A PALATABLE OPTION FOR SUGAR-COATED PALATES: LABELING AS THE LIBERTARIAN PATERNALISM INTERVENTION THAT AMERICAN CONSUMERS NEED

*Nicholas G. Miller**

Abstract

Addressing nutritional health for Americans has proven uniquely challenging in a marketplace flooded with non-nutritious food products. Compounding the issue, consumers consistently misjudge the contents of these processed foods and undervalue their pernicious effect. At the same time, consumers are wary of overly intrusive or paternalistic government interventions, such as bans and portion limits. This Article reflects on the effectiveness (or lack thereof) of previous attempts by the FDA to combat public health threats. Finally, this Article proposes a path forward, with growing political momentum, that builds on the innovative food labeling models being tested in markets around the world.

* J.D. 2021, UCLA School of Law; B.S.E., Concentration in Entrepreneurship and Innovation, 2016, Wharton School, University of Pennsylvania. Special thanks to Professor Michael T. Roberts, Director of the Resnick Center for Food Law and Policy at UCLA School of Law, for invaluable assistance in developing this Article.

INTRODUCTION

How has the land of the free become the home of the overweight? An increase in obesity is part of a larger epidemic of chronic disease stemming from the harmful dietary patterns of Americans. These harmful dietary patterns include a rise in the proportion of empty calories in the form of added sugars from processed foods and sweetened beverages, which leave little room in the diet for nutritious foods.

This Article explores how the Food and Drug Administration (FDA)—the executive agency charged with insuring food safety—can respond to the nutrition crisis with an incremental approach that relies on labeling. Part I will describe the origins of the FDA and the traditional limitations on its power as contextual background to a discussion of the FDA's authority to regulate relative to the checks of the legislative and judicial branches.[1]

Part II explains how the FDA's original goal of protecting against contamination and unsanitary food preparation has evolved into responding to the health risks imposed by non-nutritious foods.[2] The modern nutrition crisis is analyzed, along with the related issues of consumer awareness and the bounds of rational decision-making by consumers. Furthermore, the FDA's ability to respond to nutritional issues is examined, insofar as the FDA is hampered by its position in a fragmented regulatory system where overlapping agencies, such as the United States Department of Agriculture (USDA), hold the reins. The FDA is also limited by political forces, such as lobbying by industries that do not want to be restricted (as illustrated by two examples of failed regulatory efforts by the FDA), and by practical budgetary restraints.

Part III examines the increased use of food labeling and argues that labeling is an ideal tool for countering the limitations faced by the FDA in promoting good nutrition.[3] This argument is supported by tracing the strong statutory basis for the FDA's authority over labeling, which has been reinforced by legislation such as the Nutrition Labeling and Education Act of 1990 (NLEA). The effects of the NLEA are then examined, including the standardization of labels, which has helped mitigate the effects of a fragmented food regulatory system by consolidating power with the FDA. The usefulness of this incremental approach, which relies on labeling, is then discussed by reviewing a 2016 rule that the FDA released which updated the original nutrition panel with a mandatory "added sugar" disclosure.

Finally, Part IV proposes additional incremental changes that the FDA could implement to build on the 2016 rule on added sugar, and to promote more informed decision-making by consumers.[4] This Article advocates for front-of-label solutions that are meant to serve as a "nudge" for consumers. These nudges could include clear visual indicators for products that contain an excessive amount of non-nutritious ingredients, such as sugar or salt.

1. *See infra* Part I.
2. *See infra* Part II.
3. *See infra* Part III.
4. *See infra* Part IV.

I. THE FDA'S ORIGINAL MANDATE TO ADDRESS FOOD SAFETY

The United States Food and Drug Administration (FDA) is a federal agency that was originally tasked primarily with enforcing hygienic and sanitary food quality standards.[5] The parameters of that authority are set out by a series of broad statutes that have been interpreted by judicial decisions and further legislation.[6] The FDA's early history in regulating food safety provides a reference point with which to contrast the challenges the FDA now faces in attempting to regulate nutritional health risks.

A. *Historical Origins of the FDA*

Agricultural safety in the United States has been monitored since the mid-1800s by the United States Department of Agriculture (USDA).[7] However, the start of the modern, consumer-oriented era of food regulation, overseen by the FDA and the USDA, came into existence in only 1906.[8] That year, Congress enacted the Federal Meat Inspection Act (FMIA), which empowered the modern USDA, as well as the Pure Food and Drugs Act (PFDA), which empowered the modern FDA to regulate misbranding and adulteration.[9] These landmark Acts were passed in the wake of outcries over Upton Sinclair's *The Jungle*, which documented the disturbingly unsanitary conditions in American meat factories.[10] Sinclair's account prompted President Theodore Roosevelt to commission his own investigation, which resulted in a damning report, despite frantic cleanup efforts by the meat packing industry.[11] The rising public pressure compelled Congress to act, leading to the passage of these two monumental 1906 acts—FMIA and PFDA—by a landslide.[12] These two acts laid the framework for the modern FDA and USDA.[13]

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5. U.S. FOOD & DRUG ADMIN., FDA FUNDAMENTALS (Jan. 8, 2021), https://www.fda.gov/about-fda/fda-basics/fda-fundamentals [https://perma.cc/3XE6-UKB8]; *see* U.S. FOOD & DRUG ADMIN, WHEN AND WHY WAS FDA FORMED? (Mar. 28, 2018), https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed [https://perma.cc/H2DS-XJKC].

6. *See* discussion *infra* Parts I.B, I.C.

7. U.S. FOOD & DRUG ADMIN., FDA HISTORY, https://www.fda.gov/about-fda/fda-history [https://perma.cc/3R4K-Z6K5] (last visited June 29, 2018).

8. *Id.*

9. *See* U.S. FOOD & DRUG ADMIN., MILESTONES IN U.S. FOOD & DRUG LAW, https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law [https://perma.cc/36F3-VV82] (last visited Jan. 31, 2018).

10. James Harvey Young, *The Pig That Fell into the Privy: Upton Sinclair's The Jungle and the Meat Inspection Amendments of 1906*, 59 BULL. HIST. MED. 467, 470, 476 (1985).

11. *Id.* at 475–76 (describing stomach-churning conditions in a factory where a pig that slid into a latrine was fished out, only to be returned to the production line, after it had passed the cleaning stage).

12. *See* WHEN AND WHY WAS FDA FORMED?, *supra* note 5; MILESTONES, *supra* note 9.

13. HISTORY, ART & ARCHIVES, HISTORICAL HIGHLIGHTS: THE PURE FOOD AND DRUG ACT,

Over the past century, the FDA has grown much larger to keep up with the sprawling food industry. The FDA now consists of nine center-level offices and thirteen headquarter offices.[14] The FDA regulates all food, except meat, poultry, and some egg products.[15] The FDA defines itself as a "science-based agency," which is reflected in its guidance of the food industry, and it claims to be insulated from political pressures.[16] The structure of the modern FDA, with its limited authority, is a result of a handful of statutes and judicial decisions.

B. *Legislative Development of the FDA's Statutory Authority*

Food safety legislation began with the Federal Meat Inspection Act (FMIA) and the Pure Food and Drug Act (PFDA) in 1906.[17] Over the last century, Congress has added countless amendments and pieces of legislation, but the most comprehensive was the 1938 Food Drug and Cosmetics Act (FDCA).[18]

The FDCA filled in many of the gaps from the PFDA in 1906, which it replaced. The FDCA authorized standards for the identification and quality of products, as well as making court injunctions a viable remedy for enforcement.[19] The FDCA also introduced major changes, such as labeling requirements, which reflected the FDA's evolving role and its attempt to stay ahead of the rapidly developing food industry.[20] Congress drafted the FDCA in broad language and empowered the FDA to enforce prohibitions on products that are "injurious to health," as well as products that are "false or misleading in any particular."[21] Supporters of an expansive role for the FDA saw this language as providing a great deal of additional authority, while for challengers it provided fodder for claims of ambiguity as to the scope of the FDA's power. Some FDA officials in the decades since the enactment of the FDCA have interpreted the

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https://history.house.gov/Historical-Highlights/1901-1950/Pure-Food-and-Drug-Act/ [https://perma.cc/5MRZ-V2EM] (showing that the Pure Food and Drugs Act was passed by a vote of 204 to 17 on June 23, 1906) (last visited July 28, 2021).

14. U.S. FOOD & DRUG ADMIN., FDA ORGANIZATION CHARTS, https://www.fda.gov/about-fda/fda-organization/fda-organization-charts [https://perma.cc/2FB3-EM9C] (last visited Dec. 13, 2019).

15. U.S. FOOD & DRUG ADMIN., LAWS ENFORCED BY FDA, https://www.fda.gov/regulatory-information/laws-enforced-fda [https://perma.cc/7VK5-SRWL] (last visited Dec. 13, 2019).

16. Rebecca L. Goldberg, *Administering Real Food: How the Eat-Food Movement Should--And Should Not--Approach Government Regulation*, 39 ECOLOGY L. Q. 773, 787 (2012).

17. MICHAEL T. ROBERTS, FOOD LAW IN THE UNITED STATES 79 (2016).

18. MILESTONES, *supra* note 9.

19. 21 U.S.C. §§ 332, 341–50 (2018); MILESTONES, *supra* note 9.

20. Peter Barton Hutt & Peter Barton Hutt II, *A History of Government Regulation of Adulteration and Misbranding of Food*, 39 FOOD DRUG COSM. L.J. 2, 62 (1984).

21. Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 50 FOOD & DRUG L. J. 101, 102 (1995) (letter by the then Assistant General Counsel for the FDA in 1971); 21 U.S.C. §§ 342–43.

agency's mandate to protect public health broadly as authorization to promulgate regulations that provide creative and innovative food safety solutions.[22]

Congress has periodically enacted new legislation as the food landscape changes. When the public's interest in nutrition heightened in the 1960s, the FDA began to rely increasingly on regulation through labeling.[23] That trend towards labeling was initially codified through major acts such as the 1966 Fair Packaging and Labeling Act to regulate labels on goods shipped interstate.[24] That 1966 Act was later reinforced by the 1990 Nutrition Labeling and Education Act (NLEA), which required all foods to bear labels and preempted portions of state authority.[25]

In practice, the FDA is often constrained by its limited budget and by the need to please both the public and the food industry while not overstepping boundaries set by Congress and the judiciary.[26] The result is that the FDA often acts responsively, rather than proactively, by acting only when a situation becomes urgent.[27] Thus, the courts have adjudicated some food safety issues that could have been better addressed by the FDA.[28]

C. *Judicial Interpretation of Food Safety Laws*

To understand how the FDA can best create solutions for modern nutrition issues, it is important to understand the way in which the FDA's actions have been limited by the courts. Not long after the passage of the 1938 Food Drug and Cosmetics Act, Congress enacted the Administrative Procedure Act (APA), a critical piece of legislation that acted as a check on administrative agencies.[29] The APA provided, in part, that litigants had a right to judicial review when "suffering legal wrong

22. Hutt, *supra* note 21, at 102 (letter from 1971 by Peter Barton Hutt, the Assistant General Counsel at the time, who wrote "I am not at all certain that the Food and Drug Administration has begun to explore the full reaches of existing statutory authority.").

23. ROBERTS, *supra* note 17, at 4.

24. MILESTONES, *supra* note 9.

25. *Id.* (NLEA standardized certain food terms, preempting state power to regulate terms like "low fat").

26. *See* Andrea T. Borchers et al., *The History and Contemporary Challenges of the US Food and Drug Administration*, 29 CLINICAL THERAPEUTICS 1, 2 (2007); 5 U.S.C. § 801; *see, e.g.*, RENEE JOHNSON, CONG. RESEARCH SERV., RS22600, THE FEDERAL FOOD SAFETY SYSTEM: A PRIMER 10 (2016) (noting that FDA in 2012 said it would need an additional 400 to 450 million dollars to effectuate the changes from the FSMA).

27. Borchers, *supra* note 26, at 1.

28. Hutt & Hutt II, *supra* note 20, at 72; Hutt, *supra* note 21, at 105.

29. ROBERTS, *supra* note 17, at 18.

because of agency action, or adversely affected . . . by agency action."[30] This legislation provided the basis for judicial review of agency actions.

Early decisions by the Supreme Court, starting in the 1950s, revealed a tendency towards a liberal construction in the authority of administrative bodies, particularly with regard to food and drug law and the need to protect the consumer.[31] That liberal line of thinking was somewhat inconsistently followed by circuit courts that interpreted the scope of the 1938 Food Drug and Cosmetics Act.[32] However, in 1984, in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*,[33] the Supreme Court increased the power of federal agencies by holding that courts should defer to agency interpretations of statutes.[34]

There are two key principles that modern courts typically rely on to adjudicate challenges to agency powers: (1) Title 5 U.S.C. § 706 prohibits regulation that is "arbitrary [and] capricious;"[35] and (2) *Chevron* further clarifies that courts must defer to agency interpretation when the scope of an agency's power is unclear.[36]

Thus, while the APA gives litigants the right to seek redress for oversteps by administrative agencies, the bar is fairly high, and agency actions are presumed to be valid unless proven otherwise.[37] Despite some mixed results in the lower courts, the Supreme Court has ruled in favor

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30. 5 U.S.C. § 702.

31. *See* 62 Cases, More or Less, Each Containing Six Jars of Jam v. United States, 340 U.S. 593, 596 (1951) ("By the Act of 1906, 34 Stat. 768, as successively strengthened, Congress exerted its power to keep impure and adulterated foods and drugs out of the channels of commerce. The purposes of this legislation, we have said, 'touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.").

32. *See, e.g.*, Int'l Nutrition, Inc. v. U.S. Dep't of Health & Human Servs., 676 F.2d 338, 341 (8th Cir. 1982) (finding "Remedial legislation, such as the [Food Drug and Cosmetics] Act, should be given a liberal construction consistent with its statutory purpose"; United States v. Nova Scotia Food Prod. Corp., 568 F.2d 240, 246 (2d Cir. 1977) ("Yet, when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as 'consistent with the Act's overriding purpose to protect the public health'").

33. 467 U.S. 837 (1984).

34. *Id.* at 844 ("We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of *deference to administrative interpretations*.").

35. 5 U.S.C. § 706 (providing in part that courts "hold unlawful and set aside agency action, findings, and conclusions found to be (A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

36. City of Arlington v. FCC, 569 U.S. 290, 296 (2013) (finding that a "court must defer under *Chevron* to an agency's interpretation of a statutory ambiguity that concerns the scope of the agency's statutory authority")) There have also been recent challenges to *Chevron* though, *see* Regulatory Accountability Act of 2017, H.R. 5, 115th Cong. (2017) (passed by the House, attempting to reign in *Chevron* Deference as a violation of the separation of powers).

37. Jacob Gersen & Adrian Vermeule, *Thin Rationality Review*, 114 MICH. L. REV. 1355, 1356 (2016).

of agency actions on challenges of arbitrariness in over ninety percent of cases, as of 2016.[38] A broad view of the purpose of the FDCA—which gives the FDA greater latitude—was specifically endorsed in a recent 2014 case in which the Supreme Court wrote that "[t]he FDCA statutory regime is designed primarily to protect the health and safety of the public at large,"[39] which is in line with previous non-restrictive readings of the FDCA.[40]

Because of *Chevron*, the courts have not been a significant obstacle to FDA actions in recent years. The more pointed limitations that the FDA faces now come from Congress, which responds to both industry lobbyists and consumers, who often underestimate dietary health risks.

II. THE FDA'S CHALLENGES IN ADDRESSING THE ISSUE OF NUTRITION

Upton Sinclair's spotlight on food preparation and production in the early 1900s lifted a curtain into the unseemly world of unsanitary food and patently false advertising and sparked sixty years of food safety legislation.[41] Starting in the late 1950s a new focus emerged, led by nutrition scientists, concerning the nutrient quality of food in American diets and the overconsumption of particular ingredients, such as fat and sugar.[42] Just as unsanitary food issues had eventually caught the attention of President Theodore Roosevelt, protecting consumers from dietary risks caused by malnutrition was eventually addressed by President John F. Kennedy. In a speech to Congress in 1962, President Kennedy laid out the Consumer Bill of Rights noting that American consumers did not know "whether one prepared food has more nutritional value than another."[43]

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38. *Id.* at 1355.

39. POM Wonderful L.L.C. v. Coca-Cola Co., 573 U.S. 102, 108 (2014).

40. *See, e.g.*, United States v. Nova Scotia Food Prods. Corp., 568 F.2d 240, 246 (2d Cir. 1977) ("Yet, when we are dealing with the public health, the language of the Food, Drug and Cosmetic Act should not be read too restrictively, but rather as 'consistent with the Act's overriding purpose to protect the public health.'"). *But see* INST. OF MED. & NAT'L RSCH. COUNCIL, ENHANCING FOOD SAFETY: THE ROLE OF THE FOOD AND DRUG ADMINISTRATION 296 (Robert B. Wallace & Maria Oria eds., 2010) (arguing for new, more clearly defined legislation, because the FDA may be more vulnerable to challenges, due to the ambiguity of broadly stated statutory authority).

41. *See supra* discussion in Part I.B.

42. Dariush Mozaffarian et al., *History of Modern Nutrition Science—Implications for Current Research, Dietary Guidelines, and Food Policy*, BRIT. MED. J. 1, 1–2 (2018), https://www.bmj.com/content/361/bmj.k2392 [https://perma.cc/6AT2-Y7CN].

43. 108 CONG. REC. 4167–71 (1962) (statement of President Kennedy) (Kennedy outlining rights in speech to Congress, such as the right to safety; to be protected against the marketing of goods which are hazardous to health or life); *see also* Paul Diller, *Combatting Obesity with a Right to Nutrition*, 101 GEO. L.J. 969, 975 (2013) (providing a modern formulation of the right to nutrition under a constitutional basis).

Unlike the regulation of unsanitary food, this new era of food regulation, which focused on a healthy diet, did not catch hold as quickly.[44] The nutritional health issue was again addressed in 1969 during the White House Conference on Food and Nutrition Health.[45] These talks laid the groundwork for hearings in Congress. The ensuing debates, beginning in the 1970s, have continued today over the role of food regulators in modifying American diets.[46]

Because everyone interacts with food daily, it is easy for decision makers in power to believe that the solutions to diet-related health risks are simple and intuitive. As a result, nutrition policy is often shaped by one-dimensional oversimplification of the factors leading to poor dietary health.[47] For example, in the 1970s, as the public (and food industry marketers) became increasingly focused on the content of their food, there was a growing debate over whether fat or sugar was the primary culprit contributing to poor diet.[48] This oversimplified view left room for only one target, which was fat, while sugar largely escaped notice and criticism.[49] This selection was reflected in the publication of Congress's first dietary guidelines in 1980, which focused on reducing fat in diets.[50] At the same time, food regulators such as the FDA have tried to fill in the gaps left by inadequate legislation regarding sugar, and have been met with great resistance.[51] That resistance comes from consumers who do not fully understand the risks of their dietary choices within a greater nutrition crisis, and from industry, which profits from the sale of unhealthy foods.[52]

A. *The Nutritional Health Crisis*

In recent years, trends of nutritional deficiencies are emerging that can be traced not to a lack of food altogether, but to the unavailability of nutritious food. Many people have only nutrient-poor food options.[53] While this paper focuses on trends within the United States, food insecurity is a global problem, as are increasing rates of obesity and diet-

44. *See* Diller, *supra* note 43, at 975.

45. David Kessler, *The Evolution of National Nutrition Policy*, 15 ANN. REV. NUTRITION xiii, xvi (1995).

46. *Id.*

47. Mozaffarian et al., *supra* note 42, at 1–5.

48. *Id*. at 1–2.

49. *Id.* Some saw this as a result of industry influence.

50. Kessler, *supra* note 45.

51. *See* Jennifer L. Pomeranz, *The Bittersweet Truth About Sugar Labeling Regulations: They are Achievable and Overdue*, 102 AM. J. PUB. HEALTH e14, e14, e16 (2012).

52. *See* Mozaffarian et al., *supra* note 42, at 5.

53. FOOD & AGRIC. ORG. UNITED NATIONS, THE STATE OF FOOD SECURITY AND NUTRITION IN THE WORLD 90 (2019), http://www.fao.org/state-of-food-security-nutrition/en/ [https://perma.cc/L4WN-GPBP] (FAO report examining the state of food security and nutrition worldwide).

related disease.[54] Perhaps most troubling, the prevalence of high-calorie, low-nutrient processed foods has been linked to higher rates of child obesity.[55] Joint studies by world health organizations have linked dietary health diseases with greater access to processed foods.[56]

1. Impact of Processed Foods

The United States has been hit particularly hard by the epidemic of malnutrition and the associated comorbidities such as obesity—which affected 42.4% of Americans as of 2021.[57] The increase in obesity is particularly pronounced in the youth population.[58] Americans now live in an environment characterized by an overabundance of food that is low in nutrient value but high in calories.[59] The rise in these nutrient-deficient, processed foods is often attributed, in part, to the role of the government in propping up agricultural producers.[60]

The culprit in the rise in malnutrition may be not only the increase in processed foods, but also what these processed foods are replacing. The Center for Disease Control found that less than ten percent of Americans were getting their recommended daily value of fruits and vegetables.[61]

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54. *Id.* In 2018, 1.3 billion people experienced "moderate food insecurity" globally, which is characterized in part by the need to choose nutritionally inferior food products.

55. UNITED NATIONS CHILDREN'S FUND (UNICEF) ET AL., LEVELS AND TRENDS IN CHILD MALNUTRITION 2 (2019), https://www.who.int/nutgrowthdb/jme-2019-key-findings.pdf?ua=1 [https://perma.cc/R8MF-BJDR] (2019 report on trends in child malnutrition. Just since 2000, the number of overweight children grew by 10 million).

56. *Id.* The report also identifies marketing reach and decreases in physical activity as contributors.

57. CTR. FOR DISEASE CONTROL & PREVENTION, ADULT OBESITY FACTS, https://www.cdc.gov/obesity/data/adult.html [https://perma.cc/K4ST-XRHF] (last visited Jan. 26, 2021) (CDC on rising rates of obesity in the United States).

58. CTR. FOR DISEASE CONTROL & PREVENTION, CHILDHOOD OBESITY FACTS, https://www.cdc.gov/obesity/data/childhood.html [https://perma.cc/GLN3-WFZX] (last visited July 29, 2021).

59. Deborah L. Rhode, *Obesity and Public Policy: A Roadmap for Reform*, 22 VA. J. SOC. POL'Y & L. 491, 496 (2015).

60. *Id.* However, the common thinking that oversupply of processed foods may be attributed specifically to subsidies has been challenged by a recent literature review arguing that overproduction would occur even without subsidies, and thus do not affect the consumer prices. The authors theorize that subsidies benefit the farmers and don't cheapen the products. They conclude that the overproduction is a result of deregulation of standardized price, which incentives overproduction by small and midsized farmers to hedge their risk, because they cannot adjust the growth of their crops to match market shifts. FOOD & WATER WATCH & PUB. HEALTH INST., DO FARM SUBSIDIES CAUSE OBESITY?: DISPELLING COMMON MYTHS ABOUT PUBLIC HEALTH AND THE FARM BILL 3–4 (2011), https://www.foodandwaterwatch.org/wp-content/uploads/2021/09/Farm-Subsidies-Obesity-Report-Oct-2011.pdf [https://perma.cc/88LU-Q2WN]. Regardless of the cause of increased processed food production, the baseline assumption—that there is a ubiquity of processed foods in the United States—remains undisputed.

61. *See* CTR. FOR DISEASE CONTROL, MAKING HEALTHY EATING EASIER, https://www.cdc.gov/nutrition/about-nutrition/pdfs/Nutrition-Fact-Sheet-H.pdf [https://perma.cc

That diet deficiency has taken its toll on American health for the last several decades, leading to "dietary risk" becoming the leading factor for mortality in the United States as of 2016.[62]

2. Overconsumption of Sugar and Associated Health Effects

While nutritional deficiencies are generally the result of many lifestyle and dietary decisions, sugar has been consistently identified as a major contributor to poor health.[63] In particular, many Americans consume excessive amounts of sugar through their consumption of sugar-sweetened beverages.[64] Because sugar is such a major source of calories for Americans, many studies have been conducted on its effect. These studies have found that sugar promotes weight gain, among other deleterious effects.[65] With the connection of sugar to chronic disease now apparent, many prominent health organizations have recommended reductions in the intake of sugar in American diets, generally capping consumption at ten percent of daily calories.[66] Despite clear guidance, Americans continue to consume far too much sugar.[67] The cause of

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/UCP3-S6BF] (last visited Dec. 13, 2019) (CDC Division working from local to national level to encourage healthier eating).

62. The US Burden of Disease Collaborators, *The State of US Health, 1990-2016: Burden of Diseases, Injuries, and Risk Factors Among US States*, 319 JAMA 1444, 1451, 1469 (2018) ("Dietary Risk" was found to be the leading factor for death, as it was a factor in over half a million deaths in 2016. Dietary risk was assessed in part by questions that gauged the amount of fruits and vegetables individuals consumed.).

63. Vasanti S. Malik et al., *Sugar-sweetened Beverages and Weight Gain in Children and Adults: A Systematic Review and Meta-analysis*, 98 AM. J. CLINICAL NUTRITION 1084, 1084 (2013).

64. *Id.* (Sugar sweetened beverages remain the top source of calories for Americans, despite modest decreases between 2000 and 2008 in consumption.).

65. *Id.* at 1084 (systematic meta-analysis of 32 different medical studies through March of 2013 found consumption of sugar associated with weight gain); *see also* WORLD HEALTH ORGANIZATION GUIDELINE: SUGARS INTAKE FOR ADULTS AND CHILDREN 3 (2015) (Reduced sugar intake is associated with body weight reduction. Sugar is also associated with dental cavities.); Miriam B. Vos et al., *Added Sugars and Cardiovascular Disease Risk in Children*: *A Scientific Statement From the American Heart Association*, AM. HEART ASS'N J., May 9, 2017, at e1018, e1022, e1024 (AHA concludes there is strong evidence of cardiovascular disease risk among children with high consumption of sugary beverages).

66. *See* Rachel K. Johnson et al., *Dietary Sugars Intake and Cardiovascular Health*, AM. HEART ASS'N J., Sept. 15, 2009, at 1011, https://ahajournals.org/doi/pdf/10.1161/circulationaha.109.192627 [https://perma.cc/DGV2-VAHH]; *see also* WORLD HEALTH ORGANIZATION GUIDELINE: SUGARS INTAKE FOR ADULTS AND CHILDREN 3 (2015) (recommending sugar intake be limited to 10% of daily energy intake).

67. *See* Linda Searing, *The Big Number: Americans Consume 17 Teaspoons of Added Sugar Daily. That's Way too Much*, WASH. POST (Nov. 2, 2019), https://www.washingtonpost.com/health/the-big-number-americans-consume-17-teaspoons-of-added-sugar-daily-thats-way-too-much/2019/11/01/318c9f6e-fbed-11e9-8190-6be4deb56e01_story.html [https://perma.cc/3Y9G-R73F].

irrational sugar consumption may be linked to consumer misunderstanding and lack of awareness about the risks.[68]

B. *Low Consumer Awareness—Requires a New Education Effort*

Despite the high rates of mortality from diet-related risks, consumers continue to choose unhealthy products.[69] Food experts hypothesize that this may be due to the average consumer's limited ability to assess the effect that the foods they consume will have on their health and weight.[70] After all, less than one of every ten Americans can accurately assess the amount of calories they should be consuming daily,[71] and over ninety percent of people underestimate the number of calories in unhealthy foods.[72]

With such a wide array of products on the market, consumers are simply unable to keep track of which products are healthy.[73] Even when consumers are paying attention while shopping for their young children, they often choose products with high levels of sugar and salt; parents make these poor choices, in part, because they are unable to assess the nutritional value from front labels that misdirect them with vague health claims.[74] The toddlers consuming these unhealthy products may see up to 800 advertisements for junk food annually, shaping their attitude towards food products and brands when their associations are most malleable.[75]

This limited decision-making ability of consumers, coupled with the inundation of processed foods that are aggressively advertised and promoted, has created a perfect storm for malnutrition to thrive.[76] Agencies, such as the FDA, have had difficulty responding to this crisis due to the disaggregated nature of food regulation and due to political barriers.[77]

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68. *Id.* (noting that "sugars are often present in foods not thought of as sweetened: soups, bread, cured meats, and ketchup").

69. *Id.*

70. Rhode, *supra* note 59, at 499.

71. *Id.*

72. *Id.*

73. Catherine Boudreau, *Why We Don't Know what to Eat to Stay Healthy*, POLITICO (Nov. 1, 2019), https://www.politico.com/newsletters/morning-agriculture/2019/11/01/why-we-dont-know-what-to-eat-to-stay-healthy-781975 [https://perma.cc/H9SU-EB2A].

74. Laura Reiley, *Sweet Excess: How the Baby Food Industry Hooks Toddlers on Sugar, Salt and Fat*, WASH. POST (Oct. 17, 2019), https://www.washingtonpost.com/business/2019/10/17/sweet-excess-how-baby-food-industry-hooks-toddlers-sugar-salt-fat/ [https://perma.cc/TZT9-6SE3].

75. *Id.*

76. *See id.*

77. *Id.*

C. *Bureaucratic Obstacles to Sweeping Changes by the FDA*

Efforts to regulate nutrition can take many forms, from the most intrusive, such as outright bans of unhealthy foods, to less restrictive options, such as required disclosures, education, and restrictions on marketing to children.[78] The FDA has a key role in the regulation of nutrition but struggles to balance consumer protection with industry demands.[79] As the National Research Council explained: "Although food safety is the responsibility of everyone, from producers to consumers, the FDA and other regulatory agencies have an essential role. In many instances, the FDA must carry out this responsibility against a backdrop of multiple stakeholder interests, inadequate resources, and competing priorities."[80]

In attempting to navigate this gauntlet of competing interests, the FDA has seen mixed results. Its power has been expanded in some areas, such as labeling, where it appears to be making steady progress, most notably with the passage of the 1990 Nutrition Labeling and Education Act.[81] However, in other areas, the FDA's authority has been severely restricted, such as with the passage of the 1994 Dietary Supplement Health and Education Act,[82] which prohibits the FDA from regulating supplements as drugs.[83] One major obstacle in addressing nutritional health is the lack of coordination with other agencies, such as the USDA, which may also have different stakeholders, such as farmers.[84]

1. Limited by Operating Within a Fragmented Food Regulatory System

In the United States, there is a complex web of local, state, and federal overseers that seek to protect consumers by regulating the trillion-dollar food industry.[85] The sprawling regulatory system has been repeatedly examined by outside government accountability offices over the past four decades and found to be highly fragmented and lacking in cohesion.[86] That fragmentation creates both redundancy and uncertainty in legislative

78. *See* Rhode, *supra* note 59, at 493.

79. *See* INST. MED. & NAT'L RSCH. COUNCIL, *supra* note 40.

80. *Id.* at 9.

81. *Id.* at 433.

82. *Id.* at 27–28.

83. *See infra* Part II.C.2.ii discussion on caps and DSHEA.

84. *See* Rhode, *supra* note 59, at 30.

85. *See* JOHNSON, *supra* note 26, at 1 (providing an overview of the regulatory bodies and legislative jurisdiction within congress for food safety).

86. U.S. GOV'T ACCOUNTABILITY OFF., GAO-17-74, FOOD SAFETY: A NATIONAL STRATEGY IS NEEDED TO ADDRESS FRAGMENTATION IN FEDERAL OVERSIGHT 3 (2017) [hereinafter GAO FRAGMENTATION REPORT] (examining the U.S. food regulatory system, with main findings that it is highly fragmented, and recommending a national strategy to address this issue, potentially led by the Executive Office of the President).

attempts to regulate food safety.[87] Furthermore, agency responses to crises such as malnutrition and the obesity epidemic are handicapped when uncertainty as to the extent of the agency's power prevents them from taking effective action.[88] Food safety has been labeled a "high-risk" area due to the lack of coordination, leaving regulatory agencies vulnerable to fraud and mismanagement.[89]

Food in the United States is regulated by at least sixteen federal agencies and is mainly governed by thirty different federal laws—not to mention the myriad state and local agencies and ordinances.[90] The system of oversight extends to a variety of contexts, from the Federal Trade Commission for regulating the advertising of food, to the Center for Disease Control for foodborne illness management, and even to the National Marine Fisheries Service, which has power over the labeling of seafood.[91] These examples illustrate the breadth of regulatory jurisdiction among administrative agencies overseeing food safety, with many of the agencies playing a relatively minor role.

The two main pillars of food safety protection are the USDA, via its Food Safety and Inspection Service (FSIS), and the FDA, which falls under the Department of Health and Human Services.[92] The USDA, via FSIS, handles the regulation of meat and poultry while the FDA is responsible for regulating the safety of all other food.[93] Thus, the FDA is responsible for regulating 80 to 90 percent of the U.S. food supply while FSIS is responsible for the remaining 10 to 20 percent.[94] However, despite the FDA's significantly larger scope, the FDA's budget was approximately 20 percent smaller than that of FSIS in 2016.[95] Congress appears to have recognized this discrepancy, and momentum is building towards making the funding more proportionate to the scope of the agencies' oversight.[96] Thus, that 20 percent gap has since disappeared, and the FDA budget has exceeded the FSIS budget from 2019 to 2021.[97]

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87. JOHNSON, *supra* note 26, at 14 (congressional committees often uncertain as to who has jurisdiction on a given food law issue, leading to duplication and overlaps).

88. *But see* INST. OF MED. & NAT'L RSCH. COUNCIL, *supra* note 40, at 7–8 (advising rollout of new "risk-based" systematic approach of identifying and addressing the most urgent food safety issues but acknowledging that current fragmentation would be an impediment and recommending the integration of federal, state and local food systems).

89. GAO FRAGMENTATION REPORT, *supra* note 86, at 4.

90. *Id.* at 6; JOHNSON, *supra* note 26, at 5 (FDA works with over 400 state agencies nationwide).

91. JOHNSON, *supra* note 26, at 2, 7; GAO FRAGMENTATION REPORT, *supra* note 86, at 6–7.

92. GAO FRAGMENTATION REPORT, *supra* note 86, at 6.

93. JOHNSON, *supra* note 26, at 1–2.

94. GAO FRAGMENTATION REPORT, *supra* note 86, at 20 n.50.

95. *Id.*

96. JOHNSON, *supra* note 26, at 9.

97. Amber D. Nair, CONG. RESEARCH SERV., R46851, FY2020 and FY2021 Agricultural Appropriations: Federal Food Safety Activities 3 tbl. 1 (2021).

a. Influence of Agriculture Interests

While the regulatory jurisdictions of the FDA and USDA are mostly discrete, oversight of these two main agencies by Congress has been consolidated. Both agencies are overseen and have their funding administered by the Agriculture Subcommittee within Congress.[98] The fact that the Agriculture Subcommittee wields this power over funding is an institutionalized example of the deeply entrenched principle that the solvency of American farmers is paramount when executing food law and policy.[99] Thus, a linkage has developed between food assistance programs and supporting agricultural producers, which helps explain why the USDA (tasked primarily with food *production*) administers the Supplementary Nutrition Assistance Program (SNAP), rather than the FDA (tasked primarily with public health and food supply *safety*).[100]

A partial reconfiguration of the bifurcated system might reassign food programs, such as SNAP, to the FDA. SNAP is currently administered by the USDA's subgroup, known as the Food and Nutrition Service, whose mission statement lists two potentially competing goals: "reduce hunger by providing children and low-income people access to food [and] . . . a healthful diet," and doing so "in a way that supports American agriculture."[101] A question for further scholarly exploration is what happens when the two goals conflict, and whether the FDA might not be subject to such competing pressures. Either way, the bifurcated responsibility provides an obstacle to the FDA in responding to the nutrition crisis with sweeping action, because the FDA has typically had difficulty coordinating with an entirely different agency. While there is a recognition of the problems inherent in the USDA-FDA bifurcated system of food safety oversight, that division has existed since the beginning of the modern era of food regulation and has been repeatedly re-endorsed by legislators.[102]

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98. *Id.* at 13–14.

99. *See* JACOB E. GERSEN ET AL., FOOD LAW: CASES AND MATERIALS 650–51 (Rachel E. Barkow et al. eds., 2019) (discussing the linkage between buying surplus food from American farmers and hunger programs, codified in the Emergency Food Assistance Program, as part of a deeply rooted connection between farmers and the administration of nutritional assistance).

100. *Id*. at 651; *see also* U.S. DEP'T OF AGRIC., USDA STRATEGIC GOALS, https://www.usda.gov/sites/default/files/documents/usda-strategic-goals-2018-updated-1.pdf [https://perma.cc/3MS6-H5GL] (last visited Aug. 28, 2021) (USDA Strategic goals for 2108–2022 focused mostly on producers); U.S. FOOD & DRUG ADMIN., WHAT WE DO, https://www.fda.gov/about-fda/what-we-do [https://perma.cc/VGA8-AXBM] (last visited Jan. 7, 2021) (FDA mission statement focused on public health).

101. U.S. DEP'T OF AGRIC. FOOD & NUTRITION SERV., ABOUT FNS, https://www.fns.usda.gov/about-fns [https://perma.cc/F6YD-KX37] (last visited Jan. 7, 2021).

102. *See* JOHNSON, *supra* note 26, at 2–3.

b. Dietary Guidelines

The paradigm of this disjointed regulatory system is the national dietary guidelines, which direct the FDA's nutritional priorities, but are created by the USDA.[103] These guidelines have been released every five years by the USDA since 1980.[104] While the guide purports to reflect only the "current body of nutrition science" to help "guide Americans to make healthy food and beverage choice," the reality is that millions of dollars are spent by major food conglomerates in lobbying during their creation.[105] Furthermore, because the USDA's priorities are intertwined with those of farmers and suppliers, the USDA sometimes supports perverse or misleading guidelines that represent compromises not fully aligned with the FDA's nutritional health initiatives.[106] However, the USDA's formulation of dietary guidelines is not the only process subject to industry influence. All food policies must make their way through the political process, subject to both industry and consumer demands.

2. Political Feasibility Limits from Industry and Consumers

Despite the mounting scientific evidence of the health costs imposed by dietary risks, the FDA still faces resistance from Congress against its attempts to regulate nutrition. This is because Congress is influenced by

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103. AGATA DABROWSKA, CONG. RESEARCH SERV., R43733, REVISION OF THE NUTRITION FACTS LABEL: PROPOSED RULES 1–3 (2014) (guidelines are created by a panel of nutrition experts and form the basis for nutrition policy).

104. Barbara O. Schneeman, *Evolution of Dietary Guidelines*, 103 J. AM. DIETETIC ASS'N 5–9 (2003).

105. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., ABOUT THE DIETARY GUIDELINES PURPOSE, https://health.gov/our-work/food-nutrition/about-dietary-guidelines [https://perma.cc/P3LY-PTYQ] (Dec. 29, 2020); *see, e.g.*, Markham Heid, *Experts Say Lobbying Skewed the Dietary Guidelines*, TIME (Jan. 8, 2016), https://time.com/4130043/lobbying-politics-dietary-guidelines/ (meat industry influence); Arielle Duhaime-Ross, *New US Food Guidelines Show the Power of Lobbying, Not Science*, THE VERGE (Jan. 7, 2016), https://www.theverge.com/2016/1/7/10726606/2015-us-dietary-guidelines-meat-and-soda-lobbying-power [https://perma.cc/5786-TDUH] (on meat and soda conglomerate influence); Karen Perry Stillerman, *"Big Food" Companies Spend Big Money in Hopes of Shaping the Dietary Guidelines for Americans*, UNION CONCERNED SCIENTISTS (June 6, 2019), https://blog.ucsusa.org/karen-perry-stillerman/big-food-companies-spend-big-money-in-hopes-of-shaping-the-dietary-guidelines-for-americans [https://perma.cc/S4AU-96WR] (on food companies spending many millions of dollars to effect decision-making).

106. *See, e.g.*, Michael R. Taylor, Senior Fellow and Director, Resources for the Future, Address at the Nutrition Labeling and Education Act (NLEA) 10th Anniversary 39–40 (Jan. 31, 2003) (transcript available at the U.S. Food and Drug Administration website), https://www.fda.gov/media/85806/download [https://perma.cc/3GZE-5JDY] ("[I]t was the label that we had recommended, but with an interesting kind of compromise, and there is a compromise in that label. The reason you've got the column of 2,000 and 2,500, you know, the nutrients—you know what I'm talking about. I forgot. But where we show the daily value of fat and other nutrients under a 2,000- and 2,500-calorie scenario is, I believe, the President or the staff knew a way of cutting the baby with USDA…. We won, I think, on 'lite.' We lost on restaurants.").

industry lobbyists and consumer opinion. Because the FDA's statutory authority is phrased fairly broadly, its authority to regulate nutrition has mostly been derived from their mandate to protect public health and was only formally reinforced in 1990 with the Nutrition Labeling and Education Act.[107] Thus, the FDA has had to find the limits of their power by trial and error. This process has shown that, while some efforts might have been effective health interventions if implemented, they were politically infeasible and may have created backlash that limited the FDA's later ability to intervene on nutrition concerns. Hence, the solution proposed in this Article is for the FDA to take a more cautious approach through incremental change. The following two subsections trace previous attempts to regulate that are illustrative of the risks to the FDA's authority from implementing interventions that both the public and industry perceive as overly restrictive. The first was a ban on saccharine, and the second was a limit on dietary supplements.

a. Ban on Artificial Sweeteners

In the 1970s, studies on artificial sweeteners, such as saccharine, indicated a risk of a carcinogenic effect on rats—which later studies hypothesized might similarly affect humans.[108] The FDA attempted to respond to this potential threat by removing saccharine from the list of ingredients that it deemed "generally recognized as safe" (GRAS)—an expansive list of ingredients that do not require pre-market approval by the FDA.[109] The FDA was able to use this reclassification as a tool to monitor temporarily the risks posed by saccharine until they could more conclusively prove its safety.[110]

A few years later, alarmed by the possible link to cancer, the FDA attempted to implement a full ban on saccharine in the market.[111] The ban lasted for about a week.[112] After extensive public outcry, the FDA's authority was curtailed and the Senate passed the Saccharine Study and

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107. Kessler, *supra* note 45, at 20.

108. *See, e.g.*, P.G.N. Kramers, *The Mutagenecity of Saccharin*, 32 MUTATION RES. 81 (1975) (finding mixed results in review of 17 studies of saccharin on mutagenicity); *see also* Melvin Dwaine Reuber, *Carinogenicity of Saccharine*, 25 ENV. HEALTH PERSPS. 173 (1978) (National Institute of Health study showing carcinogenic effects of saccharine on rats, which indicated potential effects for human consumption as well).

109. U.S. FOOD & DRUG ADMIN. GENERALLY RECOGNIZED AS SAFE *(GRAS)*, https://www.fda.gov/food/food-ingredients-packaging/generally-recognized-safe-gras [https://perma.cc/ZVA3-4SXR] (last visited Dec. 13, 2019); Harold M. Schmeck Jr., *F.D.A. Removes Saccharin from List of Safe Foods*, N.Y. TIMES, Jan. 29, 1972, at 27.

110. *Id.*

111. Schmeck, *supra* note 109, at 27.

112. Jesse Hicks, *The Pursuit of Sweet: A History of Saccharine*, CHEM. HERITAGE MAG., May 2, 2010, at 31 (Congress received over a million letters that week about the ban prompting swift action and the passage of the Saccharine Study and Labeling Act).

Labeling Act of 1977, which placed a two-year moratorium on bans of saccharine.[113] While the FDA has occasionally been successful in complete bans, such as in the more recent efforts with trans fats, that success has only come after conclusive evidence of health risks, a sustained public education effort, willingness from the public, and cooperation with industry.[114]

b. Supplements and DSHEA Response

Limitations on the production of certain products, or on the claims printed on the products, are among the most restrictive options the FDA can use. Attempts to use these restrictions did not fare well when applied to the massively popular dietary supplement market. The effort began in 1962, following a wave of increased attention about dietary health.[115] The FDA first tried to place limits on dietary supplements that contained high levels of vitamins.[116] That effort quickly drew industry and consumer attention, and the FDA backed down after intense consumer protest.[117]

Undeterred, the FDA continued to monitor dietary supplements, expressing renewed interest in the 1970s in the regulation of potentially toxic overuse of supplements.[118] However, in 1976, in response to sustained lobbying efforts, Congress passed the Vitamin-Mineral Amendment (known as the "Proxmire Amendment" after a leading senator) which prevented the FDA from regulating supplements as a drug, regardless of potency.[119]

Finally, the FDA efforts came to a head in the 1980s, following several adverse health incidents linked to supplements. A single supplement containing L-Tryptophan caused 1,500 cases of illnesses and 39 deaths.[120] Following these incidents, and with expanded authority from the passage of the Nutrition Labeling and Education Act (NLEA) in 1990, the FDA started putting together a task force in 1991 to treat

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113. *Id.*

114. CTR. FOR DISEASE CONTROL, *TRANS FAT: THE FACTS*, https://cchealth.org/eh/food/pdf/Trans-Fat-The-Facts.pdf [https://perma.cc/9B4W-5G6P] (last visited Aug. 28, 2021); U.S. FOOD & DRUG ADMIN., *TRANS FAT*, https://www.fda.gov/food/food-additives-petitions/trans-fat [https://perma.cc/A2MH-NBYK] (last visited Dec. 13, 2019) (FDA on history of trans fat regulation leading to ban in 2018, with leeway for industry to comply by 2020).

115. Azizi Rahi, *"Supplement" the DSHEA: Congress Must Invest the FDA with Greater Regulatory Authority over Nutraceutical Manufacturers by Amending the Dietary Supplement Health and Education Act*, 98 CAL. L. REV. 439, 442 (2010).

116. *Id.*

117. *Id.*

118. *Id.*

119. *See* Michael A. McCann, *Dietary Supplement Labeling: Cognitive Biases, Market Manipulation & Consumer Choice*, 31 AM. J.L. & MED. 215, 238 (2005).

120. *See* DONNA V. PORTER, CONG. RESEARCH SERV., RL30887, DIETARY SUPPLEMENTS: LEGISLATIVE AND REGULATORY STATUS 2 (2002).

supplements as drugs for approval.[121] When the supplement industry learned of this effort, a massive grassroots campaign was initiated to call for greater restrictions on the FDA's authority.[122] The result was the enactment in 1994 of the Dietary Supplement Health and Education Act (DSHEA). The DSHEA was widely viewed as restricting the FDA's authority over supplements. The DSHEA explicitly prohibited the rollout of the NLEA to supplements because they were not considered equivalent to food for regulatory oversight.[123]

Despite demonstrative evidence that the majority of consumers view dietary supplements as a substitute for drugs, DSHEA was enacted, specifically preventing the regulation of dietary supplements as drugs.[124] The DSHEA also shifted the burden to the FDA to prove that the supplements are *not* safe or effective, rather than requiring the industry to prove their safety and efficacy.[125] Thus, supplement regulation serves as a sobering example of FDA action that did not yet have sufficient support to override industry power and consumer preferences.

3. Limitations from Budgetary Constraints

Finally, in addition to the limitations from operating with a fragmented regulatory environment and from parameters set by Congress, the FDA's power is also limited simply by its budget. Furthermore, nutrition represents a disproportionately small percentage of the FDA's budget, at just 2%, while food safety is allocated the remaining 98%—which is one billion dollars.[126] The overall budget shortfall remains a problem today, as evidenced by the underfunding of the most recent major piece of legislation, the 2011 Food Safety and Modernization Act (FSMA).

The FSMA was a major statutory expansion of the FDA's power, which passed the political gauntlet. The FSMA was enacted by Congress to better control food poisoning outbreaks, and it is viewed as one of the most consequential pieces of legislation in food law since the Pure Food

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121. *See* Rahi, *supra* note 115, at 443.

122. *See* PORTER, *supra* note 120, at 4 (grassroots efforts mobilized health supplement industry all over the country, even offering discounts on products for supporting letters and petitions).

123. *See id.* at 3; *see also* United States v. Two Plastic Drums, 984 F.2d 814, 819 (7th Cir. 1993) (similarly restricting FDA authority over supplements by holding that black currant oil, as part of a supplement, was not a food additive and thus supplier did not bear burden of proving its safety).

124. *See* McCann, *supra* note 119, at 221 (citing studies indicating that 80% of consumers took supplements as a substitute for drugs).

125. Rahi, *supra* note 115, at 441.

126. *See* U.S. GOV'T ACCOUNTABILITY OFF, GAO-18-174, FOOD SAFETY AND NUTRITION: FDA CAN BUILD ON EXISTING EFFORTS TO MEASURE PROGRESS AND IMPLEMENT KEY ACTIVITIES (2017).

and Drug Act of 1938.[127] Despite the ambitious goals laid out in the FSMA, the FDA has been slow to roll out a similarly ambitious plan, likely due, in part, to a budget shortfall of over $400 million to make the changes.[128] Given these practical economic constraints, an economically efficient model is sorely needed.

III. FDA'S SHIFT TO LABELING AS AN INCREMENTAL APPROACH TO IMPROVING NUTRITION

As Part I one of this Article discussed, the FDA has a variety of tools available within the broad mandate of protecting public health that originated with revelations about food safety at the turn of the twentieth century. In the modern era of food regulation (in the last fifty years), the concern with public health has taken on new dimensions, moving beyond the original protections against contamination and adulteration and on to nutritional quality.

This part examines the origins of food labeling, the most effective tool for combatting nutritional deficiencies in an age of abundant processed foods and consumer ignorance. Labeling is an incremental approach that addresses the problems laid out in Part II because it is politically favored, insulated from the challenges of a disaggregated system by uniform labels, and is the best tool for educating consumers.

A. *FDA Has Clear Authority Over Labeling*

Previous efforts to regulate goods that the public or industry opposed have faced pushback from Congress, resulting in limitations to the FDA's powers.[129] Hence, there is a need to make political calculations when choosing the best tool by examining which tools have been endorsed by Congress and accepted by consumers. Over the last few decades, Congress has favored labeling. The next section traces the development of that labeling authority, which the FDA can wield as a more effective approach than other regulatory approaches because it is politically favored.

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127. *See* AMANDA HEMMERICH ET AL., FARM & FOOD LAW: A GUIDE FOR LAWYERS IN THE LEGAL SERVICES FOOD HUB NETWORK 44 (MAINE ED. 2014), http://www.legalfoodhub.org/wp-content/uploads/2014/05/Farm-and-Food-Law-Guide-Maine_May-2015.pdf [https://perma.cc/N3Z9-928S] (Congress expanded the FDA's regulatory oversight to include farms that produce raw produce, an area not previously in their purview, and the FSMA also created sweeping changes for farmers heightening their responsibility for maintaining safety standards); *see also* ROBERTS, *supra* note 17, at 8; MILESTONES, *supra* note 9 (much of the overall goal was to enhance safety by integrating local and state regulation with federal oversight by the FDA).

128. JOHNSON, *supra* note 26, at 10 (FDA reports in their 2012 budget that they would need 400 to 450 million dollars of additional funding to meet FSMA goals).

129. *See generally* Henry I. Miller, *Failed FDA Reform*, 21:3 REGULATION 24, 28–29 (1998), https://www.cato.org/sites/cato.org/files/serials/files/regulation/1998/7/v21n3-ftr2.pdf [https://perma.cc/XLY7-BRUU].

1. Origins and Development of Food Labeling Authority

The FDA has been the primary agency tasked with labeling since the passage of the Food Drug and Cosmetics Act (FDCA) in 1938. The FDCA has been continually amended since 1938 with provisions to ensure standards of identity for food to avoid misbranding.[130] With the heightened focus on nutritional health beginning in the 1960s, support for labeling rose in tandem, as illustrated by President Kennedy's address to Congress outlining a Consumer Bill of Rights which included a labeling right for a consumer to "be given the facts he needs to make an informed choice."[131]

This momentum carried through to 1966, when Congress enacted the Fair Packaging and Labeling Act (FPLA), which required that labels include a standardized statement of identity, net quantity, and place of origin.[132] The Act placed labels that travelled in interstate commerce under federal agency jurisdiction (primarily the Federal Trade Commission and the FDA), and required that the labels be informative and honest.[133] In the 1970s, the FDA attempted to increase their influence, as they did with other forms of regulation, but found greater success in labeling than they had with attempts at outright bans or limitations on products.[134] Thus, the FDA was able to implement nutrition-oriented changes such as the Nutrition Quality Guidelines for popular items like frozen dinners, which were given an endorsement by the federal government on the label if they met the nutrient content criteria.[135]

The relative success of food labeling has led to its recognition as an integral tool for public education by the FDA, which now considers labeling a major tool in the mission to protect consumers.[136] Further, subsequent amendments to acts such as the FDCA made clear that the FDA would have the ultimate say in what labels passed muster.[137] Food

130. 21 U.S.C. § 341 (2018).

131. Kennedy, *supra* note 43.

132. FED. TRADE COMM'N, FAIR PACKAGING AND LABELING ACT: REGULATIONS UNDER SECTION 4 OF THE FAIR PACKAGING AND LABELING ACT, https://www.ftc.gov/enforcement/rules/rulemaking-regulatory-reform-proceedings/fair-packaging-labeling-act [https://perma.cc/S8SB-N7BZ] (last visited Jan. 7, 2021).

133. *See* 15 U.S.C. § 1451 (prohibiting unfair and deceptive packaging and requiring labels to enable consumers to obtain accurate information about the quantity of contents); *see also* MILESTONES, *supra* note 9.

134. *See supra* Part II.C.2 (discussing the failed attempts to ban saccharine and limit vitamin composition and usage); Hutt & Hutt II, *supra* note 20, at 67–70.

135. *Id.* at 69.

136. U.S. FOOD & DRUG ADMIN., IS IT REALLY 'FDA APPROVED?', https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved [https://perma.cc/7U5X-EMPP] (last visited Dec. 13, 2019); Kessler, *supra* note 45, at 20.

137. Margaret Rosso Grossman, *Food Labels and Labeling in the United States*, 10 EUR.

would be considered mislabeled if it failed to meet regulatory requirements set out by the FDA for both the principal display panel (front of label) and information panel (side or back of label).[138] The labeling requirements generally fall within two categories: affirmative statement requirements and permissible claims.

2. Types of Label Requirements—Affirmative and Permissible Claims

The basic dichotomy of labeling is requirements for affirmative statements (e.g., statement of identity, net quantity, and ingredients) and standards for permissible claims (additional information that labels may include).[139] Affirmative requirements are less controversial—and subject only to rational basis review by courts[140]—when the FDA requires producers to include only information about their products, as opposed to suppressing speech.[141] For that reason, this Article focuses on recommendations and analysis of affirmative requirements (also known as compelled speech). Affirmative labeling represents an incremental approach compared to outright bans and is more clearly within the bounds of FDA jurisdiction.[142]

The permissibility of claims made by producers is the area where much of the modern era of food litigation has taken place because of its implications on the curtailment of the first amendment right to speech.[143] Many of these disputes center on claims of health benefits asserted on the labels of food, such as positive effects on a disease or general wellbeing

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FOOD & FEED L. REV. 160, 160 (2015).

138. *Id.*; 21 U.S.C. § 343.

139. ROBERTS, *supra* note 17, at 232.

140. Micah L. Berman, *Clarifying Standards for Compelled Commercial Speech*, 50 WASH. U. J. L. & POL'Y 53, 80 (2016) (explaining that as long as factual information is being compelled, the Supreme Court's decision in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio* indicates rational basis review is the appropriate standard).

141. *Id.* at 54 (discussing a trend in regulation towards compelled speech on labels, in light of the harsh review by the Supreme court for restrictions on commercial speech).

142. *See* Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626, 651 (1985) (establishing the prevailing standard for affirmative (or "compelled") speech of rational basis review when "the State has attempted only to prescribe what shall be orthodox in commercial advertising, and its prescription has taken the form of a requirement that appellant include in his advertising purely factual and uncontroversial speech").

143. There has been a long line of cases litigating the issue of commercial speech restriction beginning with *Central Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557 (1980), the bedrock case laying out a four-part test for the evaluating whether a limitation infringes on the right to commercial free speech:

1) Threshold requirement that the content must not be inherently misleading
2) Government must have a substantial interest
3) Regulation must directly and materially advance the government's goal
4) The regulation must be narrowly tailored.

made by producers trying to entice customers.[144] Until the enactment of the Nutrition Labeling and Education Act (NLEA) in 1990, health claims were heavily monitored and it was difficult for them to pass muster given the stringent standard that they require pre-market approval in the same way as drugs.[145] A shift away from treating health claims for food with the same standard as health claims for drugs is just one of the many changes that was introduced by the sweeping legislation of the NLEA in 1990.[146]

3. Labeling is the Least Paternalistic Intervention

Another major benefit of labeling is that it may be the most palatable option to consumers in balancing their autonomy to make choices about their health, despite this personal choice narrative being fueled by industry framing.[147] Surveys have shown considerably more support for labeling options that provide information than for taxes on unhealthy foods such as sugary beverages.[148] Thus, there is support for what has been termed "libertarian paternalism," in which interventions are designed to alter consumer behavior without restricting their choice or providing economic incentives.[149] This approach is also consistent with recommendations from the National Research Council, which identified "public acceptance" as a factor to consider when assessing the risks for a new food regulation initiative.[150]

B. *Label Standardization Negates Fragmentation in the Regulatory Environment*

Fragmentation within the regulatory environment for food safety is often cited as a source of inefficiency.[151] Labeling presents a workaround for that problem because the FDA has clear authority over labeling. Following the Nutrition Labeling and Education Act, the FDA was given

144. Mara A. Michaels, *FDA Regulation of Health Claims Under the Nutrition Labeling and Education Act of 1990: A Proposal for a Less Restrictive Scientific Standard*, 44 EMORY L.J. 319, 323 (1995).

145. *Id.* at 319.

146. *Id.* at 319–20.

147. *See* Laura Nixon et al., *"We're Part of the Solution": Evolution of the Food and Beverage Industry's Framing of Obesity Concerns Between 2000 and 2012*, 105 AM. J. PUB. HEALTH 2228 (2015) (for commentary on the concerted efforts of the food industry to frame health issues as a personal choice debate).

148. Sarah E. Gollust et al., *Americans' Opinions About Policies to Reduce Consumption of Sugar-Sweetened Beverages*, 63 PREVENTIVE MED. J. 201 (2014) (results of survey show the smallest amount of support for taxes and portion control at just above 20%, while large prominently displayed labels with calorie information garnered support from 65%).

149. Rhode, *supra* note 59, at 501.

150. *See* INST. MED. & NAT'L RSCH. COUNCIL, *supra* note 40, at 8.

151. *Supra* Part II.C.

unilateral control over the standardized nutrition label that is required for all food products.

1. Nutrition Labeling and Education Act of 1990 and Rise of Uniform Labels

The 1990 NLEA marked the most influential new piece of legislation to empower the FDA since the 1938 Food Drug and Cosmetics Act.[152] It was passed on the heels of a more extensive investigation and report by the Institute of Medicine into dietary risks from poor nutritional health and the utility of labeling as a balanced policy solution.[153] The main purposes of the NLEA were: (1) to make labels clearer; (2) to help consumers make healthier choices; and (3) to incentivize the food industry to improve the nutritional quality of their food.[154] The NLEA created clear and enforceable standards with a single label requirement, and was able to be enacted in part because the FDA worked with industry leaders to garner the necessary political support.[155]

2. Expressly Preempts State Requirements

Another critical way in which the NLEA and the standardized label consolidate power for the FDA is that Congress explicitly preempted state laws that conflicted with the NLEA provisions.[156] Thus, the NLEA not only bolstered the FDA's federal authority, but also eliminated fragmentation and conflicts resulting from state authority.[157] This is important because states all have different views on how much regulation there should be of nutrition, with some viewing even minor regulations as impinging on the autonomy of industry and consumers.[158] In conflicts of law disputes, courts have generally applied Congress' explicit preemptive requirements.[159]

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152. Fred R. Shank, *The Nutrition Labeling and Education Act of 1990*, 47 FOOD & DRUG L.J. 247 (1992); 21 U.S.C. § 343-1 (2018).

153. INST. MED., NUTRITION LABELING: ISSUE AND DIRECTIONS FOR THE 1990S (1990), http://www.nap.edu/catalog/1576.html [https://perma.cc/BC3H-FHCX] [hereinafter 1989 IOM Report] (report by the Institute of Medicine, sponsored by the FDA and USDA, tasked with analyzing nutrition health issues and the appropriateness of labeling solutions).

154. Kessler, *supra* note 45, at 21.

155. *See, e.g.*, Taylor, *supra* note 106, at 49 ("[I]t was the food industry, after all, that got us from food labeling rules to food labels.").

156. *See, e.g.*, 15 U.S.C. § 1461.

157. *See* INST. MED. & NAT'L RSCH. COUNCIL, *supra* note 40, at 5–7.

158. Rhode, *supra* note 59, at 492, 500, 502 (explaining that regulators face pushback in jurisdictions all around the country due to fear of market failures from paternalistic policies).

159. *See, e.g.*, Grocery Mfrs. of Am., Inc. v. Gerace, 755 F.2d 993, 1001 (2d Cir. 1985) ("Compliance with both the state and federal requirements is impossible. To the extent that it attempts to regulate the labeling of alternative cheese, the New York law is preempted."), *aff'd sub nom.* Gerace v. Grocery Mfrs. of Am., Inc., 474 U.S. 801, 801 (1985).

C. *Labeling is an Economically Efficient Approach to Nutrition Regulation*

The FDA is often limited by the resources it has available, hence its longstanding goal to create programs that are efficient in promoting health.[160] Labeling is a strong option in advancing this goal because it spreads the cost throughout industry and requires less costly enforcement effort by the FDA to maintain.[161] More ambitious, hands-on initiatives, such as those proposed in the 2011 Food Safety and Modernization Act, which involve direct oversight of produce suppliers, have resulted in shortfalls of hundreds of millions of dollars in funding.[162] By contrast, some more modest proposals, such as calorie disclosures, are viewed as low cost initiatives that are cost effective relative to other types of government interventions.[163]

D. *2016 Nutrition Panel Update by FDA Exemplifies the Incremental Approach*

In a much overdue update, the FDA published a new rule in May of 2016 which was designed to reflect "new scientific information, including the link between diet and chronic disease."[164] These changes mark the first major update to the Nutrition Facts Panel in over twenty years since its introduction in 1993, as the FDA increasingly focuses on improving dietary health through more informed consumer choice.[165] The 2016 label update provides a recent example of the feasibility of incremental change via labeling that avoids the pitfalls of previous failed regulations because: (1) it built on existing labeling authority (politically favored); (2) in an area where FDA power is consolidated (fragmentation

160. *See* Hutt, *supra* note 21, at 103–04 ("[W]e must set priorities and develop programs designed to achieve the greatest impact possible from the limited resources available.").

161. *1989 IOM Report*, *supra* note 153, at 265 (discussing strategies of promoting dietary changes and noting that there are more personalized methods than labeling, but that they would be inefficient for large populations, whereas labeling strikes a good balance).

162. JOHNSON, *supra* note 26, at 10.

163. Rhode, *supra* note 59, at 523; *see also* Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, WIS. L. REV. 1161, 1191–92 (2004) (discussing the relatively low cost of nutritional requirements on menus for fast food restaurants).

164. U.S. FOOD & DRUG ADMIN., CHANGES TO THE NUTRITION FACTS LABEL, https://www.fda.gov/food/food-labeling-nutrition/changes-nutrition-facts-label [https://perma.cc/UG6Q-F52H] (last visited Oct. 12, 2020).

165. *Statement from FDA Commissioner Scott Gottlieb, M.D., on an Updated Approach for Including Added Sugar Information on the Nutrition Facts Labels of Pure Maple Syrup and Honey*, U.S. FOOD & DRUG ADMIN. (Sept. 6, 2018) [hereinafter *Statement from FDA Commissioner*], https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-updated-approach-including-added-sugar-information [https://perma.cc/7WKZ-EJR4].

less of an issue); and (3) it did not require excessively cost-intensive overhauls for the FDA or industry.

1. Changes Including Added Sugar and Daily Value

The 2016 update includes a few key changes and follows on the heels of the 2015–2020 Dietary Guidelines for Americans, published every five years.[166] Those changes include more prominent displays of the calorie count and servings per container, as well as an update to serving sizes to represent more accurately the actual eating habits of Americans.[167] Perhaps the most surprising update, though, was the change to the way in which sugar must now be listed on the label.

The FDA now requires an "added sugars" (non-naturally present sugar) entry on the nutrition label, both in grams and as a percentage of the daily value.[168] This follows on the inclusion of strong evidence within the Dietary Guidelines that it is difficult to obtain the necessary nutrients for a healthy diet when sugar represents more than 10% of one's daily caloric intake.[169] It remains to be seen whether the courts will endorse this form of compelled speech, considering the strongly supported public health objectives.[170] The FDA also followed recommendations from a 2010 report by the Institute of Medicine, suggesting that labels list all forms of sugar (e.g., high fructose corn syrup, glucose, fructose) as one ingredient, so that consumers could accurately assess the proportion of sweeteners in total.[171] Needless to say, these changes did not come about without resistance from the sugar-related industries.

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166. *Id.*

167. *See* U.S. FOOD & DRUG ADMIN., THE NEW AND IMPROVED NUTRITION FACTS LABEL – KEY CHANGES (Jan. 2018), https://www.fda.gov/media/99331/download [https://perma.cc/N7Z5-SETP] (reprinted in Appendix A for full visual illustration of changes); *see also* Dabrowska, *supra* note 103, at 5 (2014) (noting changes to "Reference Amount Customarily Consumed," since data for original reference was gathered in 1977 and 1988, and habits have changed).

168. U.S. FOOD & DRUG ADMIN., ADDED SUGARS: NOW LISTED ON THE NUTRITION FACTS LABEL 1, 2 (Mar. 2020), https://www.fda.gov/media/135299/download [https://perma.cc/RZ6F-K7W8].

169. *Id.* at 2; *Statement from FDA Commissioner*, *supra* note 165; Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33,742, 33,813 (May 27, 2016) (to be codified at 21 C.F.R. pt. 101).

170. *See* Colleen Smith, *A Spoonful of (Added) Sugar Helps the Constitution Go Down: Curing the Compelled Commercial Speech Doctrine with FDA's Added Sugars Rule*, 71 FOOD & DRUG L.J. 442 (2016) (discussing the unresolved nature of compelled speech doctrine and arguing that an added sugars requirement is different from the existing jurisprudence because it is not necessarily addressing deceptive practices).

171. *See* INST. MED. & NAT'L RSCH. COUNCIL, *supra* note 40; *see also* Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. at 33803.

2. Industry Influence on the "Added Sugar" Debate

Almost immediately after the FDA's announcement of the proposed "added sugar" addition to the nutrition label, sugar-related industries—termed "Big Sugar" by the press—voiced opposition.[172] "Big Sugar" claimed the evidence was lacking, even though many of the leading domestic and international health organizations had published well-supported conclusions that American rates of sugar intake were too high.[173] While consumer-oriented organizations such as the Center for Science in the Public Interest had long supported this change, the sugar industry had been running its own campaign of influence for decades.[174] That industry influence had an effect in many of the major channels that drive public opinion and legislation.

In the public domain, the food industry has employed a complex, multipronged campaign, promoting their most controversial views through non-profits that they fund, as well as through trade associations, so as not to damage their individual brands.[175] In fact, food executives have admitted as much, saying that they use non-profits to promote more proactive and irreverent criticisms specifically because donations are anonymous.[176] Perhaps more insidious, though, is the effect food executives have had on research conclusions.

Because sugar consumption is quite high, there have been many studies on the effect of sugar consumption on weight gain, and then systematic reviews analyzing the findings of those studies in the aggregate. However, a comprehensive meta-analysis of the effect of financial industry funding or conflicts of interest on the findings of those systematic reviews reveals likely bias.[177] From the eighteen systematic reviews identified, in the twelve where there was not a conflict of interest, ten of them found consumption of sugar-sweetened beverages to be a risk

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172. *See* Roberto A. Ferdman, *Why the Sugar Industry Hates the FDA's New Nutrition Facts Label*, WASH. POST (May 20, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/05/20/why-the-sugar-industry-hates-the-fdas-new-nutrition-facts-label/ [https://perma.cc/46PJ-WQ6E].

173. *See* Roberto A. Ferdman, *The Crucial FDA Nutrition Label Battle You Probably Don't Know About, but Should*, WASH. POST (July 2, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/07/02/the-crucial-fda-nutrition-label-battle-you-probably-dont-know-about-but-should/ [https://perma.cc/8DX7-6V3B]; *see also* Appendix B for visual graph of American consumption as compared to health guidelines from leading institutions.

174. *See* Ferdman, *supra* note 172.

175. *See* Nixon et al., *supra* note 147, at 2231 (industry used a variety of tactics, often promoting more controversial narratives, such as obesity not being a significant health risk, through nonprofits that they funded, rather than directly from the companies).

176. *Id.*

177. *See* Maira Bes-Rastrollo et al., *Financial Conflicts of Interest and Reporting Bias Regarding the Association between Sugar-Sweetened Beverages and Weight Gain: A Systematic Review of Systematic Reviews*, 10 PLOS MED. 1 (2013) (meta-analysis of meta-analyses on the effect of financial interests on research conclusions).

factor for weight gain.[178] By contrast, of the six systematic reviews that had conflicts of interest in funding, only one found a positive association between sugar consumption and weight gain.[179]

All of this may begin to sound similar to the story of "Big Tobacco" and its efforts to mislead the public. In fact, that conclusion is not far off, as studies have also found that corporations in the food industry manipulated evidence in ways not accepted by the scientific community, similar to the ways in which the tobacco industry misled health officials.[180] Thus, the finalization of the 2016 labeling rule after just two years of discussion represents a small but critical step forward against daunting obstacles from industry opponents.

IV. THE FDA'S FUTURE IN PROMOTING NUTRITION

The 1990 Nutrition Education and Labeling Act, as well as the recent 2016 updates to the rules by the FDA, indicate that there is the most political momentum for solutions to nutrition concerns in the labeling domain. Focusing on the FDA's clearly established power to regulate labeling, the agency can inform consumers of the health risks of food products while respecting individual freedom of choice. Thus, a strategy for the next steps in addressing nutritional deficiencies should be focused on improving labeling to communicate more effectively with consumers. Two related improvements that may advance consumer absorption of vital information would be focusing on nutritional nudges and using visual front-of-package solutions. Labeling interventions of this sort have already shown promising results in other countries facing similar nutrition crises by curbing consumption of unhealthy products.[181]

A. *Focusing on Nutritional Nudges via Informative Labeling*

An update to the nutrition panel was the first step in providing consumers with more accurate information. However, consumers still have had difficulty in comprehending and using labels in their current form.[182] Thus, the FDA should look more carefully at ways in which the

178. *Id.*

179. *Id.*

180. *See* Gary Jonas Fooks et al., *Corporations' Use and Misuse of Evidence to Influence Health Policy: A Case Study of Sugar-Sweetened Beverage Taxation*, 15 GLOBALIZATION AND HEALTH 1 (2019).

181. *See* Andrew Jacobs, *Sugary Drink Consumption Plunges in Chile After New Food Law*, N.Y. TIMES (Feb. 11, 2020), https://www.nytimes.com/2020/02/11/health/chile-soda-warning-label.html?algo=identity&fellback=false&imp_id=561700973&imp_id=83508295&action=click&module=Science%20%20Technology&pgtype=Homepage [https://perma.cc/7EX9-YSH5] (coverage of new study finding dramatic decrease in sugar consumption following an aggressive effort in Chile to educate consumers about the sugar content of food products).

182. *See* Jane Kolodinsky, *Persistence of Health Labeling Information Asymmetry in the United States: Historical Perspectives and Twenty-First Century Realities*, 32(2) J.

presentation and manner in which information is communicated may have an effect on the consumers. One approach is to design methods of communication that point the consumer in the right direction. These signposts for the consumer are known as "nudges" by experts.[183]

The main benefit of nudges is that they preserve the autonomy of the decision makers—the consumers—by not mandating what they must choose or providing economic incentives, but still guiding their decision towards the rational (or healthy) path.[184] These nudges should be designed by a special team within the FDA and be simple and intuitive indicators for consumers at the point of purchase. An example of this method would be requiring the industry to highlight or use a red font on rows in the nutrition label where an ingredient reaches a certain threshold (e.g., greater than 100% of daily value for sugar or salt per serving). The most intuitive place for these signals though is the front of the package.

B. *Front of Package Labeling and Visuals*

A slightly more aggressive method—and logical next step—is to require disclosures on the front of labels. Front-of-package solutions have been increasing in popularity in other countries and could provide models for the FDA.[185] For example, the FDA could adopt the UK system known as the Multiple Traffic Light System, which uses the familiar three-color system of stoplights to indicate the relative healthiness of a food.[186] This could be used in conjunction with a system of highlights on the nutrition facts label, which is consistent and color-coordinated. Such a system would also be in line with the findings of the second phase of an extensive report, which the FDA partially funded, by the Institute of Medicine on front-of-package solutions.[187] That report found four important attributes of successful labeling systems: (1) simple and understandable; (2) presented as interpretive guidance, not facts; (3) ordinal (scale of relative value); and (4) easily identifiable and communicated.[188]

The concept of front-of-label health information in the United States is certainly not new, but has historically been a battleground of first

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MACROMARKETING 193 (2012).

183. Cass R. Sunstein, *Nudging: A Very Short Guide*, 37 J. CONSUMER POL'Y 583 (2014).

184. *Id.*

185. Elsa Savourey, *Supermarket Heuristics: Behavioral Insights into the U.S. Nutrition Labeling Policy*, 23 VA. J. SOC. POL'Y & L. 89, 114 (2016); *see also* Jacobs, *supra* note 181 (describing a system that was implemented in 2016 in Chile that includes black stop signs on products that are high in calories or non-nutritious ingredients such as sugar).

186. Gyorgy Scrinis & Christine Parker, *Front-of-Pack Food Labeling and the Politics of Nutritional Nudges*, 38 UNIV. DENVER L. & POL'Y 234, 235 (2016).

187. *See* INST. MED., *Report Brief,* FRONT-OF-PACKAGE NUTRITION RATING SYSTEMS AND SYMBOLS: PROMOTING HEALTHIER CHOICES (Oct. 2011), https://www.nap.edu/resource/13221/frontofpackagereportbriefFINAL.pdf [https://perma.cc/Q7RQ-EG5T].

188. *Id.* at 2.

amendment rights, with an industry seeking to include health claims designed to entice buyers.[189] Serious attempts to require front-of-package disclosures or warnings have taken place, so far, only at local levels in cities such as San Francisco for sugar and New York for salt-content, with mixed results.[190] Thus, while the FDA may have the statutory authority to require additional front-of-label information, it remains to be seen if the judiciary will interpret such actions as an infringement on commercial speech rights, particularly for visual graphics, which are more controversial.[191]

CONCLUSION

The FDA has come a long way from its origins in protecting consumers from the horrendously unsanitary practices of meat factories. The challenges the FDA faces have evolved as well, as we have entered an era of abundant but nutrient-poor food. In this new era, the FDA must find solutions that make consumers aware of the degree of peril they are taking when choosing to consume unhealthy foods, so that they can make better dietary choices.

Labeling is likely the best path forward to accomplish the FDA's goals of protecting consumers, due to its political feasibility, clear statutory basis, and relative economic efficiency. Reform of the nutrition panel alone will not be sufficient to address all nutrition concerns. Therefore, the FDA should consider front-of-package labeling options, focused on guiding consumers to healthier choices, and ideally causing industry to shift their offerings over time.

189. *See supra* Part II.A.2.

190. See *supra* Part III.A.2 for a discussion on affirmative labeling; N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health, 556 F.3d 114, 132 (2d Cir. 2009) ("In light of *Zauderer*, this Circuit thus held that rules 'mandating that commercial actors disclose commercial information' are subject to the rational basis test."); Am. Beverage Ass'n v. City & County of San Francisco, 916 F.3d 749, 757 (9th Cir. 2019) ("On this record, therefore, the 20% requirement is not justified and is unduly burdensome when balanced against its likely burden on protected speech.").

191. *See* Micah L. Berman, *Clarifying Standards for Compelled Commercial Speech*, 50 WASH. U. J. L. & POL'Y 53, 69 (2016) (discussing use of visual pictures in compelled speech debate).

The New and Improved Nutrition Facts Label – Key Changes

U.S. FOOD & DRUG ADMINISTRATION

The U.S. Food and Drug Administration has finalized a new Nutrition Facts label for packaged foods that will make it easier for you to make informed food choices that support a healthy diet. The updated label has a fresh new design and reflects current scientific information, including the link between diet and chronic diseases.

1. Servings

The number of "servings per container" and the "Serving Size" declaration have increased and are now in larger and/or bolder type. Serving sizes have been updated to reflect what people actually eat and drink today. For example, the serving size for ice cream was previously 1/2 cup and now is 2/3 cup.

There are also new requirements for certain size packages, such as those that are between one and two servings or are larger than a single serving but could be consumed in one or multiple sittings.

2. Calories

"Calories" is now larger and bolder.

3. Fats

"Calories from Fat" has been removed because research shows the type of fat consumed is more important than the amount.

4. Added Sugars

"Added Sugars" in grams and as a percent Daily Value (%DV) is now required on the label. Added sugars includes sugars that are either added during the processing of foods, or are packaged as such (e.g., a bag of table sugar), and also includes sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices. Scientific data shows that it is difficult to meet nutrient needs while staying within calorie limits if you consume more than 10 percent of your total daily calories from added sugar.

5. Nutrients

The lists of nutrients that are required or permitted on the label have been updated. Vitamin D and potassium are now required on the label because Americans do not always get the recommended amounts. Vitamins A and C are no longer required since deficiencies of these vitamins are rare today. The actual amount (in milligrams or micrograms) in addition to the %DV must be listed for vitamin D, calcium, iron, and potassium.

The daily values for nutrients have also been updated based on newer scientific evidence. The daily values are reference amounts of nutrients to consume or not to exceed and are used to calculate the %DV.

6. Footnote

The footnote at the bottom of the label has changed to better explain the meaning of %DV. The %DV helps you understand the nutrition information in the context of a total daily diet.

Current Label

Nutrition Facts

Serving Size 2/3 cup (55g)
Servings Per Container About 8

Amount Per Serving	
Calories 230	Calories from Fat 72
	% Daily Value*
Total Fat 8g	**12%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**12%**
Dietary Fiber 4g	**16%**
Sugars 12g	
Protein 3g	
Vitamin A	10%
Vitamin C	8%
Calcium	20%
Iron	45%

* Percent Daily Values are based on a 2,000 calorie diet. Your daily value may be higher or lower depending on your calorie needs.

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

New Label

Nutrition Facts

1 8 servings per container
Serving size **2/3 cup (55g)**

2 **Amount per serving**
Calories **230**

	% Daily Value*
3 **Total Fat** 8g	**10%**
Saturated Fat 1g	**5%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 160mg	**7%**
Total Carbohydrate 37g	**13%**
Dietary Fiber 4g	**14%**
Total Sugars 12g	
4 Includes 10g Added Sugars	**20%**
Protein 3g	
5 Vitamin D 2mcg	10%
Calcium 200mg	15%
Iron 8mg	45%
Potassium 235mg	6%

6 * The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Transitioning to the New Label

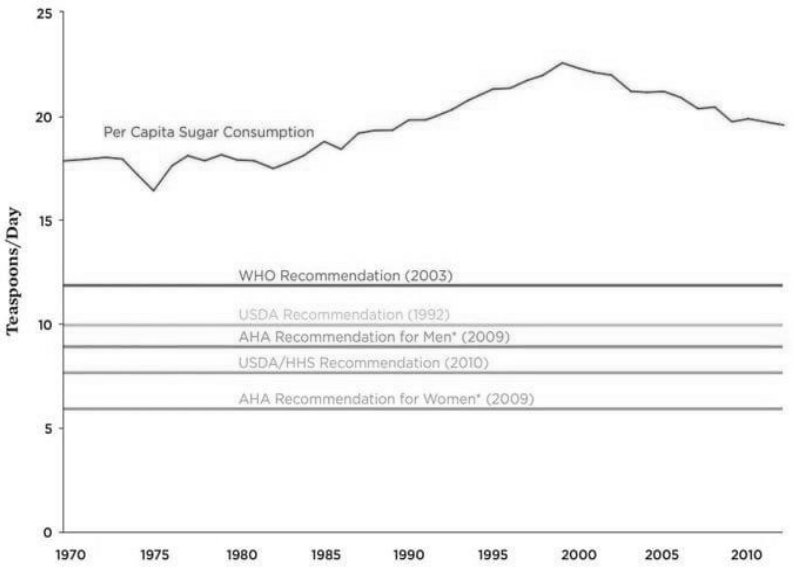
Manufacturers still have time to begin using the new and improved Nutrition Facts label, so you will see both label versions for a while. However, the new label is already starting to appear on products nationwide.

For more information about the new Nutrition Facts label, visit:
www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm

January 2018

Source: *The New and Improved Nutrition Facts Label- Key Changes*, U.S. Food & Drug Admin. (Jan. 2018), https://www.fda.gov/media/99331/download [https://perma.cc/P85U-QG4U].

FIGURE 1. Per Capita Sugar Consumption in the United States: Actual versus Recommended



The per capita consumption of sugar in the United States far exceeds the limits recommended by several scientific and governmental institutions including the WHO, the HHS, the USDA, and the AHA (CHPP 2010; AHA 2009; WHO 2003b; CHPP 1992). Starting in 2012, the USDA is using a new methodology for calculating per capita consumption, which is expected to lead to lower estimates (Strom 2012). Regardless of the decline in sugar consumption since 2000 (which is largely attributable to the replacement of regular sodas with their diet versions), the fact remains that Americans are consuming, on average, more than twice the recommended levels of sugar.

* AHA recommendations are based on a 2,200-calorie diet for men and an 1,800-calorie diet for women (AHA 2009). All other standards are based on a 2,000-calorie diet.

Source: Robert A. Ferdman, *The Crucial FDA Nutrition Label Battle You Probably Don't Know About But Should*, WASH. POST (July 2, 2014), https://www.washingtonpost.com/news/wonk/wp/2014/07/02/the-crucial-fda-nutrition-label-battle-you-probably-dont-know-about-but-should/ [https://perma.cc/9AY6-JJML].