidated the Filled Milk Act because an innovative market eroded the legitimacy of its initial basis. In its quest to redefine "healthy," the FDA will need to ensure that its regulations remain constitutional—a concern that is addressed in the next section of this paper.

If the FDA were to outright abandon its "healthy" labeling requirements, the absence of a legally enforceable and uniform food standard would create a battleground for prolonged litigation between manufacturers and consumers—a problem that is illustrated by the current crisis surrounding "natural" food products. In redefining the term "healthy," the FDA will presumably be conscious of the backlash it has received for its reluctance to apply a concrete definition to the term "natural."[94]

The FDA's current stance on what makes a food product "natural" rests on the precise opposite end of the spectrum as its interpretation of "healthy." In contrast to the FDA's rigorous requirements for a product to be labeled as "healthy," the FDA has not formally defined what makes a product "natural."[95] Instead, the exact meaning of "natural" remains ambiguous despite the enormous number of producers in the natural food industry whose very existence depends on the legality of its labeling.[96] The lack of FDA oversight has incited frequent class action lawsuits because consumers allege that products containing genetically modified organism (GMO) ingredients cannot be considered "natural."[97]

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93. *Id*. at 1.

94. Nicole E. Negowetti, *A National "Natural" Standard for Food Labeling*, 65 ME. L. REV. 581, 592–96 (2013) (critiquing the FDA's ambiguous attempt to define "natural" for food labeling purposes); *see generally*, Muller, *supra* note 32, at 512–13, 531–32 (critiquing the FDA's ambiguous attempt to define "natural" for food labeling purposes).

95. See Benny, *supra* note 34, at 1510 n. 37 (citing Letter from Margaret O'K. Glavin, Assoc. Comm'r for Regulatory Affairs, FDA, to Antonio Zamora (Dec. 12, 2005) *available at* https://www.regulations.gov/document?D=FDA-2004-P-0154-0004 (explaining that the FDA chose not to establish a definition for "natural" and that the FDA would maintain its current policy) [https://perma.cc/ZLF6-MH6Y]; See also Muller, *supra* note 32, at 522–23.

96. April L. Farris, *The "Natural" Aversion: The FDA's Reluctance to Define a Leading Food-Industry Marketing Claim, and the Pressing Need for a Workable Rule*, 65 FOOD & DRUG L.J. 403, 403, 417–18 (2010).

97. Negowetti, *supra* note 94, at 596–99 (summarizing the waves of lawsuits filed in

In light of the criticism over the FDA's reluctance to define "natural," the FDA will likely try to avoid entirely removing itself from crafting the new definition of "healthy."

VI. ADDITIONAL CONCERNS FOR THE FDA IN REDEFINING "HEALTHY" – CONSTITUTIONAL BOUNDARIES & LEAVING ROOM FOR INDUSTRY GROWTH

For all issues involving government restrictions on labeling, First Amendment free speech concerns linger in the background.[98] The First Amendment to the United States Constitution provides, in pertinent part, that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof, or abridging the freedom of speech . . . ."[99]

Although the First Amendment generally extends protection to all types of speech, it affords lesser protection to commercial speech[100] relative to other constitutionally protected expressions.[101] To be sure, although the Supreme Court has noted the importance of commercial speech,[102] courts have repeatedly emphasized that commercial speech may be reasonably restricted in terms of the time, place, and manner of its presentation.[103]

At the outset, for commercial speech to come within the realm of First Amendment protection, the speech itself must not be misleading.[104] Once a determination is made that the

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recent years concerning the use of "natural" in food products).

98. *See* Noah et. al., *supra* note 28, at 64 (noting that, as federal regulators limit manufacturers' ability to make statements about products, constitutional protections for commercial speech become increasingly important).

99. U.S. CONST. amend. I.

100. The Supreme Court has defined "commercial speech" as an expression that is solely related to the economic interests of the speaker and its audience. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of New York, 447 U.S. 557, 561 (1980). Commercial speech has also been defined as "[t]hose communications that accompany the buying and selling of goods in a marketplace." Robert Post, *Compelled Commercial Speech*, 117 W. VA. L. REV. 867, 868 (2015). However, traditionally safeguarded speech enjoys full protection notwithstanding the fact that it may pertain to a commercial activity; the mere existence of some underlying profit motive does not trigger a lesser degree of constitutional scrutiny. Board of Trustees of the State Univ. v. Fox, 492 U.S. 469, 482 (1989) ("Some of our most valued forms of fully protected speech are uttered for profit.").

101. Cent. Hudson Gas & Elec. Corp., 447 U.S. at 562–63 (noting the Court's history of decisions that reflect the distinction between commercial speech, an area which has traditionally been subject to government regulation, and other varieties of speech).

102. *Id*. at 561-62 ("Commercial expression not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information.").

103. Bates v. State Bar of Ariz., 433 U.S. 350, 384 (1977); Va. State Board of Pharmacy v. Va. Citizens Consumer Counsel, 425 U.S. 748, 771 (1976).

104. In re R.M.J.., 255 U.S. 191, 203 (1982); Stephen H. McNamara, *FDA Regulation of Labeling and the Developing Law of Commercial Free Speech*, 37 FOOD DRUG COSM. L. J.

commercial speech is not misleading[105], the scope of protection becomes less clear.[106] The extent of constitutional protection that a specific instance of commercial speech will enjoy hinges on the nature of the expression and the government's interest[107] in regulating that speech.[108]

Scholars have argued that commercial speech should be denied First Amendment protection altogether.[109] Nonetheless, the Supreme Court has rejected this "highly paternalistic" view that the government has complete power to suppress or regulate

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394, 397 (1982).

105. Under the First Amendment analysis, there is a presumption that commercial speech which contains some accurate information is better than disseminating no information at all through an outright ban of the commercial speech. *See, e.g.*, *Bates*, 433 U.S. at 374.

106. Moreover, critics continue to argue that commercial speech should continue to be excluded from First Amendment protection as it was during the late eighteenth and nineteenth centuries. *See, e.g.*, C. Edwin Baker, *The First Amendment and Commercial Speech*, 84 IND. L.J. 981, 985–86 (2009) ("I have long advanced a strongly libertarian interpretation of the First Amendment Freedom of speech: it should protect an individual's meaningfully expressive behavior, including speech."); *see also* Noah et al., *supra* note 28, at 64 ("Since initially extending the protections of the First Amendment to [commercial speech] twenty years ago, the Court has struggled to define the precise scope of these protections."); Alan Howard, *The Constitutionality of Deceptive Speech Regulations: Replacing the Commercial Speech Doctrine with a Tort-Based Relational Framework*, 41 CASE W. RES. L. R. 1093, 1093 (1991) ("[T]he critical determination of whether speech is commercial lacks standards, resulting in arbitrary rulings."); David F. McGowan, Comment, *A Critical Analysis of Commercial Speech*, 78 CAL. L. REV. 359, 371–81 (1990) (arguing that the Supreme Court has failed to articulate a principled definition of commercial speech and that the Court should define it based on the content of the speech).

107. The government's aim in regulating commercial speech is based on the informational function of advertising and the government's obligation to suppress commercial messages that are an inaccurate source of information to the public about lawful activity, even in light of the First Amendment's protection of freedom of speech. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563 (1980). Accordingly, the government may ban forms of communication that are more likely to deceive the public than to inform it. *See, e.g.*, Friedman v. Rogers, 440 U.S. 1, 11–15 (1979) (noting that trade names have the characteristics and history of being used to manipulate the public); Ohralik v. Ohio State Bar Ass'n., 436 U.S. 447, 455–56 (1978) (noting that the State can regulate commercial speech, which is afforded less protections than other varieties of speech, when it is deemed harmful). To be sure, the Court has further noted the government's authority to restrict commercial speech related to illegal activity. Pittsburg Press Co. v. Human Relations Comm'n, 413 U.S. 376, 388–89 (1973).

108. First Nat'l Bank of Boston v. Bellotti, 435 U.S. 765, 783 (1978).

109. *See generally*, Baker, *supra* note 106, at 997 (noting four reasons why the fundamental ideal of free speech should not extend to commercial speech: (1) market forces dictate the content of commercial speech; (2) commercial speech is not an exercise of freedom by morally significant flesh-and-blood individuals to the extent that the speech is properly attributed to a legally constructed commercial entity; (3) commercial speech has an integral relation to market transactions that structurally involve exercises of power subject to state regulations and therefore do not embody individual autonomy; and (4) constitutional rights related to free speech should be aimed to protect dissent).

commercial speech.[110] Justice Blackmun emphasized the importance of commercial speech in *Bates v. State Bar of Arizona*:

> [S]ignificant societal interests are served by such speech. Advertising, though entirely commercial, may often carry information of import to significant issues of the day. And, commercial speech serves to inform the public of the availability, nature, and prices of products and services, and thus performs an indispensable role in the allocation of resources in a free enterprise system.[111]

Still, the law concerning the applicability of the First Amendment to commercial speech has changed significantly over time.[112]

C. *The* Central Hudson *Test for Government Restrictions on Truthful and Lawful Commercial Speech*

The prevailing standard for constitutional government restrictions on commercial speech was enunciated in *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*.[113] In this case, Central Hudson Gas & Electric Corporation, an electric utility company, filed suit against the New York Public Service Commission after the commission summarily banned all advertising that "promot[es] the use of electricity."[114] The electric company argued that the commission's ban of its promotional advertising constituted a First Amendment violation.[115] The Court developed a four-part test to determine the constitutionality of the government's restriction on commercial speech.[116]

Under the *Central Hudson* test, a government has a substantial interest in limiting commercial speech if the following conditions are satisfied: (1) the commercial statement is not misleading, (2) the government has a substantial interest in the

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110. "[P]eople will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them." Va. State Bd. Of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 770 (1976).

111. Bates v. State Bar of Ariz., 433 U.S. 350, 364 (1977) (first citing Bigelow v. Virginia, 421 U.S. 809, 822 (1975); and then citing FTC v. Proctor & Gamble Co., 386 U.S. 568, 603–04 (1967) (Harlan, J. concurring)).

112. McNamara, *supra* note 104, at 394 (noting that, prior to the 1970s, the Supreme Court held that commercial speech was not entitled to First Amendment protection) (citing Valentine v. Chrestensen, 316 U.S. 52 (1942) and Breard v. Alexandria, 341 U.S. 622 (1951)).

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

114. *Id*. at 558.

115. *Id*. at 559.

116. *Id*. at 566.

regulation of the commercial statement, (3) it is possible for the regulation to advance the government's interest, and (4) the resulting regulation will not be more extensive than necessary to serve the purpose.[117]

In *Central Hudson*, the Court applied this new test to the commission's complete ban on the electric company's promotional material and held that an outright ban did not satisfy the constitutional requirement that the government's restriction be no more extensive than necessary.[118] "In other words, assuming the speech does not relate to some unlawful activity and is not inherently misleading, the government may restrict commercial speech only to achieve a substantial interest, and then only to the extent necessary."[119]

In light of the foregoing, the *Central Hudson* standard would also apply amid a constitutional challenge of the FDA's regulations governing what constitutes a "healthy" food product.[120] If its regulations were challenged, the government would presumably assert that it maintains a substantial interest in preventing consumers from being duped by misleading and economically adulterated food products, facilitating a marketplace that offers healthy foods, and increasing the overall health of American citizens.[121] These government interests have all been held to be legitimate in previous cases, so the crucial question becomes whether there is any other, less restrictive[122] way for the government to advance these interests such that the *Central Hudson* standard is fully satisfied.

D. *The* Zauderer *Standard for False, Misleading, or Unlawful Commercial Speech*

However, manufacturers should not end their analysis after

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117. *Id*.

118. *Id*. at 570–72.

119. *See* Noah et al., *supra* note 28, at 77.

120. The *Central Hudson* standard has been described as a variant of intermediate scrutiny. Cent. Hudson Gas & Elec. Corp., 447 U.S. at 573 (J. Blackmun) (concurring) ("I agree with the Court that this level of intermediate scrutiny is appropriate for a restraint on commercial speech designed to protect consumers from misleading or coercive speech, or a regulation related to the time, place, or manner of commercial speech.").

121. *See* Shepard, *supra* note 20, at 173.

122. *Cent. Hudson Gas & Elec. Corp*., 447 U.S. at 564. It is important to emphasize that "less restrictive" generally encompasses a requirement that the alternative be equally effective. John M. Blim, Comment, *Free Speech and Health Claims Under the Nutrition Labeling and Education Act of 1990: Applying a Rehabilitated* Central Hudson *Test for Commercial Speech*, 88 NW. U. L. REV. 733, 764 (1993).

the *Central Hudson* standard because the *Zauderer* standard is less favorable to manufacturers and exists where government regulations seek to mandate factual disclosure that corrects otherwise false or misleading commercial speech.[123] Conceivably, the *Zauderer* standard could apply to food products bearing the claim "healthy" if the FDA ultimately decided to relax its definition and allow more products to boast the claim on its labeling.[124] Those products that were misleading in adopting the claim "healthy" could be required by the government to include a mandatory disclosure on their labeling to clarify certain features of the product.

In contrast to the *Central Hudson* standard—which has been likened to intermediate scrutiny[125]—the *Zauderer* standard is considered to be more deferential to the government and closely resembles a variant of rational basis scrutiny as it is contemplated under constitutional law.[126]

Under a *Zauderer* analysis, a court initially asks whether the government has a reasonable basis for imposing the mandatory disclosure at issue.[127] For the second step, the court will determine whether the disclosure is unduly burdensome.[128] The outcome of this inquiry generally favors the government, because the commercial speech involved would be false or misleading without the required disclosure.[129] As such, courts generally uphold the government's mandatory disclosures as constitutional.[130]

The more daunting aspect of the *Zauderer* standard is that historically the Supreme Court's rationale suggested that the relaxed scrutiny as contemplated under *Zauderer* applied beyond remedial mandatory disclosures and into the realm of educationally compelled commercial speech—circumstances where the government believes more information on a product's

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123. S*ee* Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985).

124. *Id.* (announcing the standard that applies to commercial speech cases where the government proceeds against a manufacturer because its product's labeling contains false or misleading statements).

125. *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 573 (J. Blackmun) (concurring) ("Under this four-part test, a restraint on commercial communication [that] is neither misleading nor related to unlawful activity is subject to an intermediate level of scrutiny, and suppression is permitted whenever it directly advances a substantial government interest and is not more extensive than necessary to serve that interest.")(Internal quotations omitted).

126. Rebecca Tushnet, *COOL Story: Country of Origin Labeling and the First Amendment*, 70 FOOD & DRUG L.J. 25, 26 (2015).

127. Zauderer, 471 U.S. at 651.

128. *Id*.

129. *See* Tushnet, *supra* note 126, at 26.

130. *Id*. at 26–27.

labeling may be useful to consumers.[131] Put a different way, the government used to enjoy the deferential *Zauderer* standard where it simply wished to require a truthful factual disclosure to accompany commercial speech in labeling about a particular topic—even where there is no obvious falsity contained in the labeling.[132]

However, more recent decisions appear to afford manufacturers greater protection from government interference for educational—not corrective—purposes in making truthful labeling claims.[133] Thus, the extreme deference to the government is being diluted.[134] The shift in attitude has been attributed to a change in the lens through which the Supreme Court views commercial speech cases.[135] The earlier commercial speech cases were decided based on the audience's interest in hearing truthful commercial messages and without regard to the commercial speakers' constitutional interests.[136] In contrast, in more recent cases, the Court has started to recognize a right that the commercial speaker maintains freedom of speech interests of its own.[137] In doing so, the Court has drifted away from the audience-based lens that was once so powerful.[138]

An example of the Supreme Court's recent shift in attitude toward viewing commercial speech cases through the lens of the commercial speaker is illustrated by *Rubin v. Coors Brewing Co.*[139] In *Rubin*, the Court unanimously decided that a federal regulation prohibiting the disclosure of alcohol content in the labeling of malt beverages violated the First Amendment's protections over commercial speech.[140]

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131. *Id.* at 27.

132. *Id.*

133. *Id.*

134. *Id.*

135. *Id.*

136. *See, e.g.*, Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 563 (1980) ("The First Amendment's concern for commercial speech is based on the informational function of advertising."); First Nat'l Bank v. Bellotti, 435 U.S. 765, 783 (1978) (commercial speech "is constitutionally protected not so much because it pertains to the seller's business as because it furthers the societal interest in the 'free flow of commercial information.'") (quoting Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 764 (1976)).

137. G. Edward White, *The Evolution of First Amendment Protection for Compelled Commercial Speech*, 29 J.L. & POL. 481, 497 (2014)

138. *Id.* (arguing that recent developments have abandoned the idea that the First Amendment rationale for protecting truthful commercial speech was society's interest in the free flow of information; instead, the Supreme Court now believes that commercial speakers have their own First Amendment interests).

139. Rubin v. Coors Brewing Co., 514 U.S. 476, 490 (1995).

140. *Id.*

Some scholars argue that the *Rubin* opinion suggests that the government may not deprive consumers of truthful information for their own protection because it is too paternalistic for modern society.[141] Moreover, some scholarship further suggests that the holding of this case could shed light on the FDA's recently promulgated regulations that restrict "health" claims and similar statements within the food labeling industry.[142]

While FDA regulation seems to be the only option to further the government's efforts, perhaps the regulatory scheme could be more constitutionally firm if it were to adopt a malleable, sliding-scale definition of "healthy" to allow some products that have traditionally been excluded from the "healthy" market—namely, nut-based bars[143]—to enter into "healthy" territory by satisfying a wide range of criteria that does not rest solely on fat content.[144] This solution would expand the range of "healthy" food options available to the consumer market. The downside of this proposition is that a wide expansion of what it could potentially mean to be "healthy" could have the damaging effect of diluting what it actually means for a food to be healthy in the mind of a consumer.[145]

Another alternative basis for the FDA to determine whether a product is "healthy" would be to promulgate a different, particularized set of criteria for products that contain foods that naturally contain oils, such as nuts, seeds, seafood, olives, and avocados. The 2015–2020 Dietary Guidelines could serve as a basis for these determinations.[146] This method would directly

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141. Noah, et al., *supra* note 28, at 99.

142. *Id*. at 64.

143. *See* In re Kind LLC "Healthy and All Natural" Litigation, 2016 WL 4727935 at *19 (S.D.N.Y. 2016).

144. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y., 447 U.S. 557, 564 (1980) (requiring, among other things, that the government regulations limiting commercial speech be no more extensive than necessary to facilitate an important government objective). Based on the *Central Hudson* standard, an argument may be made that the FDA's current regulatory definition of "healthy," which summarily bans any such claims for food products that exceed an arbitrary maximum level of fat content, is not the least restrictive means to further the government's substantial interest in promoting public health and creating a predictable and uniform food labeling system. Accordingly, it may behoove the FDA to adopt a more tailored, less limiting definition.

145. According to the FDA's commissioner, Margaret A. Hamburg, ensuring that food product labeling provides consumers with reliable information about a particular food is considered an important objective for the agency. Margaret A. Hamburg, *Margaret A. Hamburg, M.D., Commissioner of Food and Drugs – Remarks at the Nutrition Summit*, FDA NEWS & EVENTS (April 28, 2010) (accessed November 22, 2016) (*available at* http://www.fda.gov/newsevents/speeches/speecharchives/ucm209954.htm) [https://perma.cc/G3B3-V7X5].

146. *See generally* U.S. DEP'T OF AGRIC., 2015–2020 DIETARY GUIDELINES, (*available at* https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-

relate to distinctions made in the 2015–2020 Dietary Guidelines and would result in consistency among the different health-related government agencies.[147] It would eliminate the public confusion that currently exists based on the existing, varied agency interpretations.[148]

The common thread between both the sliding scale and product-specific methods is that the FDA should begin to recognize that fat content is not the absolute determinant of whether a food product is actually healthy.[149] The FDA's proposed guidance that will serve as the standard until the new definition is promulgated appears to be headed in this direction by allowing food products to bear a claim of "healthy" where a product is not low in total fat but has a fat profile makeup of predominately mono and polyunsaturated fats.[150] The guidance also recognizes an additional category of food that may bear a "healthy" claim: foods that contain at least ten percent of the recommended daily intake of potassium or Vitamin D.[151] Perhaps the most symbolic attribute of the new guidance is that the FDA is expanding the scope of what an inherently subjective term like "healthy" means from a legally enforceable standpoint and apparently ditching the standard that exclusively looked to fat content.[152] By evaluating more than a product's fat content in designating it as "healthy," the FDA's new

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healthy-eating-patterns/#saturated-fats [https://perma.cc/R94U-ZZGD]) (providing healthy eating pattern advice with regards to various foods and eating habits).

147. *See id.*

148. *Compare* U.S. DEP'T OF AGRIC., 2015–2020 DIETARY GUIDELINES, (*available at* https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#saturated-fats [https://perma.cc/R94U-ZZGD]) (recognizing the modern view that some foods with higher fat contents, such as nuts, are nonetheless nutritious and should be considered healthy) *with* 21 C.F.R. § 101.65(d)(2)(i) (FDA's current regulatory definition of "healthy," which automatically disqualifies any product that exceeds specified levels of fat, saturated fat, or cholesterol from making an implied nutritive health claim that the product is "healthy" on its labeling, without regard to any other nutritive benefits that the product may provide).

149. *See* U.S. DEP'T OF AGRIC., 2015–2020 DIETARY GUIDELINES, (*available at* https://health.gov/dietaryguidelines/2015/guidelines/chapter-1/a-closer-look-inside-healthy-eating-patterns/#saturated-fats https://perma.cc/R94U-ZZGD).

150. U.S. FOOD AND DRUG ADMINISTRATION, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, *Guidance for Industry: Use of the Term "Healthy" in the Labeling of Human Food Products* (Sept. 2016) (*available at* http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm521690.htm [https://perma.cc/2KZ9-EDZN]) (exercising the FDA's enforcement discretion relative to foods that use the implied nutrient content claim "healthy" on their labels if: (a) the product is not low in total fat, but has a fat profile makeup of predominately mono and polyunsaturated fats, or (b) the product contains at least ten percent of the Daily Value (DV) per reference amount customarily consumed (RACC) of potassium or Vitamin D).

151. *Id.* (permitting certain foods that are not low in total fat to bear the implied nutritive health claim of "health" on their labels).

152. *Id.* at 5.

standards will presumably have a better constitutional fate than the Filled Milk Act—under which violations unconstitutionally hinged exclusively upon milk fat content.[153]

Another valid concern that the FDA should consider in its endeavor to redefine "healthy" is that it needs to craft a definition that leaves room for the continued development of healthy foods in the marketplace to promote the overall health of American citizens.[154] This is imperative, as a recent report conducted by the Nielsen Global Health and Wellness Survey revealed that younger consumers worldwide are by far the most health-conscious generation.[155] Furthermore, sales in North America for "healthy" products dramatically surpass other surveyed regions, so there is certainly a customer demand for these types of foods.[156] With a documented trend toward healthier food choices, FDA oversight is conceivably needed to ensure that these conscientious consumers are confident that when they select a product that boasts a claim of "healthy," they are receiving a nutritious product and not something that has been loaded with fat should the FDA deviate from its current fat content limitations.[157] Therefore, despite recent criticism, the FDA's regulation of "healthy" labeling claims could be more important than ever.

VII. CONCLUSION

In light of the foregoing, the time has clearly come for the FDA to settle on a new, industry-wide definition of the word "healthy" for the purposes of nutritive health claims in food product labeling.[158] In its endeavor to redefine "healthy," the FDA should be conscientious of the consequences of government avoidance as evidenced by the current "natural" controversy. It should account for current and developing food trends and leave room in the definition for the growth of additional trends, given the documented American consumer demand for healthier food choices. Importantly, the FDA should also ensure that it continues to satisfy the evolving *Central Hudson* and *Zauderer* tests to

153. *See supra* Part IV (discussing the reasons why the Filled Milk Act was struck down as unconstitutional).

154. This concern has repeatedly been emphasized in numerous areas related to food regulation. For example, it has been documented as a main concern in response to the crisis surrounding the definition of "natural" for food labeling purposes. *See, e.g.*, Shepard, supra note 20, at 204.

155. NIELSON, *supra* note 5.

156. *Id*.

157. *Id*.

158. *See, e.g.*, In re Kind LLC "Healthy and All Natural" Litigation, 2016 WL 4727935 at *18 (S.D.N.Y. 2016).

remain within the United States Constitution's freedom of speech parameters related to commercial speech. Finally, the FDA should consider any public and industry input received during the comment period in response to its request for the public to weigh in on the controversial debate.[159]

To solve the controversy, the FDA should implement a more malleable standard of the term "healthy" to replace the inflexible definition that is currently in place. This could be effectuated by using different criteria that rests on a sliding scale or by employing a product-specific method that acts as a balancing scale and not as a concrete ceiling for product determinations.

Though the parameters of the new definition remain unclear, one concern is certainly on the government's mind: avoid using a framework that mirrors the Filled Milk Act.

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159. The comment period for public and industry input on the FDA's new definition of "healthy" was extended past the original end date of January 26, 2017. U.S. FOOD AND DRUG ADMINISTRATION, *"Healthy on Food Labeling"* (Dec. 2016) (*available at* https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm520695.htm [https://perma.cc/SZU7-6UAQ]). Clif Bar & Company weighed in on the conversation on May 2, 2017.

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