The Skinny on the FOP Flop: Why the FDA Must Tighten the Belt on FOP Labeling in Light of the Obesity Crisis

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NOTE

THE SKINNY ON THE FOP FLOP: WHY THE FDA MUST TIGHTEN THE BELT ON FOP LABELING IN LIGHT OF THE OBESITY CRISIS

I. INTRODUCTION

The American obesity crisis is in desperate need of governmental intervention. Obesity has been called the “most prevalent, fatal, chronic, relapsing disorder” of the twenty-first century. Approximately 200 million adult Americans, or 66.3% of the population, are overweight. More than half of that group, or one-third of adults, classify as obese. In the past thirty years, obesity rates for adults have doubled, and even more alarming, the rates for children have tripled.

During the last half-century, the average height for adults has grown by one inch, while the average weight has risen by twenty-five pounds.

As waistlines have ballooned, so have the medical costs of obesity. Annual national costs swelled from $117 billion per year in 2000 to an

1. See The Supersizing of America: The Federal Government’s Role in Combating Obesity and Promoting Healthy Living: Hearing Before the H. Comm. on Gov’t Reform, 108th Cong. 46, 47-48, 52-53 (2004) (statement of Lynn C. Swann, Chairman, President’s Council on Physical Fitness and Sports), available at http://www.access.gpo.gov/congress/house/pdf/108hrg/95914.pdf (“The federal government needs to stimulate all levels of government ... to join with us to attack the obesity epidemic and its attendant health problems.”); see also id. at 52-53 (“We need our government to stand squarely behind initiatives and interventions to stress and encourage all Americans to be physically active every day, to eat a nutritious diet, to get preventive screenings, and to avoid risky behaviors. These are the four pillars of the President’s Healthier US initiative.”).


3. Id.

4. Id.


6. What is Obesity, supra note 2.

7. See CRS. FOR DISEASE CONTROL & PREVENTION, supra note 5, at 2 (showing that between 1987 and 2001, diseases linked to obesity caused a twenty-seven percent increase in medical costs).

8. See id.
approximate $147 billion per year in 2008.\textsuperscript{9} Compared to an American of normal weight, medical costs for an obese citizen are roughly forty-two percent higher, or $1429 more per year.\textsuperscript{10} These figures reflect the countless health risks associated with obesity, including Type 2 diabetes, high cholesterol, hypertension, gallstones, sleep apnea, stress incontinence, heart failure, fatty liver disease, degenerative joint disease, birth defects, miscarriages, and asthma.\textsuperscript{11} In addition, obesity triggers more than 100,000 cases of cancer per year in the United States.\textsuperscript{12} Consequently, obesity causes at least 112,000 excess deaths per year in the United States.\textsuperscript{13} These statistics explain why Americans have the second-worst life expectancy in the industrialized world, ahead only of Latvia.\textsuperscript{14}

Despite the overwhelming size of this problem, until recently, the nation largely ignored the obesity epidemic.\textsuperscript{15} Stigmas against obese people—characterizing them as lazy failures who were responsible for...
solving their own health problems—precluded government action. Moreover, because obesity is often impervious to treatment, biological research overlooked prevention. According to nutrition experts, “[m]ost alarming has been the national inaction in the face of crisis, the near-total surrender to a powerful food industry, and the lack of innovation in preventing further havoc.”

Many nutritionists see the food industry as a cunning culprit in keeping obesity on the national backburner. The food industry "pressures legislators, attempts to influence national nutrition guidelines, and opposes measures such as food labeling that would help consumers understand what they are eating. The industry is organized, well-funded, and expert at lobbying, and hence has friends in high places and formidable power.”

Notwithstanding these criticisms, on its face, the food industry attempts to fight obesity by marketing healthier products and providing...
increased nutritional information.\textsuperscript{21} A telling example is the recent effort by the food industry in sponsoring the Smart Choices Program ("Smart Choices"), a uniform, front-of-package ("FOP") nutrition labeling campaign designed to help supermarket shoppers make smarter food and beverage choices.\textsuperscript{22} Smart Choices used a green checkmark symbol to endorse food and beverages in nineteen different product categories.\textsuperscript{23} It also displayed the amount of servings and calories per serving on the front of the packages in an effort to educate consumers.\textsuperscript{24}

Although a nonprofit organization, the Keystone Center, developed Smart Choices, members of the food industry joined scientists and consumers in establishing its nutritional guidelines.\textsuperscript{25} The food companies bankrolled the cost of these nutrition-development meetings, which totaled more than $680,000.\textsuperscript{26} In addition, from 2008 to 2009, fourteen corporations contributed $1.47 million to sponsor the creation of Smart Choices.\textsuperscript{27}

\textsuperscript{21} Brownell & Horgen, supra note 15, at 253-54. The food industry takes a strong public stance against obesity:

The food companies say the right words. Food industry websites have information on nutrition and physical activity, they support coalitions that promote changes in diet and exercise, they say they are working to develop healthier products, and they state with no ambiguity that they are committed to the health of the nation.

\textit{Id.} See generally Lisa L. Sharma et al., The Food Industry and Self-Regulation: Standards to Promote Success and to Avoid Public Health Failures, 100 AM. J. PUB. HEALTH 240 (2010) (analyzing the food industry's self-regulatory pledges to see whether they promote public health or whether they are deceptive).


\textsuperscript{23} See id.

\textsuperscript{24} Id.; see Sharma et al., supra note 21, at 242.


\textsuperscript{26} See Ruiz, supra note 25.

\textsuperscript{27} See id. (claiming that the program "has been portrayed as in the corner of industry; food companies that participate fund the program annually based on a sliding scale ranging from $5,000 to $100,000").
Despite the industry's good intentions, nutrition experts and members of the public lambasted Smart Choices soon after it hit shelves in the summer of 2009. Critics questioned the program's nutritional criteria after it endorsed more than eight hundred products, including sugary cereals like Kellogg's Froot Loops and Frosted Flakes. As one critic observed, "you can put vitamins and minerals in garbage and it will meet the nutritional requirements as long as the garbage is low in fat." Nutritionists alleged that because the food industry dominated the development panel, it skewed Smart Choices' nutritional criteria, setting a low benchmark to include as many products as possible. According to Michael Jacobson, the executive director of the Center for Science in the Public Interest, who resigned from the Smart Choices panel in...
September 2008: “It was paid for by industry and when industry put down its foot and said this is what we’re doing, that was it, end of story.”

Criticism of Smart Choices spurred political action. Congresswoman Rosa DeLauro (D-CT) urged the U.S. Food & Drug Administration (“FDA”) to investigate whether products bearing the Smart Choices checkmarks were misbranded. In response to Congresswoman DeLauro and other critics, the FDA announced in October 2009 that it had concerns about FOP labeling “which extend beyond any particular program,” and that it planned to develop national, uniform guidelines to address the concerns. The FDA’s announcement prompted Smart Choices to “postpone active operations” and within

33. Neuman, supra note 32. Jacobson echoed Mark Bittman in his criticism of the nutritional criteria, claiming, “[y]ou could start out with some sawdust, add calcium or Vitamin A and meet the criteria.” Id. (internal quotation marks omitted); see supra note 32 and accompanying text; see also Wanjek, supra note 30 (“[T]he guidelines are so skewed by industry that they are laughable.”).

34. See Press Release, Congresswoman Rosa L. DeLauro, DeLauro Calls for FDA Investigation into “Smart Choices” Labeling (Sept. 21, 2009), http://delauro.house.gov/release.cfm?id=2653 (“I am very concerned that the Smart Choices program . . . is using criteria that are not stringent enough to protect consumers from misleading claims.”).


one week, caused eight major food manufacturers to withdraw from the program.\footnote{37} The FDA has yet to issue its new FOP guidelines. However, in its announcement, the agency said:

We want to work with the food industry—retailers and manufacturers alike—as well as nutrition and design experts and the Institute of Medicine, to develop an optimal, common approach to nutrition related FOP . . . labeling that all Americans can trust and use to build better diets and improve their health.\footnote{38}

Smart Choices posted this announcement on its website, beneath a banner reading “Group Welcomes Opportunity to Collaborate on Front-of-package Labeling with the FDA.”\footnote{39}

This Note will argue that the food industry is an untrustworthy ally, and that in light of the burgeoning obesity epidemic in the United States, the federal government must act independently in creating a uniform FOP labeling scheme. Part II will discuss the conflict between public health aims and the profit-driven food industry. Part III will explore this conflict by examining the legal history and the current framework for federal nutrition labeling. Then, Part IV will analyze recent labeling

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\footnote{38. Letter from Schneeman to the Food Industry, supra note 35; see also \textit{About the IOM}, INSTITUTE OF MEDICINE, http://iom.edu/About-IOM.aspx (last updated July 15, 2010, 2:24 PM) (“The Institute of Medicine (IOM) is an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public.”). In March 2010, the Commissioner of the FDA, Margaret Hamburg again announced the FDA’s desire to work with the food industry:

\textit{I believe we now have a wonderful opportunity to make a significant advancement in public health if we can devise a [FOP] labeling system that consumers can understand and use. We intend to work closely with food manufacturers, retailers, and others in the design process, and I hope that every food processor will contribute its views on how we can do this in the best way possible.}

Letter from Margaret A. Hamburg, Commr’r of Food & Drugs, to the Food Industry (Mar. 3, 2010), http://www.fda.gov/Food/LabelingNutrition/ucm202733.htm (emphasis added).}

\footnote{39. Press Release, Smart Choices Program, supra note 36. In its announcement, Smart Choices quoted its chairman, Mike Hughes: “Our nutrition criteria are based on sound, consensus science. . . . But with the FDA’s announcement this week that they will be addressing [FOP systems], and that uniform criteria may follow, it is more appropriate to post pone [sic] active operations and . . . to support [the FDA’s] initiative.” \textit{Id.; see William Neuman, \textit{F.D.A. to Clarify Standards for the Front of Food Labels}, N.Y. TIMES, Oct. 21, 2009, at B3. According to Hughes: “We also look forward to the opportunity to participate in [the FDA’s] initiatives on [FOP] labeling.” \textit{Id.} (internal quotation marks omitted).}
actions taken by the food industry to show that it cannot be trusted. Part V will assert that the federal government must act independent from the food industry in developing its uniform FOP labeling regulations. Further, Part V will suggest possible FOP regulations. Finally, this Note will conclude that, as a matter of public health, to combat the obesity crisis, the FDA must adopt objective nutritional criteria for its FOP labeling scheme.

II. HOT POTATO: THE BATTLE BETWEEN THE FOOD INDUSTRY AND PUBLIC HEALTH GOALS

Throughout history, there has always been a conflict between industry and public health goals.40 The impact of the tobacco industry offers the most salient comparison to the current struggle between the food industry and public health aims:41

Legislators, the press, and the public were flabbergasted when tobacco industry CEOs testified that nicotine is not addictive. This helped sensitize the nation to how badly industry leaders can behave when money and power are at stake. Decades from today, history will look back on how legislators, the press, and the public are responding right now to claims by the food industry that they support public health, to statements that their products are not contributing to obesity, and to their pleas not to be demonized.42

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40. RUDD CTR., supra note 9, at 60. See generally Brownell & Warner, supra note 19 (comparing the tobacco industry to the food industry and evaluating how both industries have goals contrary to public health).

41. See Julie Neal, Childhood Obesity Prevention: Is Recent Legislation Enough?, 27 J. JUV. L. 108, 112-15, 121 (2006) (asserting that the campaign against tobacco addiction provides helpful guidelines in the campaign against obesity); see also BROWNELL & HORGEN, supra note 15, at 255 (comparing the “dreadful history” of the tobacco industry to the current food industry). See generally Brownell & Warner, supra note 19 (asserting that there are many similarities between the food and tobacco industry). Often, “industry talks about the moral high ground but does not occupy it.” Id. at 260.

42. BROWNELL & HORGEN, supra note 15, at 255; see Neal, supra note 41, at 121 (“The tobacco crisis exemplifies the difficulty of dealing with a national health crisis when legislators on the national level are unwilling or unable to act in order to eliminate the crisis.”).
There is a major conflict of interest between the food industry and public health aims. It is "no exaggeration to say that public health has been sacrificed at the altar of profits, and that current food policy, although not quite the worst [it has] ever been, is sorely lacking." The food industry competes for consumers’ purchases with profits, not nutrition, as the main goal. Because most food companies are publicly traded corporations, they must report quarterly to Wall Street and meet profit and growth demands. Renowned nutritionist Marion Nestle further explains: “Companies must sell more, and then more, and even more. In this kind of investment economy, weight gain is just collateral damage.”

Nutrition experts argue that the food industry’s influence on nutrition policy is dangerous to public health aims. Food companies lobby the government for their individual, private aims, and often fiscally entangle themselves with nutrition experts. Thus, it is nearly impossible for nutritionists and food professionals to remain independent when they join alliances with food companies. The “food industry frames such tactics as promoting individual liberty and free will, [but] its true objective is (not surprisingly) ‘trade and unrestricted profit.’” Therefore, when the government or other private groups court the food industry’s involvement, it "scream[s] conflict of interest, but the danger is being ignored."

43. See BITTMAN, supra note 14, at 40; Emily J. Schaffer, Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?, 57 FOOD & DRUG L.J. 371, 406 (2002) (“Much ink has been spilled by nutritionists bemoaning the food industry’s influence over the content of nutrition information bearing the government’s imprimatur...[T]he dietary recommendations offered by the government...reflect significant industry influence and politically motivated concessions.”); see also Brownell & Warner, supra note 19, at 265 (noting that one feature of the food industry’s “strategy” is to “[s]tate there are no good or bad foods; hence no food or food type...should be targeted for change”); supra note 19 and accompanying text (discussing nutritionists’ perceptions of the food industry’s attempts to influence public policy).

44. BITTMAN, supra note 14, at 40.

45. See MARION NESTLE, supra note 19, at 13.

46. NESTLE, supra note 45, at 13.

47. See About Marion Nestle, supra note 19, at 361; Alderman et al., supra note 45, at 102.

48. NESTLE, supra note 45, at 13.

49. See BROWNELL & HORGEN, supra note 15, at 280.

50. See NESTLE, supra note 19, at 361.

51. Id. at 371.

52. Id. at 361; Alderman et al., supra note 45, at 102.

53. BROWNELL & HORGEN, supra note 15, at 280.
Moreover, if it helps sell products, companies will use nutrition as a marketing tool. While its promotion of health may be sincere, the food industry’s insistence that it should be involved in government decisions and that it shares public health goals could also be an ingenious way to block critics. Thus, nutritionists argue that the food industry “cannot raise [its] flag on the high ground by making superficial efforts, boasting of them, and all the while aggressively marketing high-sugar, high-fat, high-calorie products, cultivating children as customers, selling problem foods in schools, and the like.”

By inviting involvement of the food industry, government leaders believe that food companies will be responsible partners who will share their knowledge to improve Americans’ health. However, as some critics urge, these beliefs may be ill-considered. One possible solution to the conflict of interest between the food industry and public health aims “is to call a moratorium on input from the food industry, while offering it the chance to prove a commitment to public health.”

Yet, the same critics warn that creating “an ‘invite them or fight them’ dichotomy” is a potential trap. According to health policy reports, the government’s achievements in food industry regulation likely will pale in comparison to those of a motivated food industry acting alone. In 2006, a joint workshop conducted by the Federal Trade Commission (“FTC”) and the Department of Health and Human Services (“DHHS”) found that, in numerous circumstances, successful industry self-regulation trumps government regulation by tackling problems in a faster, more innovative, and more flexible manner.

54. NESTLE, supra note 19, at 362.
55. See BROWNELL & HORGEN, supra note 15, at 259.
56. Id. at 279; see RUDD CTR., supra note 9, at 60 (providing an illustration of cereal companies who publicly pledged to decrease marketing their unhealthy products to children, yet continued to “aggressively” push their worst cereals towards children).
57. See BROWNELL & HORGEN, supra note 15, at 280; Michael Pollen, Rules to Eat By, N.Y. TIMES, Oct. 11, 2009 (Magazine), at 64 (“[O]fficial government pronouncements about eating aren’t necessarily much more reliable, not when the food industry influences federal nutrition guidelines.”).
58. See BROWNELL & HORGEN, supra note 15, at 280.
59. Id.
60. Id. at 280-81.
62. See FTC & DEP’T OF HEALTH & HUMAN SERVS., supra note 61, at 39. But see Sharma et al., supra note 21, at 245 (“[A]llowing an industry to self-regulate without input from government, consumers, or public health advocates can have serious consequences.”).
The joint workshop suggested that food companies use labeling initiatives by incorporating nutritious seals to help customers easily recognize healthier products.\textsuperscript{63} Arguably, the industry followed this suggestion in its sponsorship of Smart Choices.\textsuperscript{64} Thus, in theory, self-regulation may offer more innovative solutions and proclaim the industry’s good intentions,\textsuperscript{65} but in practice, the Smart Choices fallout acts as a perfect example of the failure of industry self-regulation.\textsuperscript{66}

Whether inviting the food industry’s involvement or fighting it, each approach has drawbacks, “so it is important to not push the debate in a way that the food industry must be declared either benevolent or evil.”\textsuperscript{67} On the one hand, inviting food industry involvement and blindly trusting it can be a trap, because the industry’s priorities are not always congruent with public health goals.\textsuperscript{68} As a study on industry self-regulation noted: “Where industry and public health objectives conflict, an industry has incentives to create a public image of concern and to promise change, but then to create weak standards with lax enforcement.”\textsuperscript{69} Conversely, an absolute prohibition on the food industry’s participation destroys the possibility of effective collaboration on shared goals.\textsuperscript{70}

While this Note will not go as far as to call the food industry “evil,”\textsuperscript{71} it will show that the food industry has failed to self-regulate. Particularly, the industry has pressured the government to amend labeling laws to the detriment of public health.\textsuperscript{72} Thus, the government

\begin{enumerate}
\item See FTC \& DEP’T OF HEALTH \& HUMAN SERVS., supra note 61, at 52.
\item See Sharma et al., supra note 21, at 242.
\item See FTC \& DEP’T OF HEALTH \& HUMAN SERVS., supra note 61, at 52; CBS Evening News: Food Feud, supra note 28 (showing the Chairman of Smart Choices defending the program and claiming that it will improve Americans’ eating habits and nutritional choices); see also Sharma et al., supra note 21, at 243 (“Self-regulatory actions can be undertaken to lower the threat of negative outcomes and to build trust.”).
\item See generally Ruiz, supra note 25 (detailing the financial figures of the industry’s involvement in the creation of Smart Choices and reporting that Smart Choices’ developers did not believe there was any conflict of interest regarding the nutritional criteria); FOODUCATE BLOG, supra note 29 (describing six reasons the Smart Choices Program fails to help shoppers, including its low standards for nutritional criteria).
\item BROWNELL \& HORGEN, supra note 15, at 280-81.
\item See id. at 280.
\item Sharma et al., supra note 21, at 245. The study noted that purported self-regulation efforts by the tobacco and alcohol industries actually increased public health problems. See id.
\item See BROWNELL \& HORGEN, supra note 15, at 280-81.
\item See supra text accompanying note 67.
\end{enumerate}
should impose a "moratorium" and act independently from the industry when developing the uniform FOP labeling requirements.

III. ALPHABET SOUP: THE CURRENT LEGAL FRAMEWORK OF NUTRITION LABELING

In order to understand the food industry's influence on nutrition policy, one must first grasp the current legal framework of nutrition labeling. Section A of this Part will discuss the FDA's power over all aspects of food labeling. Section B will then explore the impact of the Nutrition Labeling and Education Act of 1990 ("NLEA"), especially as it pertains to health claims made about the nutritional content of different packaged foods. Section C will show the influence of the food industry on nutritional labeling and exemplify how the industry trumped strict scientific regulations through the passage of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). Then, Section D will describe a further food industry victory by exploring the effect of the Dietary Supplement Health and Education Act ("DSHEA"), which allowed companies to make claims about how the nutritional aspects of products benefited the structure or function of the human body. Finally, Section E will explore the FTC's overlapping jurisdiction over food advertising, and show how the food industry has taken advantage of the FTC's more lenient approach to nutritional claims.

A. The FDA's Reign

The FDA governs all aspects of food labeling. Under the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the FDA has statutory authority to protect the public health by ensuring the proper labeling of all foods. This is a broad power, as the FFDCA classifies "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such

73. See supra text accompanying note 59.
74. See 21 U.S.C. § 393(b)(2)(A) (2006); Steve Keane, Can a Consumer's Right to Know Survive the WTO?: The Case of Food Labeling, 16 TRANSNAT'L L. & CONTEMP. PROBS. 291, 294 (2006) ("The FDA is charged with 'developing policy, regulations, guidance documents, and enforcing strategies governing all aspects of food labeling.' (citation omitted)).
75. 21 U.S.C. § 393(b)(2)(A); see NESTLE, supra note 19, at 227 ("The FDA's mandate is to promote safety: its job is to ensure that conventional foods... are safe and labeled accurately . . . .").
article." The FFDCA further defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article." Thus, the FDA has authority to regulate any advertising on food packaging.

B. The NLEA and the Battle Over Health Claims: Industry Conquers Science

In an attempt to enhance Americans’ dietary behavior through strong regulation of food labels, Congress amended the FFDCA by passing the NLEA. The nutrition labeling requirements became effective in 1994, increasing both the availability of vital nutritional information and the understanding of the importance of a good diet. Furthermore, by creating a "new ‘carrot-and-stick’ regulatory incentive structure," the NLEA encouraged food manufacturers to produce and market healthier food. For instance, one “carrot” incentive regulated labels by creating uniform criteria for FDA-sanctioned, promotional claims that marketed healthy nutritional levels and disease prevention advantages. Conversely, a “stick” incentive urged manufacturers to cut unhealthy nutrient levels in foods, by creating uniform nutrition labeling standards that forced manufacturers to reveal unhealthy nutritional information about products rather than only promoting healthy information.

The NLEA’s primary purpose was to control the content and format of food labels. However, prior to its enactment, food manufacturers strongly lobbied for permission to notify consumers about their products’ health benefits and to make “health claims.” Congress

77. 21 U.S.C. § 321(k); see McNamara, supra note 76, at 422.
78. See Lisa M. Fealk-Stickler, Comment, Regulating the Regulators: The Impact of FDA Regulation on Corporations’ First Amendment Rights, 39 J. MARSHALL L. REV. 95, 104 (2005); McNamara, supra note 76, at 422.
81. See Keane, supra note 74, at 298.
82. Roller et al., supra note 80, at 422.
83. Id. at 423.
84. Id.
85. See NESTLE, supra note 19, at 250; Roller et al., supra note 80, at 422.
86. See NESTLE, supra note 45, at 343.
acquiesced, and thus the NLEA also established national uniform regulations for nutrient content and health claims.

Health claims assert the link between a nutrient and a "disease or health-related condition." For example, the FDA allows fiber-containing fruits, vegetables, and grain products to claim a reduced risk of cancer and coronary heart disease. Thus, one permissible health claim appeared on an old Post Raisin Bran box, which displayed a big red heart behind a large spoonful of cereal, while boasting: "May help reduce the risk of heart disease because it is rich in fiber." However, less obvious on the box was a subtle limiting statement required by the FDA, explaining that "[d]iets rich in fiber-containing grain products, fruits and vegetables and low in saturated fat and cholesterol may reduce your risk of heart disease, a disease associated with many factors." In her book *What to Eat*, Marion Nestle translated this health claim: "[T]his cereal helps prevent disease if you eat a good diet anyway." Thus, nutritionists remain skeptical of health claims, asserting that the main reason behind health claims is to sell products. As one commentator noted, the NLEA is one of the federal government’s "tragedies" in its attempt to educate consumers:

While the FDA claims that [health claims] allow[] consumers to make informed, intelligent choices, the reality is quite the opposite, a large-scale scam that allows packagers of processed foods to toss, say, a little calcium or soy in with their largely nonnutritive foods and claim that these foods “have the potential to prevent osteoporosis” or “reduce the risk of heart disease.”

87. See id.
88. See NESTLE, supra note 19, at 250; Roller et al., supra note 80, at 422.
90. NESTLE, supra note 19, at 257 tbl.31 (showing FDA-approved health claims) (internal quotation marks omitted).
91. NESTLE, supra note 45, at 342 (internal quotation marks omitted).
92. Id.
93. Id.
94. See BITTMAN, supra note 14, at 54; NESTLE, supra note 45, at 342-43. As Nestle noted: “[T]he Big Four Cereal companies are paying well over $2 billion a year to get you to buy breakfast cereals. The absurdity of this expense... explains much of the absurdity of health claims on cereal boxes.” See id. at 339.
95. BITTMAN, supra note 14, at 53.
The NLEA sets forth the procedure for FDA pre-approval of health claims for food products. Initially, the claims were subject to strict FDA scrutiny. Before the enactment of the NLEA, the FDA prohibited health claims on all food packages, because it equated such statements to claims about the benefits of pharmaceutical drugs. Once health claims were permitted for conventional foods, manufacturers had to meet a rigid standard of scientific proof to obtain FDA approval. The FDA only authorized health claims that were “supported by (1) published scientific evidence from (2) well-designed studies (3) conducted according to standard scientific procedures, evaluated with (4) significant agreement among (5) qualified experts.” Thus, just as the FDA required pharmaceutical companies to support claims that their drugs could reduce cholesterol levels, food companies were also forced to back their health claims with scientific studies.

Moreover, the FDA prohibited food manufacturers from freely using the word “healthy.” Under a prior loophole, food companies could assert that jelly beans were good for you because they contain nearly no fat or salt. The FDA plugged this loophole by excluding health claims about junk food under the “jelly bean rule.” The jelly bean rule prevents health claims on foods with “[d]isqualifying nutrient levels.” Thus, it restricts the use of the word “healthy” to foods “low in fat and saturated fat, limited in sodium and cholesterol, and containing at least 10% of the recommended amount of at least one key nutrient: vitamin A, vitamin C, iron, calcium, protein, or fiber.” The FDA also

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97. See Hahn, supra note 89, at 318; McNamara, supra note 76, at 422; Ziker, supra note 96, at ¶ 18.
98. See NESTLE, supra note 45, at 343.
100. NESTLE, supra note 19, at 256.
101. NESTLE, supra note 19, at 256.
102. NESTLE, supra note 19, at 256.
103. See id.
104. See id.; Heller, supra note 89, at 201; Ziker, supra note 96, at ¶ 18.
105. 21 C.F.R. § 101.14(a)(4) (2010); see Heller, supra note 89, at 201, Ziker, supra note 96, at ¶ 18.
106. NESTLE, supra note 19, at 256; see 21 C.F.R. § 101.14(a)(4); Hahn, supra note 89, at 319 (“The disqualifying levels for fat, saturated fat, cholesterol, and sodium are 13 grams, 4 grams, 60 milligrams, and 480 milligrams, respectively.”); Heller, supra note 89, at 201; Ziker, supra note 96, at ¶ 18.
created a policy to prohibit manufacturers from fortifying foods for no other reason than meeting the definition of “healthy.”

C. The Food Industry Prevails—The Effects of the FDAMA

Congress passed the FDAMA due to the strong industry lobbying efforts of dietary supplement manufacturers. However, the savvy food industry rode the coattails of this major victory and used the FDAMA to its advantage. The FDAMA loosened the regulations for health claims by providing an exception to the FDA pre-approval requirement. Claims do not need pre-approval if they are “substantiated by an ‘authoritative statement’ published by ‘a scientific body of the Government with official responsibility for public health protection or research directly relating to human nutrition.’” Under the FDAMA, manufacturers can alert the FDA that they plan to introduce a health claim supported by an authoritative statement from a single federal scientific body, without proving widespread scientific agreement. Thus, although this rule appears stringent, it is a less severe standard than “‘significant scientific agreement.”

107. See Nestle, supra note 19, at 256. Fortification of foods originated when scientists sought techniques to cure common nutrient deficiencies in the general population’s diet. See id. at 301. The practice blossomed in the late 1970s, as better technology made it easy for manufacturers to increase the vitamin and nutrient content of their products, and the marketplace showed a higher demand for healthy food. See id. at 304-05. While fortifying foods may benefit some aspects of one’s health, most of its advantages are uncertain. See id. at 296. For example, it is unlikely that improvements in health will result from the growing trend of adding vitamins and minerals to products that run the gamut from candy to water to cereal. See id. In fact, such practice “raises concerns about the possible hazards of too much of a good thing.” Id.


109. See Nestle, supra note 45, at 344 (noting that courts usually ruled in favor of companies on First Amendment grounds when those companies sued the FDA for denying petitions for health claims).

110. See McNamara, supra note 76, at 422-23; Ziker, supra note 96, at ¶ 18.

111. See Ziker, supra note 96, at ¶ 18 (quoting 21 U.S.C. § 343(r)(2)(G)(i) (2000)). An example of an FDA-authorized health claim for calcium is, “‘regular exercise and a healthy diet with enough calcium helps teens and young white and Asian women maintain good bone health and may reduce their risk of osteoporosis.’” Id. (quoting Heller, supra note 89, app. at 221); see McNamara, supra note 76, at 423-24.


113. Nestle, supra note 45, at 344. But see Fortin, supra note 112, at 124-25 (explaining that in practice, the different standards did not have a large impact on the approval of health claims). Although the FDAMA offered a technical change to hasten review of health claims, by giving the FDA a 120-day deadline for evaluating suggested new health claims, this expedited review frequently resulted in rejection. See id.
After the enactment of the FDAMA, dietary supplement companies sued the FDA almost every time it denied their petitions for health claims. The industry often prevailed in these cases because courts held that the companies were exercising their First Amendment rights to freedom of speech. The landmark case granting companies this right was *Pearson v. Shalala*, the "industry's most impressive court victory."

In *Pearson*, dietary supplement manufacturers sued the government after the FDA rejected four separate health claims about their products. Although supported by evidence, the claims failed to comply with the FDA's "significant scientific agreement" requirement. The court rebuked the FDA, calling the requirement "almost frivolous." As interpreted by the court, the FDA's stance was that "health claims lacking 'significant scientific agreement' are inherently misleading because they . . . make it virtually impossible for [consumers] to exercise any judgment at the point of sale." The court criticized this argument, claiming "[i]t would be as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled." Thus, the court rejected the FDA's argument that health claims could mislead consumers, dismissing it as an unsound, "simplistic view of human nature or market behavior."

Ultimately, the court held that if the FDA could require disclaimers on labels to satisfy its scientific substantiation objectives, it could not prohibit health claims. Later cases reflected this freedom of speech trend. As one court held: "[T]he complete ban of a claim would be approved only under narrow circumstances—where there was little-to-no scientific evidence in support of the claim and where the government could prove that the public would still be deceived by the claim even with the use of accompanying disclaimers." Thus, *Pearson* opened the field for more flexible rules on health claims for supplements, and

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114. See NESTLE, supra note 45, at 344.
115. See id.
117. NESTLE, supra note 19, at 265-66.
118. See Pearson, 164 F.3d at 651-53.
119. See id. at 653-54; Ziker, supra note 96, at ¶ 21.
120. Pearson, 164 F.3d at 655; see NESTLE, supra note 19, at 266.
121. Pearson, 164 F.3d at 655.
122. Id. The thrust of this holding was re-emphasized in another case three years later, where the court held that the First Amendment represents a "clear preference for disclosure over suppression of commercial speech." Whitaker v. Thompson, 248 F. Supp. 2d 1, 15 (D.D.C. 2002).
123. See Pearson, 164 F.3d at 656; see NESTLE, supra note 19, at 266.
124. See Pearson, 164 F.3d at 658-59; Ziker, supra note 96, at ¶ 21.
pushed conventional food-manufacturers to claim, obstinately, that they
deserved the exact same First Amendment rights.\textsuperscript{126} As a result, the food
industry compelled the FDA to compromise its science-based method.\textsuperscript{127}
This decision and its consequences irked nutritionists like Nestle:

Any sensible person might think that the Founding Fathers devised the
First Amendment to protect political dissent rather than the right of
food marketers to use overblown health claims on cereal boxes. But
that is how the courts interpret this constitutional amendment, and the
FDA chose not to press alternative legal arguments.\textsuperscript{128}

The courts' overly indulgent application of the First Amendment,
when it comes to the obesity crisis, is particularly troublesome. The
FDA's lowered standard for health claims allows the industry more
creativity in its use of nutrition claims.\textsuperscript{129} Nutritionists find this
alarming, as "[a] health claim on a food product is a good indication that
it's not really food."\textsuperscript{130}

Although Smart Choices did not utilize health claims per se, the
program illustrates the danger inherent in this creative freedom.\textsuperscript{131} For
example, apart from endorsing sugary cereals, Smart Choices promoted
as healthy: Breyers' ice cream, both regular and light Hellmann's Real
Mayonnaise, and Kid Cuisine's Magical Cheese Stuffed Crust Pizza
(containing twenty-three percent of a person's recommended daily
saturated fat intake).\textsuperscript{132} These claims can confuse consumers and lead to
poor nutrition.\textsuperscript{133} In announcing his investigation of Smart Choices,
Connecticut Attorney General Richard Blumenthal warned: "'At a time
when healthcare efforts rightly focus on prevention of obesity and
malnutrition, false and misleading labels may derail, destroy and delay
such laudable national goals.'"\textsuperscript{134}

However, according to the Pearson precedent, the industry prevails
on this argument. As the court held in the landmark decision, the FDA's
argument that health claims lacking significant scientific agreement

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\item 126. Nestle, supra note 19, at 266.
\item 127. See id. at 267.
\item 128. See Nestle, supra note 45, at 344.
\item 129. See id.
\item 130. Bittman, supra note 14, at 54 (quoting nutritionist Michael Pollan).
\item 131. See Wanjek, supra note 30 ("[A]ny consumer relying solely on Smart Choices
checkmarks will surely be diabetic, obese or even dead within a few years.").
\item 132. See Ruiz, supra note 25; Press Release, Conn. Att'y Gen., Attorney General Investigates
"Smart Choices" Food Labels that Endorse Mayonnaise and Sugary Cereals (Oct. 15, 2009),
\item 133. See Press Release, Conn. Att'y Gen., supra note 132 (quoting Connecticut Attorney
General Richard Blumenthal).
\item 134. Id. ("Meaningful nutritional information is welcome, but not faux food facts.").
\end{footnotes}
\end{footnotesize}
could mislead consumers was "simplistic" and nearly "frivolous."\textsuperscript{135} This Note contends that the burgeoning obesity crisis warrants the FDA's "simplistic" view.\textsuperscript{136} The industry's success in pushing the FDAMA and lowering the bar for health claims is further proof that it should not be trusted to self-regulate.

\section*{D. Industry Adds Another Cherry on Top—the DSHEA and Structure/Function Claims}

Notwithstanding the lowered bar for health claims, the FDA provides even more leniency for "structure/function claims."\textsuperscript{137} In fact, to dodge FDA requirements, some food manufacturers started using structure/function claims rather than health claims.\textsuperscript{138} Structure/function claims stem from the nutritional value of a product, and state how the "product affects the structure or function of the body."\textsuperscript{139} Thus, a company can assert that "calcium builds strong bones" or "fiber maintains bowel regularity," if it guarantees the truth of the claim.\textsuperscript{140} Moreover, the FDA does not pre-approve these claims.\textsuperscript{141} The FDA only requires that these claims be "'[t]ruthful, not misleading, [and] substantiated'" by "'scientifically valid evidence.'"\textsuperscript{142}

The food industry can again thank the dietary supplement industry for these relaxed regulations, as strong lobbying efforts by the latter allowed for looser structure/function requirements.\textsuperscript{143} In response to the

\begin{footnotes}
\item[135.] See Pearson v. Shalala, 164 F.3d 650, 655-56 (D.C. Cir. 1999); NESTLE, supra note 19, at 266.
\item[136.] See Pearson, 164 F.3d at 656.
\item[137.] See Heller, supra note 89, at 206 ("Much controversy has arisen over the fine line separating structure/function claims, which do not require FDA premarket approval, from health claims, which do require such approval.").
\item[138.] See id.
\item[139.] Ziker, supra note 96, at ¶ 19.
\item[140.] See Sarah Skidmore, Kellogg Pulls Immunity Claims from Rice Krispies, FOOD MANUFACTURING (Nov. 6, 2009), http://www.foodmanufacturing.com/scripts/ShowPR-RID-13170-wnvnyz-c1p87V1KLyVm9b.asp.
\item[141.] See id.
\item[142.] See NESTLE, supra note 19, at 228 tbl.27 (comparing the policies of the FDA and FTC on health claims and structure/function claims); Marion Nestle, Kellogg's Withdraws Immunity Claim!, FOOD POLITICS (Nov. 6, 2009), http://www.foodpolitics.com/2009/11/kelloggs-withdraws-immunity-claim/. See generally 21 C.F.R. § 101.93(f) (2010) (outlining the requirements for permitted structure/function statements).
\item[143.] See NESTLE, supra note 19, at 262-63; Hahn, supra note 89, at 323. According to Nestle, the dietary supplement industry employed scare-tactics to achieve its success with the DSHEA: The New York Times called DSHEA a "retreat for the FDA" and noted how few issues during that congressional session "generated as much grass-roots emotion, largely because the supplement industry waged a well-financed scare campaign that had many health-minded Americans convinced, wrongly, that the [FDA] was about to ban these popular products."
\end{footnotes}
lobbying, Congress amended the FFDCA in 1994 by enacting the DSHEA. The DSHEA limited the FDA’s power over dietary supplements. Combined with pressure from Congress, the DSHEA effectively forced the FDA to loosen its regulations and to permit statements of nutritional support for dietary supplements.

The FDA recognized the inherent double standard, and then similarly liberalized regulations for foods to avoid the contradiction presented by dietary supplements. The agency understood that it could not allow claims on dietary supplements to explain the value of an ingredient and its effect on the structure or function of the body, while still confining the use of structure/function claims for conventional foods. Moreover, food companies also noticed the double standard, and protested that they should be able to make the same type of claims as dietary supplement manufacturers.

Initially, the FDA sent warning letters to companies using structure/function claims, but it eventually quit after Pearson and other freedom of speech victories for the food industry. The FDA now permits structure/function claims if they are “truthful and not misleading.” Given food manufacturers’ creative use of structure/function claims, “[m]isleading, of course, is in the eye of the beholder.”

E. The FTC’s Supplemental Jurisdiction Further Muddies the Waters

In addition to the FDA’s over-arching power, the FTC also has statutory authority to regulate food advertising. Thus, the two agencies often share overlapping responsibilities, and there is a slim

Nestle, supra note 19, at 262-63.

144. See Barbara A. Noah, Foreword: Dietary Supplement Regulation in Flux, 31 AM. J.L. & MED. 147, 147-48 (2005); Hahn, supra note 89, at 315.

145. Hahn, supra note 89, at 323.

146. See id.

147. See id.

148. See id.

149. Nestle, supra note 142.

150. Id. See generally Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) (holding that even if health claims lacked significant scientific agreement, the First Amendment still protected them because they were not misleading enough to warrant an outright ban); Whitaker v. Thompson, 248 F. Supp. 2d 1 (D.D.C. 2002) (holding that suppressing health claims, rather than using disclaimers, was unconstitutional because the claims were not inherently misleading).

151. Nestle, supra note 142.

152. Id.

153. See Keane, supra note 74, at 294 (describing how the FDA has primary responsibility for food labeling, but “[o]ther federal agencies have supplemental jurisdiction”); McNamara, supra note 76, at 422 (claiming that the FTC governs “claims used in television, radio, magazine, newspaper or other ‘advertising’”).
margin between their levels of authority. 154 The fine line between
the FDA and the FTC causes a regulatory headache due to the different rules
created by the different agencies for labels versus advertisements. 155
Thus, the authorization of health claims for foods and supplements
"becomes exceptionally messy."

Despite the narrow difference in their powers, FTC policies are
much more relaxed than those of the FDA. 157 The FTC does not
differentiate health claims from nutritional support assertions, does not
force companies to get authorization for health claims before using them
in marketing, and has lower standards for support of these claims. 158
Thus, overall, the FTC will authorize advertisements proclaiming health
benefits about products that the FDA will not allow on product labels. 159

In his announcement of the creation of the FDA Obesity Working
Group, the chairman of the FTC stated that both agencies should "further
the free flow of truthful and non-misleading information about the
nutritional profile and health effects of foods" because "food labeling
and advertising can be critical channels to provide consumers with the
information to make better food choices." 160 Furthermore,
"competition about the health effects of food also can provide a
powerful economic incentive for companies to develop and market
healthier foods, including foods with fewer calories."

154. See Fealk-Stickler, supra note 78, at 103-04.
155. See NESTLE, supra note 19, at 227; James M. Serafino, Developing Standards for Health
156. NESTLE, supra note 19, at 227.
157. See id. at 226-29.
158. See id. at 227.
159. See id. at 229-30. Nestle further elaborated on the different powers of the FDA and the
FTC:
In advertisements . . . marketers are permitted to make much more blatant statements
about health benefits, just as long as they can produce a supporting study if anyone asks
for it. The books in health food stores are protected by First Amendment rights to free
speech, and DSHEA explicitly prohibits the FDA from considering books, pamphlets,
and fliers distributed at the point of sale as "labeling."
Id. at 230; see McNamara, supra note 76, at 435 ("There is no requirement for FTC preclearance
of health claims used in advertising, and [a] company would be free to use [a] claim in
advertising . . . even though the claim could not properly be used in labeling without first complying
with [FFDCA] health claim requirements.").
160. Press Release, Timothy J. Muris, Chairman, FTC, Announcement of FDA Obesity
rpt.pdf. After the DHHS's Roundtable on Obesity and Nutrition in July 2003, the FDA established
its Obesity Working Group to create an action plan outlining the FDA's standpoint on the obesity
Eris. See Questions and Answers—the FDA's Obesity Working Group Report, FDA (June 2, 2006),
This “powerful economic incentive” backfired on the food industry—Exhibit A is the collapse of Smart Choices. It will continue to boomerang unless the FDA strengthens regulations. Thus, it is even more crucial that the FDA act independently in its creation of FOP uniform guidelines, so that consumers who are misled by media advertisements will not be further confronted in supermarkets by bogus health and structure/function claims.162

IV. MISLEADING: THE FOOD INDUSTRY’S MIDDLE NAME

According to the FFDCA, a food product classifies as misbranded if its label is false or misleading in any particular way.163 This provision is especially pertinent given the increased use of health and structure/function claims attributable to the advent of functional foods.164 Functional foods have health advantages that extend beyond their typical nutrient levels, as manufacturers intentionally add ingredients so that the foods will qualify for FDA-sanctioned health claims.165 Questionable research, paired with eager advertising claims about functional foods, often leads to consumer confusion.166 The food industry exacerbates this confusion, because manufacturers can market a product as healthy regardless of whether it nearly exceeds the nutrient level or it just barely contains a nutrient.167 Because consumers face “a barrage of conflicting studies about the link between diet and


[A]s a general rule it’s a whole lot easier to slap a health claim on a box of sugary cereal than on a raw potato or a carrot, with the perverse result that the most healthful foods in the supermarket sit there quietly in the produce section, silent as stroke victims, while a few aisles over in Cereal the Cocoa Puffs and Lucky Charms are screaming their newfound “whole-grain goodness” to the rafters.

Watch out for those health claims.

Id.


165. See Nestle, supra note 45, at 104. Among the extra ingredients that food manufacturers use to doctor functional foods are “oils, artificial sweeteners, indigestible starches, cholesterol reducers, soy or milk (whey) proteins, phytochemicals, and other such things.” See id. at 478. For example, some yogurt manufacturers infuse their products with bacteria intended to combat constipation. See id. at 104-05; Artificial Success: The Fad for Functional Foods, ECONOMIST, Sept. 26, 2009, at 81 (singling out Dannon’s Activia brand).

166. See Ruiz, supra note 164 (explaining that although scientific research hints at how to attain the best health, scientists still don’t understand how the body optimally absorbs particular nutrients).

167. See id.
health, . . . it should come as no shock that [the food industry] . . . has promoted confusion in the media and in the mind of the American consumer to contribute to our culture of overconsumption."  

The food industry capitalizes on this confusion and the consumers' desire for healthier food. The American market for functional foods and beverages totaled more than $30 billion in 2008. Moreover, economists expect the global market for functional foods to swell from $78 billion in 2007 to $128 billion in 2013. The Smart Choices campaign is just one example of the burgeoning functional foods industry and its potential to mislead consumers.

The breakfast cereal market provides an even better illustration of the dangers inherent in the industry's infatuation with functional foods. Kellogg's recent advertising blunders epitomize these dangers. First, in early 2009, Kellogg claimed that "clinical" studies showed that its Frosted Mini-Wheats cereal improves a child's attention

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168. BITTMAN, supra note 14, at 54.
169. See id. at 55. Bittman compares the science of "nutritionism" to physics, asserting that research is often disputed and frequently replaced by newer findings. See id. He asserts that while money is at stake in physics, it is "usually small potatoes—not a lot of people read about or make money on muons—compared with what's at stake in 'discovering' a 'new' nutrient that can be marketed to the American public as The Next Big Thing." Id.
170. See Ruiz, supra note 164.
171. See Artificial Success: The Fad for Functional Foods, supra note 165, at 81.
172. See id.; see also supra notes 29-37 and accompanying text (criticizing the misleading nature of Smart Choices).
173. See NESTLE, supra note 19, at 308-10 (describing Kellogg's and General Mills' campaigns to convince the public that their products are essential to a healthy breakfast and to sell more cereal by advertising new fortified ingredients).
174. See generally Bruce Horovitz, Kellogg Pulls Immunity Claim from Rice Krispies, USA TODAY (Nov. 6, 2009, 10:05 AM), http://www.usatoday.com/money/industries/food/2009-11-04-kellogg-immunity_N.htm (explaining the controversy where Kellogg claimed its Rice Krispies supported children's immunity); Ruiz, supra note 164 (reporting on the disciplinary action the FTC took after Kellogg made one of its controversial claims); The Today Show: A Box a Day? Critics Blast Cereal Immunity Claims (NBC television broadcast Nov. 3, 2009), available at http://today.msnbc.msn.com/id/26184891/vp/33599776#33599776 (criticizing Kellogg's claims as "flimsy science").
span by twenty percent. The FTC reprimanded Kellogg, rejecting its "unsatisfactory" study for the advertisement. Moreover, it banned Kellogg from making related claims about its other cereals and snacks.

However, Kellogg rebounded later the same year with more controversial claims. In late 2009, during the height of the H1N1 (swine flu) pandemic, Kellogg boasted on its Cocoa Krispies and Rice Krispies boxes that the cereals boosted immunity. This time, Kellogg voluntarily withdrew its claims due to the intense criticism they received. However, before Kellogg pulled the claims, the FDA responded to criticism by claiming: "The manufacturer is responsible for ensuring the accuracy and truthfulness of these claims; they are not pre-

175. KidsCommercialsRock, Noah Munck—Frosted Mini Wheats Commercial (2009), YOUTUBE (Aug. 19, 2010), available at http://www.youtube.com/watch?v=uxQKM7gxo08. In one commercial, a frazzled elementary school teacher, talking to herself at the beginning of class, asks "Okay, now where were we?" Id. While most of the students appear either fidgety or bored, one student raises his hand and launches into an explanation: "We were on the third paragraph of page fifty-seven and you were explaining that the stone structures made by ancient Romans were called aqueducts, and as you were writing that up on the board, your chalk broke . . . into three pieces." Id. The stunned teacher agrees with the student, and an animated Frosted Mini-Wheat, perched on the student's book, sheds a tear claiming, "I've never been so proud." Id.; see also Lawrence Rubin, What do Frosted Mini Wheats, Mick Jagger and Superheroes Have in Common?, PSYCHOL TODAY (Sept. 30, 2009, 12:16 PM), http://www.psychologytoday.com/blog/popular-culture-meets-psychology/200909/what-do-frosted-mini-wheats-mick-jagger-and-superheroes ("In one fell swoop, Kelloggs [sic], by promising that their product will energize as well as enhance childrens' focus, has laid claim to both the health-enhancing and implied medicinal value of Frosted Mini Wheats. Who needs Adderall, Ritalin, fruit and vegetables, when a heaping bowlful of cereal will do."); Ruiz, supra note 164 ("Earlier this year, [Kellogg] was reprimanded when it used the results of a study to advertise Frosted Mini-Wheats cereal as 'clinically' shown to improve a child's attentiveness by 20%.").


177. See Ruiz, supra note 164.

178. See infra notes 179-80 and accompanying text.

179. See Horovitz, supra note 174.

180. See id. (quoting a Kellogg's representative, who said that the company pulled the claims "given the public attention on H1N1," even though "[i]t was purely coincidental that this package made it to shelves at a similar time as H1N1"); see also The Today Show: A Box a Day? Critics Blast Cereal, supra note 174 (quoting Dr. Nancy Snyderman to the effect that, "the idea that the cereal you eat in the morning could make that big a deal for your immune system is very flimsy science").
approved by [the] FDA but must be truthful and not misleading."181 The 
FDA’s lack of power to address the situation makes one wonder what 
the cereal makers will dream up next.

Recognizing the nutritional hot-bed of cereal claims, The Rudd 
Center for Food Policy and Obesity at Yale University (the “Rudd 
Center”) recently evaluated the marketing and nutritional quality of 
children’s cereal.182 As a result, “obesity researchers for the first time 
have hard data proving that the least healthy cereals are the ones 
marketed most aggressively to children.”183 In examining FOP 
marketing, the Rudd Center found that cereals with poor nutrition 
rankings—like General Mills’ Lucky Charms, Cookie Crisp, and 
Reese’s Puffs (bearing the worst nutrition rating)—averaged three to 
four health claims per box.184 Moreover, the study discovered that 
the cereals with the worst nutrition rankings still qualified for the Smart 
Choices stamp and the “better-for-you” endorsement.185 “[B]etter-for-
you” is another FOP labeling campaign, created by the Council of Better 
Business Bureaus as part of its Children’s Food and Beverage

181. See The Today Show: A Box a Day? Critics Blast Cereal, supra note 174. The FDA’s 
inaction sparked criticism, including a satirical list of the top reasons the agency permitted the 
claims. See Mike Adams, Ten Reasons Why the FDA Allows Cocoa Krispies Cereal to Make 
Outrageous Claims of Boosting Immunity (Satire), NATURALNEWS (Nov. 3, 2009), 
http://www.naturalnews.com/027387_Rice_Krispies_breakfast_cereal.html (listing the top reason as 
“nutritional health claims carry more scientific weight when they’re introduced by magical singing 
elves”).

182. See RUD CTR., supra note 9, at 10. In 2008, the Rudd Center researched the effect of 
food marketing aimed at children. See id. It conducted objective, science-based analysis of 
marketing practices and nutrition-content for different food products—cereal was the first category 
of foods that it examined. See id. The purpose of the study was to underscore both positive and 
negative industry practices. See id. One of the dimensions of the study evaluated FOP marketing. 
See id. at 23. In its inspection of FOP marketing, the Rudd Center evaluated the package for 
marketing features in three categories: child engagement messages, health messages (including 
health claims), and website advertising (giving the URL for the cereal). See id. at 23-24.

183. Bonnie Rochman, Sweet Spot: New Data on How the Least Healthy Cereals Do the Most 

184. RUD CTR., supra note 9, at 58, 60, 76 tbl.9. The study used a broad definition of health 
claims, incorporating both health claims and structure/function claims into one umbrella term. See 
id. at 23-24. According to the Rudd Center: “Health claims describe the product’s health outcome 
benefits, overall healthfulness, or role in a healthy lifestyle (e.g. ‘lower your cholesterol,’ ‘heart 
healthy’). Health claims include functional benefits related to certain ingredients (i.e., health claims 
regulated by the FDA) and unregulated claims that suggest health benefits.” Compare id. at 24 
(seemingly merging the definitions of health claims and structure/function claims), with supra notes 
89-92 and accompanying text (defining health claims), and supra text accompanying note 138 
(defining structure/function claims).

185. RUD CTR., supra note 9, at 11, 60.
Advertising Initiative ("CFBAI").\(^{186}\) Fifteen major companies participated in the initiative, pledging to limit their marketing directed at children and heighten their promotion of "better-for-you" foods.\(^{187}\) Significantly, rather than marketing the products as healthy, the food manufacturers simply claim that the products represent choices that are "better for you."\(^{188}\) This marketing strategy suggests that slight enhancements make the products healthier, and thus improve consumers' health.\(^{189}\)

Like the low nutritional benchmarks set by Smart Choices, the "better-for-you" program also uses lax nutritional criteria.\(^{190}\) Because the industry establishes the nutritional criteria for the "better-for-you" program, most, if not all, products can receive a "better-for-you" designation.\(^{191}\) Thus, there are significant loopholes in the food companies' pledges.\(^{192}\) According to the Rudd Center: "When industry is involved in developing their own nutritional standards, the resulting standards are unacceptable to the public."\(^{193}\)

The "Guiding Stars" program highlights these loopholes in industry-created nutritional standards.\(^{194}\) In 2006, a supermarket chain enlisted an independent panel of leaders in the nutrition field, who used independently established standards to create a nutrition-ranking program called Guiding Stars.\(^{195}\) Guiding Stars ranks foods on a three-star scale: products marked with one star have good nutritional value, products with two stars have better nutritional value, and products with

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187. *RUDD CTR.*, supra note 9, at 11.

188. *NESTLE*, supra note 19, at 388.

189. *Id.* For example, Post/Kraft enhanced Fruity Pebbles by cutting sugars from twelve to nine grams per serving and including three grams of polydextrose fiber. *Id.* However, as Nestle noted: "It remains uncertain whether artificial sweeteners and polydextrose are better for children or whether such products produce measurable health benefits." *Id.*

190. *RUDD CTR.*, supra note 9, at 11.

191. *See id.* The Rudd Center noted the dubious nature of the CFBAI: "The question is whether industry's self-regulatory efforts such as the CFBAI are good faith efforts to create real change or a public relations tool meant to offset criticism and forestall government action." *Id.* at 57.

192. *See id.* at 11-12.

193. *Id.* at 61.

194. *NESTLE*, supra note 19, at 389 (describing the program created by the northeastern supermarket chain, Hannaford).

three stars have the best nutritional value. Significantly, based on the Guiding Stars’ nutritional criteria, more than three-quarters of the supermarket’s 27,000 products failed to qualify for even one star. Moreover, almost all of the food industry’s self-endorsed products were ineligible for any stars.

Even seemingly independent organizations succumb to the powerful food industry. The industry sponsors both the American Heart Association (“AHA”) and the American Diabetes Association (“ADA”), and in turn, these organizations endorse questionable food products. The AHA allows its “food criteria” claim on many General Mills cereals, including “such sugary treats as Lucky Charms, Count Chocula, and Cocoa Puffs.” Like all cereals, these brands derive from plant seeds, and thus are low in saturated fat and cholesterol. However, they also contain high levels of calories and sugars. Connecting the dots to highlight the campaign’s irony, Nestle observed: “Sugars have calories. Calories contribute to weight gain. Obesity is a factor for heart disease.”

Equally conspicuous, obesity is a factor in diabetes. Despite this, the ADA sponsored Post’s Honey Nut and Frosted Shredded Wheat Cereals. Significantly, Kraft Foods, the parent company of Post cereals, donated at least $500,000 to the ADA in 2004. Nestle again emphasized this irony:

After hearing me speak about this sponsorship arrangement with Post cereals, Jane Brody, who has long reported for The New York Times Science Section, wrote in September 2004 that the [ADA] seemed like a “surprising bedfellow for a sweetened cereal, even one made from whole grain.” The association, she said, told her it had changed its policy and would “no longer automatically permit such

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197. See NESTLE, supra note 19, at 389.
198. See id. ("By independent criteria, junk foods are not health foods.").
199. See infra notes 200-08 and accompanying text.
200. See NESTLE, supra note 45, at 351.
201. Id.
202. Id. According to Nestle, the AHA “is doing important work to promote heart health, and I find it depressing that arrangements with food companies are not more transparent.” Id. at 353; see Ruiz, supra note 164 (reporting that the AHA approves General Mills’ Oatmeal Crisp Crunchy Almond cereal as a “heart-healthy” product, and “[t]hough it contains whole-grain oats and whole-grain wheat, it also has two types of sugar as some of it highest ingredients and, in addition, has added corn syrup and honey”).
203. See What is Obesity, supra note 2.
204. See NESTLE, supra note 45, at 354-55.
205. See id. at 355.
statements from companies that contribute to it.” Perhaps, but more than a year later I was still finding the acknowledgment of Post’s sponsorship of the [ADA] on new boxes of Honey Nut and Frosted Shredded Wheat cereals. 206

Food manufacturers often escape such scrutiny, because the FDA does not require manufacturers to show the added sugar content on packages, which illustrates “yet another instance of how slowly evolving guidelines can create a gray area in food manufacturing and marketing.” 207 The food companies’ sponsorship of health organizations shows the “inherent psychological deception and predatory marketing practices of the American food industry.” 208 Moreover, they exemplify why the FDA should act independently when creating uniform FOP labeling regulations.

V. THE FDA MUST ESTABLISH AN INDEPENDENT, UNIFORM FOP LABELING SCHEME TO LIMIT CONSUMER CONFUSION

Clearly, the FDA needs to strengthen national food labeling regulations. 209 Without strong government regulation, consumers cannot trust the food industry to adopt reliable FOP labeling. 210 A recent European study found the proof in the proverbial pudding when it measured consumers’ understanding of FOP labels, together with the effect that the labels had in encouraging consumers to make healthier choices. 211 The study urged the adoption of a uniform FOP labeling format, concluding that too many different FOP labeling formats cause

206. Id.
207. Ruiz, supra note 164 (“Such blind spots in nutrition can open the door for misleading health claims, which can then leave consumers feeling overwhelmed.”).
208. Rubin, supra note 175. Rubin compared the cereal advertising to marketing for psychotropic and erectile dysfunction drugs, equating consumers’ desires for these medicinal benefits to parents’ desires for “miracle substance[s]” for their children. See id. The comparison led Rubin to ponder: “But what’s next, a Black Box Warning on Cocoa Puffs, a voice-over shooting machine gun disqualifiers on Captain Crunch commercials, or perhaps small print on cereal boxes saying something like “if signs of increased focus last for more than four hours, please contact your child’s pediatrician?” See id.
209. See Neal, supra note 41, at 121 (“More national regulation of food manufacturers is needed to eliminate the problems associated with unclear food labeling and hidden ingredients.”).
211. See generally Feunekes et al., supra note 210 (evaluating consumer data from four different European countries—the United Kingdom, Germany, Italy, and the Netherlands—measuring the consumers’ opinions of the different FOP labeling schemes used by various products).
consumer confusion, and thus reduce the effectiveness of all FOP labeling formats.\(^{212}\)

It is essential that the American food market take note of the European study’s conclusion, as consumer confusion continues to mount due to the more than half-dozen health labels crowding packages.\(^{213}\) The FDA has already recognized the need for action.\(^{214}\) As FDA Commissioner Hamburg noted in October 2009: “‘There’s a growing proliferation of forms and symbols, check marks, numerical ratings, stars, heart icons and the like…. There’s truly a cacophony of approaches, not unlike the tower of Babel.’”\(^{215}\)

Interestingly, this was not the first time that Hamburg compared food packaging to the Tower of Babel.\(^{216}\) A month before her remarks on FOP labeling, Hamburg addressed the obesity crisis and emphasized the importance of food labeling as a crucial way of educating consumers about nutrition.\(^{217}\) She stressed that food labeling is “critical for the health and vitality of our nation,” but acknowledged that the issue had not been properly in focus since the 1990 enactment of the NLEA.\(^{218}\) According to Hamburg:

> Back then, the FDA labeling rules addressed a “Tower of Babel” on food packages proclaiming nutritional and sometimes specific disease-related health benefits that were either unfounded or misleading.

> Recently, however, we’ve seen the emergence of claims that may not provide the full picture of their products’ true nutritional value. It will be important to re-establish a science-based approach to protect the public.\(^{219}\)

\(^{212}\) Id. at 69.

\(^{213}\) See FDA Cracks Down on Deceptive Food Labels, supra note 35 (citing as examples the AHA’s “heart-shaped logo, Giant Food Store’s Healthy Ideas box and Supervalu’s Nutritional IQ logo”).

\(^{214}\) See supra notes 35-39 and accompanying text.

\(^{215}\) FDA Cracks Down on Deceptive Food Labels, supra note 35 (quoting FDA Commissioner Margaret Hamburg); see Genesis 11:1–9 (King James). According to the biblical story of the Tower of Babel, God was angered at the men who dared to erect a tower “whose top may reach unto heaven” to make a name for themselves, rather than to worship God. Id. 11:4. As a punishment, God confused their language so “that they [could] not understand one another’s speech” and scattered the people all over the earth. Id. 11:4–9.

\(^{216}\) See Margaret Hamburg, Comm’r, FDA, Keynote Address at the National Food Policy Conference (Sept. 8, 2009), http://www.fda.gov/NewsEvents/Speeches/ucm182061.htm [hereinafter Hamburg, Keynote Address].

\(^{217}\) See id.

\(^{218}\) Id.

\(^{219}\) Id.
Smart Choices tried to simplify the “Tower of Babel” syndrome by creating a uniform FOP labeling system, but its plan backfired. According to Michael Jacobson, the former Smart Choices’ panel member who resigned due to his apprehension of the program’s lax nutritional guidelines, the food industry expected to ward off federal regulation for FOP labeling by proving that it could create an effective system by itself. Yet, “it clearly blew up in their faces.”

The failure of Smart Choices epitomizes why industry self-regulation is not a solution to the obesity crisis. The Rudd Center’s cereal study provides another valid illustration, as it emphasized that industry self-regulation must not preclude necessary government enforcement. Cereal manufacturers’ flimsy self-regulatory pledges have failed to shield children from being bombarded with messages to consume the most unhealthy foods.

The Rudd Center noted that this represents a common “phenomenon,” in which industry proclaims that there is no need for government action, because instead, it will improve the public health by policing itself. Yet it is time that food manufacturers be held responsible for both failing to effect meaningful changes through self-regulation, and for how their products affect consumers’ health. The government must employ independent nutrition experts, with no ties to the food industry, to establish uniform standards; otherwise the food

220. See supra note 215 and accompanying text.
221. See supra notes 29-38 and accompanying text.
222. See supra note 33 and accompanying text (explaining Jacobson’s opposition to Smart Choices).
224. Id. (quoting Michael Jacobson, Executive Director of the Center for Science in the Public Interest). Jacobson noted the irony in the collapse of Smart Choices, stating that “their device for pre-empting government involvement actually seems to have stimulated government involvement.” Id. (internal quotation marks omitted).
225. See supra notes 29-38 and accompanying text.
227. Id.; RUDD CTR., supra note 9, at 60.
228. RUDD CTR., supra note 9, at 60. This “phenomenon” occurred within the alcohol and tobacco industries, where there was an “abject failure of self-regulation.” Id. As the study noted: “An industry suffering from negative public relations and the specter of government intervention engages in a predictable set of responses, among them the launch of self-regulatory actions.” Id.; see also Brownell & Warner, supra note 19, at 267 (noting that there is reason to be on “high alert” of the food industry self-regulation pledges, like the Council of Better Business Bureaus’ CFBAI initiative).
229. RUDD CTR., supra note 9, at 61.
industry's self-regulation measures will be doomed just like the efforts made by the tobacco and alcohol industries.\footnote{See \textit{id.} at 60-61.}

One way to ensure independently established nutritional criteria is to "erect a higher and stronger 'firewall' between Congress and regulatory agencies."\footnote{See id.} This restructuring could help both the industry and the public health, because all companies would start on an equal-playing field.\footnote{Id.} However, the success of this reformation depends on Congress's willingness to revise regulations that affect FDA functions, such as the DSHEA and the FDAMA, both of which "handicap the agency's ability to regulate the food...supply."\footnote{Id.} Alternatively, the FDA and other regulatory agencies can create a more independent work environment by curbing the ability of government officials to take jobs within the food industry.\footnote{Id.} Further, agencies could require full disclosure about conflicts of interest from advisory committee participants.\footnote{See id.} Finally, the FDA "could be more sensitive to the need to avoid even the appearance of working hand in glove with the industries [it] regulate[s]."\footnote{Id.} Nevertheless, it is clear that there is one option that simply will not work: "Food companies cannot resolve the impossible dilemma on their own. For business reasons, they cannot—and will not—stop making nutritionally questionable food products and marketing them..."\footnote{Id. at 393.}

The Rudd Center suggested that the government follow the example of the United Kingdom and set objective nutritional standards that cereal manufacturers would be required to follow in order to market their products to children.\footnote{See \textit{RUDD CTR.}, supra note 9, at 15, 57, app. A at 78-80.} The United Kingdom employed researchers at the University of Oxford, independent of food industry funding, to create uniform nutrition requirements.\footnote{See \textit{id.} at 57, app A. at 78-80.} Significantly, based on these independent standards, "not one cereal that is marketed directly to children [in the United States] would be allowed in advertising to children on television in the United Kingdom."\footnote{Id. at 31.}

Thus, the United States should emulate the United Kingdom's more stringent, independent regulations. Similar to how the United Kingdom
employed Oxford researchers, the United States can employ an independent organization, like the Institute of Medicine ("IOM"), to set its nutritional criteria. While the FDA stated that it plans to consult the IOM in order to create an "optimal, common approach to nutrition-related FOP[,]" in the same breath, it also expressed its desire to work with the food industry. Because the food industry's participation poses such a dangerous conflict of interest, the FDA must remove the industry from the equation.

In order to create an effective uniform FOP standard, the U.S. government's independent nutrition experts should adopt simplified nutritional labels to alert consumers about the health values and risks of products. The FDA acknowledged the success of the United Kingdom's traffic light nutrition labeling system, which marks products with red, yellow, and green lights to rank their nutritional value. This system informs consumers by providing them with a complete nutritional profile of products; for example, it ranks the level of fat, saturated fat, sugar, and salt in its products, and then correlates the levels to traffic light colors. Thus, the FDA should take a similar approach and update nutrition labels to include placement of adjectives (high, medium, or low) alongside nutritional information to aid consumers in understanding products' nutritional information. Of the eight FOP labeling schemes it measured, the European study found that the traffic light FOP labeling scheme offered the most consumer-friendly format. However, the study also cited a slight caveat to the traffic

241. See HARRIS ET AL., supra note 226.
242. See Letter from Schneeman to the Food Industry, supra note 35; supra note 38 and accompanying text.
243. See supra text accompanying notes 49-53.
244. See McCabe, supra note 72, at 495, 501 (suggesting the government and the food industry join forces and that the FDA can implement "negative labels"). Michael R. Taylor, a senior FDA advisor, acknowledged the danger of only showing a product's benefits: "What we don't want to do is have [FOP] information that in any way is based on cherry-picking the good and not disclosing adequately the components of a product that may be less good." See Neuman, supra note 32 (internal quotation marks omitted).
245. See Neuman, supra note 39; FDA Cracks Down on Deceptive Food Labels, supra note 35.
246. See CDC, Comment on Proposed Rule: Food Labeling: Revision of Reference Values and Mandatory Nutrients, REGULATIONS.GOV, http://www.regulations.gov/search/Regs/home.html#documentDetail?R=090000648053e4da (follow Microsoft Word icon under "Comment") (last updated May 2, 2008); Feunekes et al., supra note 210, at 58 (explaining that green means "Go," yellow means "Ok," and red means "Think before you eat too much of this...although a little bit will never hurt" (internal quotation marks omitted)); McCabe, supra note 72, at 512-13.
247. See CDC, supra note 246; McCabe, supra note 72, at 512-13.
248. See supra notes 211-12 and accompanying text.
249. Feunekes et al., supra note 210, at 64; see also McCabe, supra note 72, at 527 (explaining that the traffic light system links scientific evidence with nutritious eating, using a simple method to educate consumers how to eat better diets).
light system, noting that it is “the most inconsistent differentiator between healthier and less healthy products.” Thus, the FDA can attempt to tailor the traffic light system to better distinguish the nutritional value of products, or it can look to the other successful European FOP labeling schemes.

VI. CONCLUSION

In her Keynote Address at the 2008 National Food Policy Conference, FDA Commissioner Hamburg noted the “alarming” obesity rate among the American population and its consequential “staggering” costs. According to Hamburg, the obesity crisis “brings into sharp focus the public health importance of food labeling as an essential means for informing consumers about proper nutrition.” Because the food industry has shrewdly succeeded in keeping obesity on the backburner, the government must shield itself from the powerful lobbying muscle of the food industry and adopt new, objective dietary recommendations. As one commentator noted: “What we are witnessing right now is a nutritional house of cards, built upon the ill advised federal nutritional guidelines that were constructed specifically to increase demand of corporate processed foods.” Unless the FDA acts independently in creating FOP labels, the food industry will...
continue to mislead consumers, and as a result, spread the obesity epidemic.257

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