SUPERSIZING THE PINT-SIZED: THE NEED FOR FDA-MANDATED CHILD-ORIENTED FOOD LABELING

*Gail H. Javitt**

I. INTRODUCTION

In 1990, Congress enacted the Nutrition Labeling and Education Act (NLEA).[1] The Act standardized food labels and created procedures for reviewing health claims.[2] The purpose of the NLEA was to ensure consumer access to information about food that is scientifically valid, truthful, reliable, understandable, and non-misleading, in order to foster more healthful food choices.[3]

* B.A., Columbia College; J.D., Harvard University; M.P.H., Johns Hopkins University. Ms. Javitt is Law and Policy Director at the Genetics and Public Policy Center, Johns Hopkins University; and, Research Scientist at the Berman Bioethics Institute, Johns Hopkins University. She was previously an Adjunct Professor of Law at the University of Maryland School of Law, a Policy Analyst at Johns Hopkins University, and an Associate at Covington & Burling in Washington, D.C., where she specialized in FDA regulatory issues. Ms. Javitt was also a Greenwall Fellow in Bioethics and Health Policy at Johns Hopkins and Georgetown Universities, and has written on a variety of science, regulatory and legal issues. Ms. Javitt would like to thank Cynthia Abrams, Ph.D., Miriam Guggenheim, Esq., and Deena Berkowitz, M.D., M.P.H., for their review of and very helpful comments on earlier drafts of this paper. Special thanks to Professor Larry Gostin and Professor Richard Merrill for their advice and support over the years. Any errors are solely those of the author.

1. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

2. *See id.* § 6, 104 Stat. at 2362–63 (requiring national uniform nutrition labeling); *id.* § 3, 104 Stat. at 2357–62 (describing when regulations authorizing health claims will be promulgated and how these claims will be reviewed).

3. *See* Nutrition Labeling and Education Act § 2(b)(1), 104 Stat. at 2356–57 136 CONG. REC. 35,093, 35,096 to 35,097 (1990) (statement of Rep. Madigan).

By many accounts, the NLEA has improved the amount, quality, and accessibility of information available to consumers about many foods. However, in implementing the NLEA, the U.S. Food and Drug Administration (FDA) has neglected one important constituent of the public—namely, children. The FDA regulations implementing the NLEA are targeted primarily toward adult consumers in both tone and content, and have ignored fast food, a large component of many children's diets.[4] In implementing the NLEA, with the exception of infants and very young children, the FDA has not specifically considered the informational and nutritional needs of older children and adolescents, or of the parents and other caregivers who make dietary decisions for these children.[5] Yet, as has been noted in recent years with respect to pharmaceuticals, children are not "mini-adults" and differ from adults physiologically, cognitively, and behaveiorally.[6] As discussed in Part II.C below, the FDA's failure to tailor its provisions to children's needs is particularly apparent when considering foods of dubious nutritional value, the labeling and advertising of which clearly target children.[7]

The FDA's failure to consider the needs of children in promulgating its rules may have significant public health consequences. A recent study by the National Academy of Sciences' Institute of Medicine confirms what the media has increasingly reported: obesity in children is a significant and growing public health problem.[8] The FDA has recognized the seriousness of childhood obesity as well. It recently characterized the epidemic as "a

4. *See* Nutrition Labeling and Education Act of 1990, 104 Stat. 2353.

5. *See id.* § 2, 104 Stat. at 2355; *id.* § 3, 104 Stat. at 2360 (exempting infant formulas from other food regulations). Special labeling instructions for foods intended for infants and children under four are provided in 21 C.F.R. § 101.9(c)(8)(i) (2005). For further discussion, see *infra* Part II.C.

6. *See* Ctr. for Drug Evaluation & Research, Fed. Drug Admin. (FDA), *Pediatric Drug Studies: Protecting Pint-Sized Patients*, *in* FROM TEST TUBE TO PATIENT: IMPROVING HEALTH THROUGH HUMAN DRUGS 78, 79–81 (Marcia L. Trenter ed., 1999), http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf; *see also* Best Pharmaceuticals for Children Act, Pub. L. No. 107-109, 115 Stat. 1408 (2002) (codified as amended in scattered sections of 21 U.S.C. and 42 U.S.C.) (encouraging pharmaceutical companies to conduct pediatric studies of drugs used in pediatric populations by extending their market exclusivity).

7. *See infra* Part II.C.

8. COMM. ON PREVENTION OF OBESITY IN CHILDREN & YOUTH, INST. OF MED., PREVENTING CHILDHOOD OBESITY: HEALTH IN THE BALANCE (Jeffrey P. Koplan et al. eds., 2005).

pervasive public health problem in the United States"[9] and noted that the trends for children are even more worrisome than for adults.[10] Obesity, however, is not the only potential consequence of incomplete nutritional information. Childhood represents an important opportunity for teaching the importance of healthful food choices that can have a lifelong impact on health status.[11] Moreover, the FDA's failure to focus on nutritional labeling in a child-oriented context limits parents' ability to make fully informed nutritional choices for their children.

Because we tend to think that the commercial messages children receive about food derive primarily from advertising, a significant part of this symposium issue focuses on the impact of food advertising on children. We must recognize, however, that food labeling is also an important influence on consumer choices.[12] More generally, food labeling is also a potentially useful source of consumer education.[13] Studies have shown that the nutrition labeling changes implemented by the FDA pursuant to the NLEA do influence adult consumers to make more healthful food choices.[14] It is therefore reasonable to predict that nutritional labeling for foods consumed mostly by children would lead to improved food choices if that labeling were tailored to the informational needs of children and their adult caregivers.

This paper reviews the purposes and goals of the NLEA and the extent to which they have been achieved. It argues that the FDA can and should do more to implement the NLEA in a manner more meaningful and useful to children and the adults making nutritional

9. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, CALORIES COUNT: REPORT OF THE WORKING GROUP ON OBESITY, at Executive Summary (2004), http://www.cfsan.fda.gov/~dms/owg.toc.html.

10. *Id.*

11. *See* NAT'L INST. OF DIABETES & DIGESTIVE & KIDNEY DISEASES, NAT'L INSTS. OF HEALTH, NIH PUBL'N NO. 04-4096, HELPING YOUR OVERWEIGHT CHILD 1 (2004), http://win.niddk.nih.gov/publications/PDFs/overwtchild7-04.pdf.

12. *See, e.g.*, 136 CONG. REC. 18,883, 18,883–84 (1990) (statement of Rep. Hoagland).

13. *Id.*

14. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 16–17; Matthew W. Kreuter et al., *Do Nutrition Label Readers Eat Healthier Diets? Behavioral Correlates of Adults' Use of Food Labels*, 13 AM. J. PREVENTIVE MED. 277, 281–82 (1997).

choices for them. Part II reviews the history of the FDA's regulation of food labeling, the events leading up to the passage of the NLEA, and the FDA's implementation of the Act. Part III presents data concerning childhood obesity and nutritional deficiencies in children. Part IV discusses the recommendations of the FDA's Obesity Working Group. Part V presents case studies that identify troubling food types and suggests ways in which the NLEA could be implemented to provide improved information regarding these products for children and their caregivers. Finally, Part VI suggests ways in which the FDA could more forcefully and clearly communicate with the American public about the nutritional shortcomings of many foods consumed by children, and thereby foster more informed food choices by children and those who make dietary decisions for them.

II. HISTORY OF THE NLEA

A. The FDA's Historical Role in Food Safety

Federal oversight of the U.S. food supply dates back to the latter half of the nineteenth century.[15] Prior to that time, oversight of food quality was largely the province of the states.[16] With the advent of the industrial revolution and the concomitant shift from a largely rural, agrarian economy to one both urban and manufacturing based, food began to be transported over longer distances and became more highly processed.[17] As a result, the need emerged for stronger oversight to ensure food safety and quality.[18] Interest in federally mandated food standards was driven in part by the competitive concerns of traditional food industry interests regarding the introduction of cheaper food substitutes such as glucose (a threat to sugar suppliers) and lard (a threat to butter suppliers).[19] Interest was also driven by frustration with the obligation to comply with inconsistent state food laws.[20] In addition, government scientists working

15. Jean Lyons & Martha Rumore, *Food Labeling—Then and Now*, 2 J. PHARMACY & L. 171, 172–73 (1993).

16. *Id.* at 171; *see also* Wallace F. Janssen, *The Story of the Laws Behind the Labels*, FDA CONSUMER, June 1981, at 32, 32.

17. Janssen, *supra* note 16, at 32.

18. *Id.*

19. *Id.*

20. *Id.*

in what was then the Department of Agriculture's Division of Chemistry—a predecessor of the FDA[21]—began to raise concerns about various additives in food, such as chemical preservatives, artificial colors and flavors, and their potential to harm public health.[22]

The arrival of the provocative Dr. Harvey W. Wiley in 1883 as the new head of the Division of Chemistry ushered in a more aggressive federal stance toward food safety.[23] Wiley garnered public attention when he and his "Poison Squad" consumed a variety of food containing additives and preservatives to discern their effect on human health.[24] Wiley's campaign for federal legislation was bolstered by the 1906 publication of Upton Sinclair's novel, *The Jungle*.[25] Shortly thereafter, Congress enacted the Pure Food and Drugs Act of 1906 ("the 1906 Act").[26]

The 1906 Act provided that any food containing an "added poisonous or other added deleterious ingredient which may render such article injurious to health" would be deemed adulterated.[27] The 1906 Act was revolutionary in the sense that it granted the federal government, for the first time, the authority to oversee the national food supply. Nevertheless, the 1906 Act was quite limited in the scope of the authority it conveyed.[28] For example, if federal officials suspected that a food was unsafe, they could initiate an enforcement action to remove the product from the market, but the government would bear "the burden of proving that the food ingredient, as

21. Lyons & Rumore, *supra* note 15, at 172–74.

22. *Id.*

23. *Id.* at 172.

24. *Id.* at 172–73.

25. *Id.*; *see also* UPTON SINCLAIR, THE JUNGLE (Penguin Books 1986) (1906) (portraying in graphic detail the unsanitary conditions in the U.S. meatpacking industry).

26. Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended in scattered sections of 21 U.S.C.). On the same day that Congress enacted the Pure Food and Drugs Act, Congress also passed the Meat Inspection Act, Pub. L. No. 59-382, 34 Stat. 669 (1906) (codified as amended at 21 U.S.C. §§ 601–624).

27. Pure Food and Drugs Act § 7, 34 Stat. at 760–70; *see also* Lars Noah & Richard A. Merrill, *Starting From Scratch?: Reinventing the Food Additive Approval Process*, 78 B.U. L. REV. 329, 331 (1998).

28. Noah & Merrill, *supra* note 27, at 331; *see* Pure Food and Drugs Act § 10, 34 Stat. at 771–72.

consumed, posed 'a reasonable possibility of injury.'"[29] The 1906 Act also did not require a labeling statement by the manufacturer, but rather provided that a food package would be considered "misbranded" if statements about its contents were false or misleading.[30] Furthermore, the law did not give the government affirmative power to establish standards for purity and content.[31] Ersatz products—such as "fruit" jams made with water, glucose, grass seed, and artificial color—continued to undercut the demand for their legitimate counterparts (i.e., jams made with real fruit).[32]

While Congress made a few piecemeal attempts to strengthen government oversight of the food industry,[33] a more substantial overhaul was ultimately required. The Federal Food, Drug, and Cosmetics Act of 1938 ("FD&C Act")[34] expanded the newly-formed FDA's authority over drug safety.[35] The FD&C Act also substan-

29. Noah & Merrill, *supra* note 27, at 331 (quoting United States v. Lexington Mill & Elevator Co., 232 U.S. 399, 411 (1914) ("If it cannot by any possibility, when the facts are reasonably considered, injure the health of any consumer, such [product], though having a small addition of poisonous or deleterious ingredients, may not be condemned under the act.")); *see* Pure Food and Drugs Act § 10, 34 Stat. at 771.

30. Pure Food and Drugs Act § 8, 34 Stat. at 771; *see* Lyons & Rumore, *supra* note 15, at 173.

31. *See* Pure Food and Drugs Act § 10, 34 Stat. at 771; *see also* Lyons & Rumore, *supra* note 15, at 173.

32. Pure Food and Drugs Act § 8, 34 Stat. at 770–71; *see also* Janssen, *supra* note 16, at 37; Lyons & Rumore, *supra* note 15, at 173.

33. For example, Congress enacted the Gould Amendment of 1913, Pub. L. No. 62-419, 37 Stat. 732, 732, which required manufacturers to include a declaration of the net quantity of contents of food labels "in terms of weight, measure, or numerical count." Furthermore, the McNary-Mapes Amendment of 1930, Pub. L. No. 71-538, 46 Stat. 1019, 1020, authorized the United States Department of Agriculture (USDA) to establish standards for canned food so as to "promote honesty and fair dealing in the interest of the consumer." *See* Lyons & Rumore, *supra* note 15, at 173.

34. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–397 (2000)).

35. *See* Federal Food, Drug, and Cosmetic Act §§ 201(p), 52 Stat. at 1041–42. The Bureau of Chemistry enforced the 1906 Act until 1927 when the Bureau was reorganized. Janssen, *supra* note 16, at 35. The reorganization of the Bureau separated law enforcement functions from agricultural research. *Id.* In addition, the Food, Drug, and Insecticide Administration was formed. *Id.* at 37; *see also* Agricultural Appropriation Act, Pub. L. No 69-552, 444 Stat. 976 (1927) (reorganizing the Bureau). This agency was later renamed the Food and Drug Administration in 1931. Janssen, *supra* note 16, at 37. "In 1940, to prevent recurring conflicts between producer interests and consumer interests,

tially expanded the FDA's authority with respect to food. First, the FD&C Act statutorily defined food as "articles used for food or drink," "articles used for components of any such article," and "chewing gum."[36] Second, the FD&C Act required the following basic information to be included on all food labels: (1) the "common or usual name" of the food;[37] (2) the net quantity of contents;[38] and (3) the name and address of the manufacturer, packager, or distributor.[39] Third, the statute established tolerance levels for poisonous or otherwise harmful substances added to food during the manufacturing process,[40] and granted the FDA specific authority to issue definitions and standards for food.[41] Fourth, like the 1906 Act, the FD&C Act prohibited false or misleading representations in labeling.[42] Finally, the FD&C Act expanded the remedies available to the FDA to include not only seizure of products violating the Act and the imposition of criminal penalties, but also the ability to seek injunctive relief from a federal court to enjoin the distribution of proscribed products.[43]

The FD&C Act also notably laid the foundation for the NLEA and more comprehensive food labeling provisions by adding section 201(n).[44] Section 201(n) expanded the general prohibition on false or misleading representations by specifying that a label could be

FDA was transferred from the U.S. Department of Agriculture to the Federal Security Agency which, in 1953, became the Department of Health, Education, and Welfare." *Id.* The Department is now named the Department of Health and Human Services. *Id.*

36. Federal Food, Drug, and Cosmetic Act § 201(f), 52 Stat. at 1040 (codified as amended at 21 U.S.C. § 321 (2000)).

37. *Id.* § 403, 52 Stat. at 1048.

38. *Id.* at 1047.

39. *Id.* § 403, ch. 675, 52 Stat. at 1040 (codified as amended at 21 U.S.C. §§ 301–397 (2005)).

40. *Id.* § 406, 52 Stat. at 1049.

41. *Id.* § 401, 52 Stat. at 1046.

42. *Compare id.* § 403(a), 52 Stat. at 1047 (2000) (codified as amended at 21 U.S.C. § 343(a) (2005)) (providing that a food shall be deemed "misbranded" if its labeling is "false or misleading in any particular"), *with* Pure Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, 771 (preventing the manufacture, sale, or transportation of adulterated or misbranded foods and drugs).

43. Federal Food, Drug, and Cosmetic Act §§ 302–04, 52 Stat. at 1043–45; *see also* Janssen, *supra* note 16, at 37.

44. Federal Food, Drug, and Cosmetic Act § 201(n), 52 Stat. at 1041 (codified as amended at 21 U.S.C. § 32(n) (2000).

misleading not only through overtly false representations, but also through omission of information material to the consumer.[45] This provision gave the FDA authority to require disclosure of material facts regarding potentially adverse consequences of consuming food.[46]

However, the authority granted to the FDA was conditional, and therefore limited: a manufacturer was required to disclose information only if it was material "in the light of" the manufacturer's representations.[47] Thus, the FDA was not free to impose its own view of materiality de novo; its review was restricted by the context of the manufacturer's disclosure.[48] Consequently, the FDA has used this authority sparingly.[49] For example, the FDA required disclosure of the presence of phenylalanine in soft drinks because it causes harm to those with phenylketonuria.[50] The FDA also required that labels on foods containing olestra warn consumers of olestra's potential to cause gastrointestinal discomfort and inhibit vitamin absorption.[51] Moreover, the FDA found that irradiation of certain

45. *Id.* Section 201(n) provides that if an article

> is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Id.

46. Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 FOOD & DRUG L.J. 49, 51 (1997).

47. Federal Food, Drug, and Cosmetic Act § 201(n), 52 Stat. at 1041 (codified as amended at 21 U.S.C. § 321(n)).

48. Degnan, *supra* note 46, at 51–52.

49. *Id.* at 52.

50. *Id.* Phenylalanine is an amino acid that cannot be processed in large quantities by people born with the metabolic disorder phenylketonuria. *See, e.g.*, WebMDHealth.com, Phenylketonuria (PKU): Topic Overview, http://www.webmd.com/hw/raising_a_family/hw44747.asp (last visited Nov. 11, 2005). If left untreated, phenylketonuria results in retarded mental development in children. However, if diagnosed early, the disease can be controlled by administering a diet very low in phenylalanine. *Id.*

51. Degnan, *supra* note 46, at 52.

foods was a material fact requiring disclosure to prevent deception under section 201(n).[52] The agency acknowledged that irradiation did not pose a safety risk, but determined that disclosure was necessary because irradiation could cause changes to flavor and shelf life—changes that could be significant and material to a consumer who believed the food to be unprocessed.[53] The agency reasoned that irradiation "may not change the food visually so that in the absence of a statement that a food has been irradiated, the implied representation to consumers is that the food has not been processed."[54]

Amendments after 1938 for the most part continued to expand the FDA's authority to protect consumers by, *inter alia*, setting permissible levels of certain intentional or unavoidable additives to food,[55] and requiring a standardized format for the packaging and

52. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. 13,376, 13,376 (Apr. 18, 1986) (codified at 21 C.F.R. pt. 179 (2005)). Irradiation of food refers to the process of exposing the food to radiation sources in order to disinfect the food or inhibit the growth and maturation of fresh foods. *Id.* Some examples of radiation sources include gamma rays, electrons, e-rays, radio waves, microwaves, ultra-violet rays, and pulsed light. *See* 21 C.F.R. §§ 179.26–.41 (2005).

53. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. at 13,390; *see also* Degnan, *supra* note 46, at 52–53.

54. Irradiation in the Production, Processing, and Handling of Food, 51 Fed. Reg. at 13,388; *see also* Degnan, *supra* note 46, at 53.

55. *See* Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 397 (prescribing conditions and tolerances for the use of color additives in food, drugs, and cosmetics); Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (prohibiting the use of additives in food which have not been adequately tested for safety); Miller Pesticide Amendments, Pub. L. No. 83-518, 68 Stat. 511 (1954) (regulating the residues of pesticides in or on raw agricultural commodities). In particular, the "Delaney Clause" of the Food Additives Amendment classified any food or color additive found to cause cancer in humans or laboratory animals as unsafe and therefore prohibited them from use. Food Additives Amendment § 409(c)(3)(A), 72 Stat. at 1786. *But see* Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (codified as amended in scattered sections of 21 and 42 U.S.C.) (facilitating the use of dietary supplements by minimizing their regulation). The Dietary Supplement Health and Education Act has arguably undermined the FDA's efforts to protect the public from dangerous products. *See* Peter J. Cohen, *Science, Politics, and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J. L. & MED. 175, 182–83 (2005).

labeling of a variety of consumer commodities, including food.[56] Nevertheless, as will be discussed in the next Part, the FDA's ability to require disclosure of information by manufacturers and to monitor claims made about the benefits of food remained limited, leading Congress to enact the NLEA in 1990.

B. The Passage of the NLEA

Prior to the passage of the NLEA, the FDA's ability to require disclosure was largely conditioned on the manufacturer's action: if the manufacturer chose to disclose information, the FDA could take action if the disclosure was misleading.[57] However, if the manufacturer remained silent, the FDA's ability to compel disclosure was limited, notwithstanding the examples described above.[58] The FDA thus lacked the authority to require complete nutritional labeling on all packaged foods. To compound the situation, according to the legislative history accompanying the NLEA, a significant percentage of food was being sold without disclosing any nutrition information.[59]

While Congress acknowledged the FDA's efforts to develop a regulatory scheme to "modernize and improve the nutrition labeling requirements,"[60] it criticized the slow pace of the agency's activity.[61] The legislative history also noted that legislation would "avoid the possibility of protracted litigation over any regulations that the

56. *See* Fair Packaging and Labeling Act, 15 U.S.C. §§ 1451–61 (2005). Among its provisions, this Act required consumer commodities to bear a label "specifying the identity of the commodity and the name and place of business of the manufacturer, packer, or distributor," and to include in the "principal display panel" of the label a separate and accurate statement of the "net quantity of contents (in terms of weight or mass, measure, or numerical count)." *Id.* § 1453.

57. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 403, 52 Stat. 1040, 1047–48 (1938).

58. *Id.* §§ 302–04, 52 Stat. at 1043–45; *see supra* footnotes 30–39 and accompanying text.

59. H.R. REP. NO. 101-538, at 9 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 3336, 3338.

60. *Id.*

61. *Id.* Noting the FDA's lack of progress, the House remarked: "Since the FDA has been extremely slow in issuing comprehensive nutrition regulations, legislation with a mandatory timetable is necessary to ensure that the program is implemented within a reasonable period of time." *Id.*

[FDA] might issue."[62]

In addition, during the 1980s, manufacturers increasingly began to include statements that their food was valuable in preventing or treating a particular disease—on the labels of their products.[63] The FDA largely failed to initiate regulatory action against such claims, despite the agency's historical stance that such claims rendered the food a "drug" within the meaning of the FD&C Act.[64] Congress found that despite the agency's acknowledgment that "'unfounded health claims are being made in the marketplace,'"[65] the FDA was unable to "establish clear, enforceable rules regarding claims that may be made on food."[66] Furthermore, although the FDA had considered adopting regulations to permit health claims under certain conditions,[67] Congress found that "there is a serious question" regarding the agency's legal authority to do so.[68]

Thus, the purpose of the NLEA was two-fold: Congress sought "to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods."[69]

62. *Id.*

63. *Id.*

64. *Id.* "[P]rior to 1984 . . . the FDA took the position that the statement that the food could prevent a disease was tantamount to a claim that the food was a drug . . . and therefore that its sale was prohibited until a new drug application had been approved." *Id.* Yet, during the mid-1980s, when companies began making such claims, the FDA brought virtually no enforcement action against them. *Id.*

65. *Id.*

66. *Id.*

67. *Id.; see, e.g.*, Food Labeling: Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. 28,843 (Aug. 4, 1987) (proposing criteria for the placement of health-related claim on food labels).

68. H.R. REP. NO. 101-538, at 9. The proposed program would have allowed labels to bear claims regarding a food's usefulness in treating a disease. *Id.* Congress questioned whether the FDA bore the legal authority to permit such claims without first requiring the foods to meet the premarket approval requirements applicable to drugs. *Id.*; Food Labeling: Public Health Messages on Food Labels and Labeling, 52 Fed. Reg. at 28,843.

69. H.R. REP. NO. 101-538, at 7.

The NLEA amended the FD&C Act by adding two new subsections to section 403, the provision addressing the misbranding of food.[70] Under new subsection (q), a food was deemed misbranded unless the label contained the following nutritional information: (1) serving size; (2) number of servings per container; (3) total number of calories per serving and the number of calories derived from fat; (4) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, total protein, and dietary fiber per serving; and (5) under certain circumstances, the presence and amount of vitamins, minerals, and other nutrients.[71] The new provision also mandated that the serving size indicated on the label reflect "the serving size which is an amount customarily consumed and which is expressed in a common household measure."[72]

New subsection (q) further authorized the FDA to require that information on the label "be highlighted on the label or labeling by larger type, bold type, or contrasting color" if such a requirement "will assist consumers in maintaining healthy dietary practices."[73] Conversely, subsection (q) also sanctioned the removal of label information that was deemed not useful to consumers in maintaining healthful dietary practices.[74] The Act further directed that regulations be developed to ensure that the information on labels is "conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet."[75] Of particular relevance for this article, subsection (q) exempted from its labeling requirements food "served for immediate human consumption," a category comprising so-called "fast food."[76]

70. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353.

71. *Id.* § 2(a), 104 Stat. at 2353 (codified as amended at 21 U.S.C. § 343(q) (2000)).

72. *Id.*

73. *Id.* (codified as amended at 21 U.S.C. § 343(q)(1) (2000)). The statute authorized the Secretary of Health and Human Services, who delegated authority to implement the statute to the FDA Commissioner. *See* 21 U.S.C. § 393; 21 C.F.R. § 1.4 (2005).

74. Nutrition Labeling and Education Act of 1990 § 2, 104 Stat. at 2354 (codified as amended at 21 U.S.C. § 343(q)(2)(B) (2000)).

75. *Id.* at 2356.

76. *Id.* at 2355 (codified as amended at 21 U.S.C. § 343(q)(5) (2000)) *see*

With respect to health claims, new subsection (r) of the NLEA authorizes the FDA to establish the circumstances under which so-called "health claims"—claims characterizing the relationship between a nutrient and a disease or health-related condition—could be made by manufacturers.[77] Additionally, subsection (r) enables the FDA to establish the circumstances under which a manufacturer can make "nutrient content" claims, i.e., claims that "characterize" the level of a nutrient found in a food.[78]

In addition to the new subsections addressing the misbranding of food, the NLEA further directed the FDA to "carry out activities which educate consumers about (1) the availability of nutrition information in the label or labeling of food, and (2) the importance of that information in maintaining healthy dietary practices."[79] Such education requirements would work in tandem with the new subsections addressing the misbranding of foods to further the NLEA's goal of improving consumer nutritional practices through better labeling.

C. The FDA's Implementation of the NLEA

The FDA's implementation of the NLEA has been an evolving process. Particularly in the area of health claims, the FDA has, since the NLEA, been criticized for the high level of proof and long time period required to establish health claims.[80] As a result of subsequent legislation and industry pressure, the FDA has expanded the options for making health claims by reducing the level of scientific evidence required for certain categories of claims.[81]

---

infra Part IV.

77. Nutrition Labeling and Education Act § 2, 104 Stat. at 2357 (codified as amended at 21 U.S.C. § 343(r) (2000)). An example of a health claim is a claim regarding the link between consumption of calcium and prevention of osteoporosis. *Id.* at 2361.

78. *Id.* Examples of nutrient content claims are phrases such as "high in calcium" or "low in fat." *Id.*

79. *Id.* at 2357.

80. *See* Clement Dimitri Pappas, *Maintaining a Level Playing Field: The Need for a Uniform Standard to Evaluate Health Claims For Food and Dietary Supplements*, 57 FOOD & DRUG L.J. 25, 28 (2002).

81. *See id.* Congress passed the Food and Drug Administration Modernization Act of 1997 to streamline the health claim approval process if another government agency made an "authoritative statement" showing a diet-disease relationship. Pub. L. No. 105-115, § 304, 11 Stat. 2296, 2352 (1997) (codified

Although critical to a full critique of the FDA's implementing regulations under the NLEA, a detailed discussion of the development of health claims since the NLEA is beyond the scope of this article.[82]

With respect to food labeling, on January 6, 1993, the FDA issued several regulations implementing section 403(q) of the NLEA.[83] First, the agency finalized the now familiar "nutrition facts" panel that requires information about serving size, calories, and presence and amount of required nutrients to be displayed in a boxed format on most packaged foods.[84] The preamble to the regulation provided significant details regarding the amount of public input that had been solicited—in the form of focus groups, public meetings, and surveys—to ensure that the food label conveyed information in a format that consumers could easily understand.[85] Notably, however, all of the research cited was conducted in adult populations, despite the fact that children make up a significant percentage of the food-purchasing public.[86]

The regulations also listed the mandatory and voluntary components of the label and specified the order in which they were required to appear in the nutrition information panel.[87] Mandatory components included information regarding the serving size, servings per container, total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron.[88] Voluntary

at 21 U.S.C. § 343(r)(2)(G)(i) (2000)).

82. For discussion of the implementation of the health claims provisions of the NLEA, see, for example, 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 (1995).

83. Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2109 (Jan. 6, 1993) (codified at 21 C.F.R. pts. 1, 101).

84. *Id.* at 2080; 21 C.F.R. § 101.9(A) (2005).

85. Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. at 2114–15.

86. *Id.* at 2115–16. In the Obesity Working Group's 2004 report , the FDA noted its extensive use of agency-conducted focus groups "to evaluate the appropriateness and effectiveness of its messages." CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 9. However, none of the focus groups cited, either before or after the implementation of the NLEA, involved participants younger than 18. *Id.*

87. 21 C.F.R. § 101.9(c).

88. *Id.* § 101.9(c)(2).

components included information regarding: (1) the amounts of potassium, sugar alcohols, fiber (soluble or insoluble), and other essential vitamins and minerals; (2) the percentage of vitamin A present as beta-carotene; and (3) the number of calories from different fats—e.g., saturated, polyunsaturated, and monounsaturated.[89] However, if the manufacturer made claims about the optional components, or if a food was fortified or enriched with them, then information regarding these components became mandatory.[90]

The final rule excluded all other components from the nutrition facts panel.[91] The FDA selected those required nutrients because it believed them to "address today's health concerns," and sequenced them in a manner that "reflects the priority of current dietary recommendations."[92] However, the FDA has shown a willingness to revisit the list in response to pressure from advocacy groups or Congress. For example, in 2003, a Citizen's Petition by the Center for Science in the Public Interest prompted the FDA to amend its regulations to require the disclosure of trans fatty acids beneath the saturated fat declaration on food labels.[93] The new regulation was meant to "provide information to assist consumers in maintaining healthy dietary practices."[94] More recently, the Food Allergen Labeling and Consumer Protection Act of 2004, which became effective in 2006, requires manufacturers to identify on the label in plain language the presence of any of the eight major food allergens.[95]

As part of the nutrition facts panel, the FDA required that the percent "Daily Value" (DV) of required nutrients be included alongside the list of nutrients.[96] The percent DV is a "reference

89. *Id.*
90. *Id.*
91. *Id.* § 101.9(c).
92. FDA, U.S. DEP'T OF HEALTH & HUMAN SERVS., PUBL'N NO. BG 99-5, THE FOOD LABEL (1999), http://www.fda.gov/opacom/backgrounders/foodlabel/newlabel.html.
93. Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims, 68 Fed. Reg. 41,434, 41,434 (July 11, 2003) (codified at 21 C.F.R. § 101 (2005)).
94. *Id.*
95. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905, 906–08 (codified as amended at 21 U.S.C. §§ 343(w), 321(qq)), *available at* http://www.cfsan.fda.gov/~dms/alrgact.html.
96. 21 C.F.R. § 101.9(c).

value" that reflects the percentage of the recommended daily intake of a particular nutrient contained in the food.[97] In the case of some nutrients (e.g. fat) the recommended daily value reflects the uppermost limit, whereas for others it reflects a lower limit.[98] According to the FDA, the purpose of including the percent DV was to "prevent misinterpretations that arise with quantitative values."[99] For example, the percent DV would help prevent the misconception that five grams of saturated fat is low, because five is a small number, when in fact it reflects 25% of the recommended DV for saturated fat.[100]

In a separate regulation, the FDA established DVs for mandatory and voluntary components.[101] The DVs comprised two separate sets of dietary standards: "Daily Reference Values" (DRV) and "Reference Daily Intakes" (RDI).[102] For simplicity, both were subsumed under the heading "Daily Value."[103] With limited exceptions, the FDA based the percent DVs on a 2000-calorie daily intake.[104] The FDA required a footnote to appear in conjunction with the nutrition information panel stating that the percent DVs "are based on a 2,000 calorie diet" and that an individual's DVs may be higher or lower.[105] In yet another rule, the FDA established specific DVs for required and optional nutrients.[106] Furthermore, separate DVs were established for certain nutrients ingested by infants from birth to twelve months of age, children under four, pregnant women,

97. 21 C.F.R. § 101.9(d)(7)(ii); *see* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, HOW TO UNDERSTAND AND USE THE NUTRITION FACTS LABEL (2004), http://www.cfsan.fda.gov/~dms/foodlab.html.

98. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 97.

99. FDA, *supra* note 92.

100. *Id.*

101. 21 C.F.R. § 101.9(c).

102. *Id.* DRVs have been established for macronutrients including fat, carbohydrate, fiber, protein, cholesterol, sodium, and potassium. FDA, *supra* note 92. RDI was established for vitamins, minerals, and protein, and was previously known as "U.S. RDA," which was used in voluntary nutrition labeling since 1973. *Id.* Thus, the primary difference is that the DRV and RDI have different set of nutrients, and there are some overlaps, for example. protein.

103. 21 C.F.R. § 101.9(c).

104. *Id.* § 101.9(c)(9).

105. *Id.* § 101.9(d)(9)(i).

106. *Id.* § 101.9(c).

and lactating women.[107]

However, with the exception of these special populations, the FDA adopted a one-size-fits-all approach in setting DVs, categorizing all children over four years of age together with adults.[108] The FDA acknowledged that it was making trade-offs in this decision, but reasoned that:

> Because of space constraints on the food label–a problem that is becoming ever more compelling given the mandatory requirement for nutrition labeling on most foods–[the] FDA does not believe that a viable option exists other than to develop a single set of label reference values for most consumers of the general food supply. Clearly, children over the age of 4 years consume the same foods that the rest of the population consumes.[109]

With respect to serving size—information that is also mandated to appear in the nutrition panel—the FDA established "reference amounts customarily consumed" (RACCs) for 139 food categories.[110] The RACCs reflected the amount of a food customarily consumed in one sitting.[111] These reference amounts were developed using food consumption surveys of the United States Department of Agriculture (USDA).[112] The surveys were descriptive; they collected information on what members of selected households ate during a given period of time.[113] Indeed, "the FDA

107. Food Labeling: Reference Daily Intakes and Daily Reference Values, 58 Fed. Reg. 2206, 2213 (Jan. 6, 1993) (codified at 21 C.F.R. §§ 101.9(c)(8)(i)). Deviations from the nutrition panel format were required in some instances as well. For example, labels of foods for children under two (other than infant formula, which is governed by a separate statute) may not carry information about saturated fat, polyunsaturated fat, monounsaturated fat, cholesterol, calories from fat, or calories from saturated fat. 9 C.F.R. § 381.500(c)(1). In addition, the labels of foods for children under four may not include the Percent Daily Values for "total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber," because the FDA has not established DVs for these nutrients for this age group. 21 C.F.R. § 101.9(j)(5)(ii)(A); *accord* 9 C.F.R. § 381.500(c)(2).

108. 21 C.F.R. § 101.9(b)–(c).

109. Food Labeling: Reference Daily Intakes and Daily Reference Values, 58 Fed. Reg. at 2213.

110. 21 C.F.R. § 101.12.

111. *Id.*

112. *Id.* § 101.12(a)(1)–(2).

113. *Id.*

acknowledged that the RACCs for several foods were not consistent with serving sizes provided in dietary guidance; the latter are meant to represent what people should consume and not what they customarily consume."[114] Moreover, of particular relevance to this Article, in developing the RACCs the FDA included in one category all "persons 4 years of age or older,"[115] apparently assuming that children and adult consumption patterns were similar. However, the FDA did not clearly articulate a scientific basis for this assumption.[116] Given that the FDA's food labeling provisions apply to children four years of age and up, children may consume more than they require when presented with a serving size that is larger than they would customarily consume, since, as discussed below, chilren may not be as wellequipped as previously thought to regulate their intake.[117]

Manufacturers must utilize the RACCs in determining an appropriate label serving size, using procedures specified by the FDA.[118] In selecting a serving size, manufacturers are required to choose an amount that most closely approximates the RACC for that food category.[119] The serving size must be listed in the nutrition panel of the food package,[120] and expressed in terms of "household

114. Frances H. Seligson, *Serving Size Standards: Can They Be Harmonized?*, NUTRITION TODAY, Nov.–Dec. 2003, at 247, 248. "The FDA used mean, median, and modal data on amounts consumed per eating occasion from the 1987–1988 Nationwide Food Consumption Survey (NFCS) and, as necessary to verify amounts, data from the 1977–1978 NCFS and 1985–1986 Continuing Survey of Food Intake by Individuals." *Id.*

115. 21 C.F.R. § 101.12(a)(1).

116. *See* 21 C.F.R. § 101.12(a). The regulation, however, provides a separate table for RACC factors in reference amounts for infants and children under four years of age. *Id.* § 101.12(b) tbl.1; *see also id.* § 101.12(a)(1)–(a)(2); Food Labeling: Serving Sizes, 58 Fed. Reg. 2,229, 2,235–38 (Jan. 6, 1993) (referring to Comments 17–19 where the FDA responds to various critiques of data, but does not discuss its reason for grouping ages four to adult).

117. *See infra* Part III.

118. 21 C.F.R. § 101.9(b)(2).

119. *Id.*

120. *Id.* § 101.9(a)(1). The FDA's implementing regulations provide details on how the RACCs are to be used to determine the labeled serving size and the number of servings per container. *Id.* § 101.9(b). The labeled serving size is the amount of food that most closely approximates the RACC. *Id.* § 101.9(b)(2). For instance, the RACC for carbonated beverages is 240 mL, or 8 fl. oz. *Id.* § 101.12(b) tbl.2. Packages of carbonated beverages weighing less

measures" (e.g., cups, teaspoons).[121] The serving size, in turn, is used as the basis for calculating the percent DV of each nutrient present in the food.[122]

Fifteen years after the passage of the NLEA, the nutrition label has become nearly ubiquitous. According to a 2001 FDA-sponsored survey, "[a]n estimated 98.3% of FDA-regulated processed, [and] packaged foods sold annually have nutrition labels with an additional 1.7% of products exempt from nutrition labeling requirements."[123] The widespread adoption of the NLEA's food labeling provisions should be viewed as a success. Further, as discussed in the next Part, there is evidence of positive consumer impact from nutrition labeling.[124] Nevertheless, it should be recognized that the implementation of the NLEA to date has overwhelmingly ignored the nutritional and informational needs of children and adolescents, notwithstanding their burgeoning presence in the marketplace and the growing problem of obesity and undernutrition in this population.[125] Until the needs of this population are taken into account, the implementation of the NLEA should be considered as a work in progress rather than a completed endeavor.

D. Consumer Impact of the NLEA Labeling Provisions

In the preamble to the final rule implementing the new food label, the FDA disagreed with the proposition articulated in some comments that "nutrition label[s] should not play a role in educating consumers."[126] Rather, the agency asserted that "the nutrition label

than 360 mL, or 12 fl. oz. (150% of 240 mL), must be labeled as a single serving. *See id.* § 101.9(b)(6). Containers weighing between 360 mL and 480 mL, i.e., 16 fl. oz. (200% of 240 mL), may be labeled as a single serving or as "about 2" servings per container. *Id.* § 101.9(b)(8)(i).

121. *Id.* § 101.9(b)(5).

122. *Id.* § 101.9(b). *See id.* § 101.9(c).

123. Lori LeGault et al., *2000–2001 Food Label and Package Survey: An Update on Prevalence of Nutrition Labeling and Claims on Processed, Packaged Foods*, 104 J. AM. DIETETIC ASS'N 952, 952 (2004).

124. PREVENTION INST., NUTRITION LABELING REGULATIONS 2, http://www.preventioninstitute.org/pdf/CHI_nutrition_labeling.pdf (last visited Nov. 10, 2005) ("Thirty percent of respondents of a 1991 survey reported changing their minds about buying food products after reading the nutrition label."); *see infra* Part II.D.

125. For further discussion on this issue, *see infra* Part III.

126. Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079, 2123 (Jan. 6,

is an important source of basic information for consumers."[127] Moreover, the NLEA requires "that the label facilitate consumer education."[128]

According to some consumer studies undertaken after the NLEA's enactment, many consumers do indeed use nutrition information on food labels when making purchasing decisions. A 1997 report by the U.S. government found that "nearly three-quarters of the U.S. population age eighteen and over report reading food labels."[129] In addition, there is evidence that nutrition labeling affects consumer choices. In a 1997 survey, 61% of respondents stated that they changed their minds about buying food products after reading a nutrition label.[130] Among college students, one study found that the NLEA was "associated with greater knowledge about labels, more favorable attitudes toward them, and increased use of labels in making food choices."[131] Other studies of adult populations found a correlation between label use and lower consumption of fat and cholesterol and higher vitamin C intake.[132] However, some

1993) (codified at 21 C.F.R. pts. 1, 101).

127. *Id.*

128. *Id.*

129. PREVENTION INST., *supra* note 124, at 2 (citing U.S. DEP'T HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2000 REVIEW 1997 (1997)).

130. *Id.* (citing Joanne F. Guthrie et al., *What People Know and Do Not Know About Nutrition*, *in* AMERICA'S EATING HABITS: CHANGES & CONSEQUENCES 243, 271 (E. Frezao et al. eds., 1999).

131. Anne B. Marietta et al., *Knowledge, Attitudes, and Behaviors of College Students Regarding the 1990 Nutrition Labeling Education Act Food Labels*, 99 J. AM. DIETETIC ASS'N 445, 448 (1999).

132. PREVENTION INST., *supra* note 124, at 2; *see also* Matthew W. Kreuter et al., *Do Nutrition Label Readers Eat Healthier Diets? Behavioral Correlates of Adults' Use of Food Labels*, 13 AM. J. PREVENTIVE MED. 277, 281–82 (1997) (finding a relationship between patients' label reading and their dietary practices). On the other hand, another study found that individuals who consume more total fat, saturated fat, and cholesterol are less likely to seek out information about these nutrients on food labels. Chung-Tung Jordan Lin et al., *Do Dietary Intakes Affect Search for Nutrient Information on Food Labels?*, 59 SOC. SCI. & MED. 1955, 1964 (2004). The study also found that encouraging consumers with unhealthy dietary habits to search for food label information would require innovative approaches, but that nutrition education can be instrumental in encouraging this search by providing motivation and technical help. *Id.*; *see also* Rodolfo M. Nayga Jr., *Retail Health Marketing: Evaluating Consumers' Choice for Healthier Foods*, HEALTH MARKETING Q., Vol. 16, Issue 4, 1999, at 53 (concluding that individuals who are less likely to choose a more healthful alternative of a food product include those who less

evidence suggests that certain populations, such as older[133] and low-income Americans,[134] are less likely to use nutrition labels.

No research has been reported concerning the effect of nutrition labeling on young children,[135] and very little has been reported concerning its effect on the adolescent population.[136] One study of approximately 300 adolescents found that those who reported reading labels did not necessarily report a more healthful diet.[137] The study posited that "lack of understanding of label information or inability to translate the information into practical use" were possible reasons for this finding.[138] Another study of ninety adolescents found that although food labels are somewhat important to adolescents when selecting food items, factors other than nutrition information—specifically, taste, habit, and price—were more likely to influence food selection among high school-aged adolescents.[139] According to the study, nutritional education that emphasizes food label reading skills is needed to improve adolescent food choices.[140]

frequently use nutrition panels and labels that describe health benefits on food packages).

133. Janet F. Macon et al., *Food Label Use by Older Americans: Data From the Continuing Survey of Food Intakes by Individuals and the Diet and Health Knowledge Survey 1994–96*, J. NUTRITION FOR ELDERLY, Vol. 24, Issue 1, 2004, at 35.

134. Laura McArthur et al., *Behaviors, Attitudes, and Knowledge of Low-Income Consumers Regarding Nutrition Labels*, 12 J. HEALTH CARE FOR POOR & UNDERSERVED 415 (2001).

135. *See* National Center for Biotechnology Information, http://www.ncbi.nlm.nih.gov/ (last visited Nov. 10, 2005) (contention based on a search in the "PubMed" database using the search terms "nutrition label" and "children").

136. *See id*. (contention based on a similar search using the search terms "nutrition label" and "adolescent").

137. Terry T.K. Huang et al., *Reading Nutrition Labels on Fat Consumption in Adolescents*, 35 J. ADOLESCENT HEALTH 399, 401 (2004)

138. *Id.*

139. Christine McCullum & Cheryl L. Achterberg, *Food Shopping and Label Use Behavior Among High School-Aged Adolescents*, 32 ADOLESCENCE 181, 194 (1997).

140. *Id.* at 196. According to the study, male adolescents were more likely to consider package appearance and size when selecting food products, whereas female adolescents were more likely to use front label and nutrition claims. *Id.* at 194. The study suggests developing programs that teach male adolescents to use other parts of the package and female adolescents to properly evaluate "health" and "diet" claims. *Id.* at 194–95.

III. CHILDHOOD OBESITY AND NUTRITIONAL DEFICITS IN CHILDREN AND ADOLESCENTS

According to the most recent national survey conducted by the National Center for Health Statistics, over nine million—about 16%—American children and adolescents aged six to nineteen are overweight.[141] An additional 31% are considered at risk of becoming overweight.[142] The 19992002 National Health and Nutrition Examination Survey (NHANES),[143] which surveyed a representative sample of the U.S. population, defines a child as overweight if his height and weight places him at greater than or equal to the 95th percentile of the age- and sex-specific Body Mass Index (BMI).[144] A child is considered at risk of becoming overweight if his height and weight places him at or above the 85th percentile of the age- and sex-specific BMI but below the 95th percentile.[145] The data from the 1999–2002 survey were substantially higher than the figures from a survey conducted between 1988–1994; in the earlier survey, 11% of children were overweight and 14% were at risk.[146]

The 1999–2002 survey data reflect a prevalence of overweight as more than three times the target prevalence of 5% set forth in the Department of Health and Human Services' Healthy People 2010

141. Allison A. Hedley et al., *Prevalence of Overweight and Obesity Among US Children, Adolescents, and Adults, 1999–2002*, 291 J. AM. MED. ASS'N 2847, 2848 (2004).

142. *Id.*

143. NAT'L CTR. FOR HEALTH STATISTICS, CTRS. FOR DISEASE CONTROL & PREVENTION, PREVALENCE OF OVERWEIGHT AMONG CHILDREN AND ADOLESCENTS: UNITED STATES, 1999–2002, http://www.cdc.gov/nchs/products/pubs/pubd/hestats/overwght99.htm (last visited Nov. 11, 2005).

144. *Id.* In adults, the BMI is expressed as a ratio of weight to height squared (kg/m^2). *Id.* An individual with a BMI of greater than twenty-five is considered overweight, and a person with a BMI of greater than thirty is classified as obese. Hedley et al., *supra* note 141, at 2847. In children, the BMI is expressed as percentile growth that is based on gender and age specific growth charts. CTRS. FOR DISEASE CONTROL & PREVENTION, BMI—BODY MASS INDEX: BMI FOR ADULTS, http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-adult.htm (last visited Nov. 11, 2005).

145. Hedley et al., *supra* note 141, at 2848.

146. Richard P. Troiano & Katherine M. Flegal, *Overweight Children and Adolescents: Description, Epidemiology, and Demographics, Pediatrics*, 101 PEDIATRICS 497, 499 (1998).

report.[147] A report in the Journal of the American Medical Association discussing the NHANES data concluded that "[s]ubstantial progress will need to be made in the efforts to lower the prevalence of overweight and obesity if the goals of Healthy People 2010 are to be met."[148] Data on children younger than six also indicate a growing problem. Among two to five year olds, for example, the percentage who were overweight doubled from 5% in the early 1970s to more than 10% in 2000.[149]

The consequences of overweight for children and adolescents are serious. Type II diabetes mellitus, once termed "adult onset" diabetes because of its virtual absence in children, is now affecting an increasing number of children.[150] According to one study, the incidence of Type II diabetes among children and adolescents increased ten-fold between 1982 and 1994.[151] Another study found that Type II diabetes accounts for as many as 50% of newly diagnosed cases of diabetes in the pediatric population.[152] Earlier onset of Type II diabetes is also associated with earlier onset of complications, including nerve problems, blindness, kidney failure, stroke, heart attack, and sudden death.[153] Moreover, overweight or obesity is the most important risk factor for the development of Type II diabetes in youth.[154]

147. U.S. DEP'T HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2010: UNDERSTANDING AND IMPROVING HEALTH, LEADING HEALTH INDICATORS, OVERWEIGHT AND OBESITY 28 (2000), *available at* http://www.healthypeople.gov/document/pdf/uih/2010uih.pdf. This report provides a "set of health objectives for the Nation to achieve over the first decade of the new century" and is intended for use by "States, communities, professional organizations, and others to help them develop programs to improve health." Healthy People, What is Healthy People?, http://www.healthypeople.gov/About/whatis.htm (last visited Nov. 10, 2005).

148. Hedley et al., *supra* note 141, at 2850.

149. Jean A. Welsh et al., *Overweight Among Low-Income Preschool Children Associated With the Consumption of Sweet Drinks: Missouri, 1999–2002*, 115 PEDIATRICS at e223, e223 (2005), http://www.pediatrics.org/cgi/doi/10.1542/peds.2004-1148.

150. Tamara S. Hannon et al., *Childhood Obesity and Type 2 Diabetes Mellitus*, 116 PEDIATRICS 473, 473 (2005).

151. *Id.*

152. *Id.*

153. *Id.*

154. *Id.*

Diabetes is not the only adverse health consequence of overweight in children. Overweight children also are more likely to become overweight adults,[155] in part because dietary practices learned during childhood may transfer to adulthood.[156]

Furthermore, studies have demonstrated a positive association between excess weight in childhood and increased blood pressure,[157] elevated cholesterol and triglyceride levels, respiratory disease, and orthopedic and psychosocial disorders.[158] According to a recent Consensus Statement of the American Heart Association, "[t]he atherosclerotic process begins in youth, culminating in the risk factor-related development of vascular plaque in the third and fourth decades of life."[159] A key factor cited for this process is poor nutrition.[160]

Certain populations are particularly at risk of becoming overweight. Analysis of NHANES 1999–2000 data indicates a greater prevalence of overweight children among twelve- through nineteen-year-old non-Hispanic blacks and Mexican Americans than among non-Hispanic whites.[161] However, overweight prevalence does not clearly track socioeconomic status (SES). According to one study, SES was inversely correlated with overweight only among white female adolescents, suggesting that factors in addition to income and education affect overweight in other ethnic groups.[162]

The causes of obesity in children and adolescents are multi-factorial, and, as is the case for adults, include genetic and environmental causes,[163] cultural factors, and lifestyle preferences.[164]

155. Samuel S. Gidding et al., *AHA Scientific Statement: Dietary Recommendations for Children and Adolescents*, 112 CIRCULATION 2061, 2064 (2005), *available at* http://circ.ahajournals.org/cgi/content/full/112/13/2061.

156. Huang et al., *supra* note 137, at 401.

157. *See* Sarah C. Couch & Stephen R. Daniels, *Diet and Blood Pressure in Children*, 17 CURRENT OPINION PEDIATRICS 642, 643 (2005).

158. Welsh et al., *supra* note 149, at e223.

159. Gidding et al., supra note 155, at 2061.

160. *Id.*

161. Cynthia L. Ogden et al., *Prevalence and Trends in Overweight Among US Children and Adolescents, 1999–2000*, 288 J. AM. MED. ASS'N 1728, 1729 (2002).

162. Penny Gordon-Larsen et al., *The Relationship of Ethnicity, Socioeconomic Factors, and Overweight in U.S. Adolescents*, 11 OBESITY RES. 121, 127 (2003).

163. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 2.

However, what children eat and the amount of food they consume are also essential pieces of the puzzle.[165] Some posit that declining physical activity—caused in part by increased television viewing and computer use, along with a corresponding decrease in participation in school-based physical education[166]—coupled with the easy availability of nutritionally dense (i.e., high fat, high sugar) foods, has resulted in caloric intake that exceeds energy output.[167]

At the same time, as the number of overweight children in the U.S. population is increasing, the quality of their nutrition is declining. The ironic result is that some children may be simultaneously overfed and undernourished. A study examining food intake trends from 1965 to 1996 in adolescents ages eleven to eighteen noted a considerable shift in the adolescent diet during this time period.[168] While the study noted a decrease in total energy intake and total fat, it found that the percentage of energy coming from fat exceeded dietary recommendations.[169] In addition, the study observed a decrease in the consumption of raw fruits, non-potato sources of vegetables, and calcium-rich dairy sources, and an increase in soft drink consumption.[170] It also noted that the intake of fiber, folate, and calcium for the entire age group, and the intake of iron among females, were "lower than optimal for proper growth and development during adolescence."[171] The study concluded that these food consumption trends "are compromising the nutritional and health status of US adolescents and may contribute to important increases in nutrition related chronic diseases."[172]

164. Mahshid Dehghan et al., *Childhood Obesity, Prevalence and Prevention*, NUTRITION J., Sept. 2, 2005, art. 24, http://www.nutritionj.com/content/4/1/24.

165. *Id.* at 2–3.

166. *Id.* at 4.

167. *See* Troiano & Flegal, *supra* note 146, at 502–03.

168. Claude Cavadini et al., *US Adolescent Food Intake Trends From 1965 to 1996*, 83 ARCHIVES DISEASE CHILDHOOD 18, 18 (2000).

169. *Id.* at 22–23. The authors noted that the observation of decreased energy intake was counterintuitive in light of the rising prevalence of overweight and obesity shown by other studies in this population, but hypothesized that there has been a concomitant decrease in energy expenditure caused by a decrease in physical activity. *Id.* at 22.

170. *Id.* at 22–23.

171. *Id.* at 23.

172. *Id.*

A study of diet quality in a nationally representative sample of preschoolers—ages two to five—between 1977 and 1998 also revealed troubling trends.[173] The study concluded that while overall diet quality among preschool children has marginally improved during the twenty-one year time period, total energy intake and consumption of fruit juices and added sugar have significantly increased.[174] It noted that "[n]utritional concerns for American children have shifted from problems of deficient intakes to overconsumption of energy-contributing food groups . . . "[175]

Other studies have also noted the unhealthful nature of childrens' diets. According to one source, "[m]ost American children consume too many highly processed, high-fat, or sweetened foods and too few fruits and vegetables."[176] Consumption of sweet drinks in particular has been associated with increased risk of overweight in children.[177]

Another study examining dietary fat and cholesterol intake in children in grades two through five concluded that 50% of children exceeded the recommended dietary intake of fat and cholesterol.[178] The low intake of fiber, fresh fruits, and vegetables among children and adolescents is also of concern because these foods are thought to protect against diet-related cancers in adulthood.[179]

Other data also indicate that many children and adolescents do not meet national dietary intake standards for calcium.[180] A decrease in milk consumption and a concomitant increase in soft drink consumption is one factor to which this trend is attributed.[181] Adequate calcium intake during childhood is essential for bone development, while inadequate calcium during this period can

173. Sibylle Kranz et al., *Changes in Diet Quality of American Preschoolers Between 1977 and 1998*, 94 AM. J. PUB. HEALTH 1525, 1527–30 (2004).

174. *Id.* at 1529.

175. *Id.* at 1529–30.

176. Hannon et al., *supra* note 150, at 476.

177. Welsh et al., *supra* note 149, at e223.

178. Kerry J. Stewart et al., *Dietary Fat and Cholesterol Intake in Young Children Compared With Recommended Levels*, 19 J. CARDIOPULMONARY REHABILITATION 112, 112 (1999).

179. Kathryn A. Muñoz et al., *Food Intakes of US Children and Adolescents Compared With Recommendations*, 100 PEDIATRICS 323, 323 (1997).

180. Nancy Badenhop-Stevens & Velimir Matkovic, *Calcium Needs in Children*, 23 ORTHOPAEDIC NURSING 228, 228 (2004).

181. *Id.* at 230.

increase the risk of bone fracture and osteoporosis.[182] Consumption of carbonated beverages has also been shown to negatively affect adequate intake of vitamin A and magnesium in children.[183]

Data also indicate that, like adults, children consume inadequate amounts of fiber for adequate health.[184] Indeed, constipation accounts for 25% of visits to pediatric gastroenterology clinics.[185] In addition to ensuring proper digestive functioning, fiber is also important in preventing diet-related cancer, reducing serum cholesterol concentrations, and preventing obesity and the risk of adult-onset diabetes.[186] Yet, as discussed in Part V below, highly processed packaged and fast foods are notoriously low in fiber.[187]

Recent data also suggest that, contrary to what was previously believed, young children are not able to regulate energy intake more precisely than adults, and therefore are equally vulnerable to obesity caused by excess consumption.[188] Rather, the major determinant of energy intake in a group of children ages four to six was the amount served to them by their caregiver.[189] One study also found that total daily intake was directly related to the number of snacks consumed, indicating that children did not adjust intake at meals in response to the energy content of snacks.[190] The study concluded that a child's environment is a more powerful determinant of his or her energy

182. *See id.* at 228–29; *see also* Comm. on Nutrition, Am. Acad. of Pediatrics, *Calcium Requirements of Infants, Children, and Adolescents*, 104 PEDIATRICS 1152, 1152 (1999); Lois D. McBean & Gregory D. Miller, *Enhancing the Nutrition of America's Youth*, 18 J. AM. C. NUTRITION 563, 565 (1999).

183. Carol Ballew et al., *Beverage Choices Affect Adequacy of Children's Nutrient Intakes*, 154 ARCHIVES PEDIATRICS & ADOLESCENT MED. 1148, 1148 (2000).

184. Mauro B. Morais et al., *Measurement of Low Dietary Fiber Intake as a Risk Factor for Chronic Constipation in Children*, 29 J. PEDIATRIC GASTROENTEROLOGY & NUTRITION 132, 132 (1999).

185. *Id.* (citing Vera Loening-Baucke, *Chronic Constipation in Children*, 105 GASTROENTEROLOGY 1557, 1557–64 (1993)).

186. PANEL ON MACRONUTRIENTS ET AL., INST. OF MED., DIETARY REFERENCE INTAKES FOR ENERGY, CARBOHYDRATE, FIBER, FAT, FATTY ACIDS, CHOLESTEROL, PROTEIN, & AMINO ACIDS 54–56, 59–60, 63 (2005).

187. *See infra* Part V.A.

188. *See* Gordana Mrdjenovic & David A. Levitsky, *Children Eat What They are Served: The Imprecise Regulation of Energy Intake*, 44 APPETITE 273, 280–81 (2005).

189. *Id.* at 280.

190. *Id.*

intake than the amount of food the child ate at the previous sitting.[191]

It is therefore clear from the above data that many children are consuming too much of the wrong foods and too little of the right ones. Determining the appropriate caloric intake for children under eighteen, however, is dependent on many factors, such as the child's age, sex, weight, and activity level.[192] Additionally, nutritional needs change for different age groups between the ages of four and eighteen, as children go through periods of increased growth.[193] Nevertheless, as a Consensus Statement recently published by the American Heart Association makes clear, many children require significantly fewer calories than the 2,000 calorie assumption upon which the FDA's food labeling requirements are based.[194] According to the Consensus Statement, females four to eight years of age require an estimated 1200 calories per day, while males in this age group require an estimated 1400 calories.[195] Females ages nine to thirteen require 1600 calories, while males in this age group require 1800 calories.[196] Finally, females fourteen to eighteen years of age require an estimated 1800 calories, and males in this age group require an estimated 2200.[197] Thus, at least some females between the ages of four and eighteen may *never* require 2,000 calories a day. As a result, the FDA's food labeling requirements consistently overestimate the caloric requirements of such children.[198] By lumping children ages four and over together with

191. *Id.*
192. *See* Gidding et al., *supra* note 155, at 2061–63.
193. *See id.* at 2063.
194. *Id.*
195. *Id.*
196. *Id.*
197. *Id.*
198. The American Heart Association's calorie estimate was based on a sedentary lifestyle, and the Consensus Statement acknowledged that increased physical activity would require additional calories. *Id.* The 2002 Dietary Reference Intake manual published by the Institute of Medicine provides year-by-year estimated energy requirements for boys and girls ages three to eighteen that are based on four different activity levels ranging from sedentary to very active. PANEL ON MACRONUTRIENTS ET AL., INST. OF MED., *supra* note 186, at 176–78 tbls.5-20, 5-21. For example, a four-year-old girl may require anywhere from 1113 to 1730 calories per day depending on her level of activity. *Id.* at 178 tbl.5-21. Nevertheless, similar to the American Heart Association's Consensus Statement, the Institute of Medicine data clearly indicate that many children require far fewer than 2000 calories per day. *Id.* at

adults in its nutritional labeling rules, the FDA has implemented a regulatory system that is inadequately tailored to children's nutritional needs.

IV. RECOMMENDATIONS OF THE FDA OBESITY WORKING GROUP REGARDING FOOD LABELING

In the past few years, the FDA has begun to focus on the growing problem of obesity and to consider how it can use its existing authority to address the problem. In August 2003, FDA Commissioner Mark McClellan established the FDA's Obesity Working Group (OWG) "to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition."[199] The Commissioner charged the Working Group with preparing a report outlining an "action plan to cover critical dimensions of the obesity problem from [the] FDA's perspective and authorities."[200] The FDA viewed its responsibility to address obesity as stemming from its position as a "public health agency with responsibility for regulating the labeling of most packaged foods."[201] Thus, among the goals established for the OWG was the development of "an approach for

176–78 tbls.5-20, 5-21.

199. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, app. D at 49–50.

> The OWG was composed of professionals across FDA who provided a range of expertise in areas such as food labels, communication and education efforts, the role of industry and restaurants, and therapeutic interventions for obesity. The OWG met eight times and received briefings from several invited experts from other government agencies. In addition, the OWG held one public meeting, one workshop, two round table discussions (one with health professionals/academicians, and one with consumer groups), and solicited comments on obesity-related issues, directing them to a docket established in July 2003.

Food Labeling: Prominence of Calories, 70 Fed. Reg. 17,008, 17,008 (Apr. 4, 2005) (to be codified at 21 C.F.R. pt. 101).

200. Ctr. for Food Safety & Applied Nutrition, FDA, Questions and Answers (2004), http://www.cfsan.fda.gov/~dms/owg-qa.html#gen1. The Obesity Working Group grew out of a Department of Health and Human Services' initiative, *Steps to a Healthier US*, "which emphasizes personal responsibility for the choices Americans make for healthy behaviors," and includes a "focus[] on reducing the major health burden created by obesity and other chronic diseases." *Id.*

201. *Id.*

enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity."[202]

In developing its recommendations to improve food labeling, either on a mandatory or voluntary basis, the OWG conducted focus group research to ascertain general attitudes toward nutrition as well as to learn how consumers use the nutrition information on food labels.[203] The FDA also gauged participants' reactions to specific symbols and formats used to convey particular nutrient information.[204] Among its findings, the focus groups revealed that participants viewed as misleading packages that were labeled as containing more than one serving size when the entire package was customarily consumed at one sitting.[205] The focus groups also revealed that very few participants reported using the %DV column on the nutrition fact panel, either because they did not understand it or because they thought that it was irrelevant since they did not consume a 2000 calorie diet.[206]

The OWG issued its report in February 2004.[207] The report addressed "multiple facets of the obesity problem under [the] FDA's purview."[208] Of particular relevance to this article was its attention to the development of "specific new initiatives to improve the labeling of packaged foods with respect to caloric and other nutritional information."[209] In particular, the OWG report recommended that the FDA issue two Advanced Notices of Proposed Rulemaking (ANPRM), one relating to serving sizes and one

202. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, app. D at 49–50.

203. *Id.* at 17.

204. *Id.* at 17–18.

205. *Id.* at 18.

206. *Id.* at 17.

207. Lester M. Crawford & Robert E. Brackett, *Preface to* CT. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, supra note 10 (referring to the Memorandum of Transmittal preceding the OWG Report).

208. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 36.

209. *Id.* Other facets of the report addressed: (1) the development of "effecttive consumer messages to aid consumers in making wiser dietary choices"; (2) forming partnerships with stakeholders to "support the dissemination and understanding of these messages"; (3) the development of new therapeutics; and (4) the "design and conduct of effective research in the fight against obesity." *Id.*

regarding the prominence of calorie information on the food label.[210] With respect to serving sizes, the OWG suggested soliciting comments specifically regarding: (1) whether manufacturers should be required to declare a food package to be a single serving if the package could reasonably be consumed in one sitting; (2) which, if any, RACCs of food categories need to be updated; and (3) whether to provide comparative calorie claims for smaller portions of identical foods.[211] In April 2005, the FDA issued an ANPRM requesting public input regarding these suggestions.[212]

With respect to the prominence of calorie information, the OWG report revealed that, while most consumers are familiar with the nutrition information on food labels, the percentage of consumers who actually use the Nutrition Fact Panel (NFP) information productively for weight management purposes is low.[213] Thus, the OWG recommended that the FDA solicit comments to ascertain how to give more prominence to calories on the food label.[214] Possible changes suggested by the OWG were: "(1) increasing the font size for calories; (2) providing a %DV for calories; and (3) eliminating the 'calories from fat' listing to prevent taking the emphasis away from the listing of 'total calories.'"[215] The FDA issued an ANPRM requesting public comments on these issues in April 2005.[216]

Other recommendations of the OWG focused on encouraging voluntary changes by food manufacturers, such as labeling foods as a single serving when the entire contents can be consumed in one sitting—e.g., a twenty-ounce bottle of soda could be labeled as one serving at 275 calories rather than as 2.5 servings at 110 calories each.[217] The OWG further suggested using appropriate comparative

210. *Id.* at 19.
211. *Id.* at 19–20.
212. Food Labeling: Serving Sizes of Products That Can Reasonably Be Consumed At One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes, 70 Fed. Reg. 17,010, 170,010–11 (Apr. 4, 2005) (codified at 21 C.F.R. pt. 101 (2005)).
213. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 16.
214. *Id.* at 19.
215. *Id.* at ii.
216. Food Labeling: Prominence of Calories, 70 Fed. Reg. 17,008, 17,008 (Apr. 4, 2005) (codified at 21 C.F.R. pt. 101).
217. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10,

labeling statements that would make it easier for consumers to make healthy substitutions—e.g., statements that low fat cherry yogurt has fewer calories and less fat than cherry pie.[218]

Interestingly, despite its recognition that obesity is a significant problem among children, the OWG did not make any policy recommendations with regard to food labeling that specifically reflected childrens' distinct nutritional needs or cognitive capabilities.[219] The OWG reviewed data showing that (1) parents often misjudge their children's weight status and consider them to be at a healthy weight when they are not; (2) parents do not have a clear picture of their children's diets; and (3) children give little thought to good health or to the importance of their food choices.[220] Yet, unlike its approach with adults, the FDA conducted no similar focus group research to learn about children and adolescent reactions to food labeling, or to determine what changes to the food label format or content might improve their use of the information.[221] Only in the area of education did the OWG specifically address children, and even then, it did so only in the context of partnering with youth-oriented organizations to help educate children about the need to make informed food choices.[222] For example, the OWG referred to an initiative considered by the FDA and the Girl Scouts of the USA entitled "Healthy Living," which would "provide girls and their families with the skills, knowledge, and support needed to make healthier food choices, engage in physical activity, build self-esteem, and maintain a healthier lifestyle."[223] The initiative would include "developing a charm of the food label as a part of the Studio B teen collection."[224]

at 19.

218. *Id.* at 22–23. With respect to nutrient content claims, the OWG also recommended that the FDA "publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term 'net' in relation to carbohydrate content of foods." *Id.* at 21.

219. *See id.*

220. *Id.* at 11–12.

221. *See id.*

222. *See id.* at 13–14.

223. *Id.* at 13.

224. *Id.*

While appropriate fashion accessories are doubtlessly an important part of any campaign to reduce childhood obesity, the FDA appears to have missed an important opportunity to harness its broad powers under the NLEA to develop nutritional labeling tailored to children. Educating America's youth should, of course, be a serious priority, and organizations such as the Girl Scouts, 4-H, and others should be commended for undertaking these efforts. However, their efforts are made more difficult, and may be undermined, when the foods to which children are exposed and intentionally targeted, are unhealthful and not adequately labeled for their intended audience.

V. CASE STUDIES: WHY A CHILD-CENTERED LABELING APPROACH IS NEEDED FOR FOOD MARKETING THAT TARGETS CHILDREN

Other articles in this symposium issue address the aggressive advertising practices used by some food manufacturers to increase consumption of their products among children.[225] Such marketing practices are used particularly to sell "junk food," i.e., food that is high in fat, sugar, and overall calories, and low in vitamins and minerals.[226] These articles propose a variety of approaches to combat these aggressive practices, such as enacting legislation that prohibits certain types of marketing communication.[227]

Indeed, research data indicate that children are a growing presence in the marketplace, including the food industry. Consequently, children are a growing target of food marketers.[228] "It is estimated that US adolescents spend $140 billion a year [on food]. Children under 12 years of age spend another $25 billion, [and] may influence another $200 billion of spending per year."[229]

225. *See, e.g.*, Angela J. Campbell, *Restricting the Marketing of Junk Food to Children by Product Placement and Character Selling*, 39 LOY. L.A. L. REV. 447 (2006) (discussing the "deceptive" practice of product placement and the use of popular characters to promote products to children).

226. *Id.*

227. *Id.*; *see also* Janet Hoek & Ninya Maubach, *Self-Regulation, Marketing Communications and Childhood Obesity: A Critical Review from New Zealand*, 39 LOY. L.A. L. REV. 139 (2006).

228. *See, e.g.*, Mary Story & Simone French, *Food Advertising and Marketing Directed at Children and Adolescents in the US*, INT'L J. BEHAV. NUTRITION & PHYSICAL ACTIVITY, Feb. 10, 2004, art. 3, http://www.ijbnpa.org/content/1/1/3.

229. *Id.* at 4.

Children are also playing an increasing role in selecting food for themselves and their families. One study noted:

> Because of the increasing number of two-working parent families and single-parent households, the number of adolescents who are either doing food shopping for themselves or their families is increasing. A recent survey by Teenage Research Unlimited revealed that as many as 90% of teenagers (both boys and girls) shop for their families spending 4 billion dollars annually on food and snacks alone. In addition, teenagers receive an additional 19.2 billion dollars from their parents for family shopping.[230]

The NLEA could provide another tool for combating food manufacturing practices that are unhealthful to children. However, the FDA has yet to convene working groups or hold hearings to consider how the NLEA could be implemented to help children develop healthful dietary practices, and therefore, has yet to explore all the possibilities.[231]

This Part provides two case studies that demonstrate how the FDA's authority to regulate food labeling could improve labeling for some of the more troubling products currently confronting children, thereby assisting children in making more healthful food choices. These examples illustrate how a child-centered approach might aid in achieving the NLEA's overarching goals of improving consumer information and food choices in a heretofore largely ignored segment of the consuming public.

A. Case Study 1: Lunch-in-A-Box: Less than the Sum of Its Parts

A popular credit card commercial asks consumers the ominous question, "What's in your wallet?"[232] For school age children, a

230. McCullum & Achterberg, *supra* note 139, at 182 (citations omitted).

231. *But see The Supersizing of America: The Federal Government's Role in Combating Obesity and Promoting Healthy Living: Hearing Before the H. Comm. on Government Reform*, 108th Cong. 36 (2004) (statement of Lester M. Crawford, Acting Comm., FDA) (testifying that the Centers for Disease Control and Prevention, a sister agency within the Department of Health and Human Services, will "conduct a comprehensive review of the effects of advertising and marketing on children's behavior").

232. Capital One, http://www.capitalone.com/indexa.php (last visited Oct. 21, 2005).

more appropriate question might be, "What's in your lunchbox?" Indeed, making lunch for one's children is among the little heralded, but much despised chores of modern two-working-parent-households. Between the rules imposed by schools (e.g., no nuts or peanut butter) and the preferences of one's own picky eaters, preparing a school-compliant, child-approved brown-bag lunch can be a daunting task.

Oscar Mayer, the manufacturer of Lunchables, had the sanity of modern parents—in particular, working moms—in mind when it developed Lunchables in 1988.[233] This product is an attractively packaged "lunch-in-a-box" option clearly aimed at a youthful audience. It enables parents to bypass the homemade alternative with a pre-packaged box containing a drink, lunch, and snacks.

However, this convenience comes at a nutritional cost—one that is lost amid the neon colors, cartoon drawings, and kid-friendly games on the box. For example, the Lunchables Turkey & Cheddar Mega Pack consists of six crackers, Oscar Mayer cured oven-roasted turkey breast, Kraft "pasteurized processed cheddar cheese food," Oreo cookies, Pringles "reduced fat" potato crisps, and a Capri Sun "mixed fruit flavored juice drink blend."[234] According to the nutrition facts panel, the box contains 710 calories, of which 230 come from fat.[235] The percent DV chart indicates that the box contains 40% DV of fat, 45% DV of saturated fat, and 15% DV of cholesterol.[236] The product also contains 2.5 grams of trans fat,[237] for which no DV has been established.[238] The product also contains

233. *See* Kraft Foods Inc., Packaging Innovations, Lunchables, http://www.kraft.com/100/innovations/lunchables.html (last visited Oct. 16, 2005).

234. Oscar Mayer Lunchables Lunch Combinations, Turkey & Cheddar Mega Pack (purchased on Oct. 15, 2005 at Pavillions Store #2228, S. Pasadena, Cal.).

235. *Id.*

236. *Id.*

237. *Id.*

238. According to the FDA, no percent DV has been established for trans fat because "[w]hile scientific reports have confirmed the relationship between *trans* fat and an increased risk of [Coronary Heart Disease], none has recommended an amount of *trans* fat that FDA could use to establish a Daily Value (DV)." Ctr. for Food Safety & Applied Nutrition, FDA, Office of Nutritional Prods., Labeling and Dietary Supplements, Questions and Answers about *Trans* Fat Nutrition Labeling (Jan. 1, 2003), http://www.cfsan.fda.gov/~dms/qatrans2.html.

65% DV of sodium, 35% DV of carbohydrate, 8% DV of dietary fiber, 6% RDI of Vitamins A and C, 25% RDI of calcium, and 20% RDI of iron.[239] All DV and RDI information is based on a 2000-calorie diet,[240] even though many consumers in the demographic targeted by this product likely require fewer calories per day.[241]

The Lunchables Lunch Combination is clearly targeted at children, and, given the type of games printed on the box, appears to be specifically aimed at children in middle school or younger.[242] While the packaging does not contain words such as "for kids only," the implied message is clear to any parent or child: this lunch is intended for children and will provide a fun eating experience. Indeed, according to the product Web site, "LUNCHABLES® allows kids to MAKE FUN OF LUNCH® by providing them with food that they love in a manner that allows them to build and eat any way they want."[243]

At the same time, nutritionists give Lunchables poor grades in many categories.[244] Indeed, the product contains more than a third of overall daily calories and recommended DV for fat, about two thirds the recommended DV for sodium, and less than 10% DV of fiber and vitamins A and C.[245] Also disturbing are the nutrients conspicuously absent from the product, including B vitamins (thiamin, riboflavin, niacin, folic acid, pantothenic acid, biotin, vitamins B6 and B12),

239. *Id.*

240. *Id.*; CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, HOW TO UNDERSTAND AND USE THE NUTRITION FACTS LABEL (Nov. 2004), http://www.cfsan.fda.gov/~dms/foodlab.html.

241. *See* PANEL ON MACRONUTRIENTS ET AL.,, INST. OF MED., *supra* note 186, at 176–78 tbl.5-20 (noting that the recommended caloric intake for children is less than that for adults); Kraft Foods Inc., Oscar Mayer Products, Lunchables, http://www.kraftfoods.com/om/bn/c_Products/Lunchables.htm (last visited Nov. 10, 2005) (referring to product descriptions indicating that Kraft primarily markets Lunchables to children).

242. Oscar Mayer Lunchables Lunch Combinations, *supra* note 234. For example, the bottom of the box features a maze through which the consumer "helps" children ride on skateboards.

243. Kraft Foods Inc., *supra* note 241.

244. Kim Pierce, *Lunchables a Mother Can Love*, http://www.wwltv.com/sharedcontent/health/nutrition/stories/080204cckkHealthlunchables.3b8d9a39.html (last visited Oct. 16, 2005).

245. Oscar Mayer Lunchables Lunch Combinations, *supra* note 234.

vitamin D, and fresh fruits and vegetables.[246]

What then, could be done within the parameters of the FDA's food labeling authority to inform both children and those who make food-purchasing decisions for them of the nutritional deficiencies of this product and others like it? Perhaps the most extreme approach would be to apply the misbranding provision of § 201 of the FD&C Act to require explicit and prominent disclosure of the calorie and fat content of the product. As discussed in Part II.A above, § 201(n) of the FD&C Act provides that a food label can be misleading not only through overtly false representations but also through omission of information material to the consumer.[247] In the case of Lunchables, the product is clearly intended to be consumed by children, and its advertisements arguably imply that the product contains a nutritionally appropriate selection of food for a child's lunch. However, unless other meals consumed by a child during the course of the day are both very low in fat and very high in the nutrients lacking in Lunchables, a child is likely to be both under-nourished and overfed as a result of consuming it. An example of an appropriate required disclosure might be: "This food contains 45% of maximum recommended daily fat intake. To ensure a healthful diet, reduce other sources of fat accordingly." Another appropriate disclosure might be: "This food contains only 6% of the RDI of vitamins A and C. To ensure adequate intake of these vitamins, make sure to consume at least 94% of the RDI of vitamins A and C from other sources."

Any attempt at compelling additional disclosures on the food label, particularly statements that highlight the less favorable features of a food product, would likely meet with stiff resistance from food manufacturers. Food manufacturers would probably argue, among other things, that no claims of nutritional appropriateness are made on the food label, and that they have already provided adequate disclosure through the FDA-mandated nutrition facts panel. They would also likely argue that compelling disclosure on the food label in the absence of a demonstrated health threat would constitute a violation of their First Amendment rights to commercial free speech.[248] The FDA might therefore be reticent to require additional

246. *See id.*
247. 21 U.S.C. § 321(n) (2000).
248. *See, e.g.*, Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) (holding

disclosures of the type suggested here in the absence of evidence demonstrating (1) that consumers of Lunchables and similar goods interpret the product as making implied nutritional claims, and (2) that the nutrition facts panel is insufficient to make such consumers aware of the food's nutritional deficiencies. That the FDA has apparently not recognized the need for such evidence or attempted to obtain it, highlights the agency's longstanding exclusion of children from focus groups and other venues in which such information could be obtained. The apparent lack of such evidence also demonstrates that the FDA has not specifically queried caregivers regarding the impact of non-disclosure of nutrient deficiencies in child-oriented food products on the food selections they make for their children.

Other approaches could also improve the labeling of products that are targeted to children, such as lunch-in-a-box meals. For example, the FDA could require manufacturers of food products targeted to specific age groups to label the products in accordance with the average number of calories consumed by that age group. In other words, the FDA could abandon its "2000 calorie diet-fits-all" approach to calculating DVs and require age-group specific DV calculations.

In its 2005 report, the Institute of Medicine (IOM) considered, but summarily dismissed, the possibility of developing age-specific DVs as "not feasible."[249] The IOM noted that "the committee did not see a practical way in which the Nutrition Facts panel could incorporate all the % DV figures that would correspond to the energy needs of children at different ages."[250]

While it admittedly may be difficult to develop age-specific DVs for *all* food products, the IOM report did not sufficiently consider whether a more limited set of DVs might be possible in the case of foods predominantly consumed by children within a specific age group, particularly when the manufacturer has explicitly targeted

that the FDA's refusal to authorize marketing of dietary supplements to include questionable health claims violated the First Amendment because the FDA did not demonstrate a health threat); Int'l Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 (2d Cir. 1996) (holding that a statute requiring disclosure of bovine growth hormone is unconstitutional because the public's right to know is insufficient to justify compromising producers' First Amendment rights).

249. COMM. ON PREVENTION OF OBESITY IN CHILDREN & YOUTH, INST. OF MED., *supra* note 8, at 168.

250. *Id.*

the product toward a particular demographic.[251] It is true, as the IOM noted, that energy requirements of "children and adolescents differ by age, gender, and activity level."[252] Nevertheless, as the recent Statement of the American Heart Association and the Institute of Medicine RDI Report indicate, data on nutritional requirements for different age groups do exist.[253] Serving sizes could be developed based on these data. Furthermore, alternative, age-group specific RACCs could be developed based on consumption pattern data of children in different age groups, e.g., four to eight, nine to twelve, and thirteen to eighteen. If such data do not exist, then the FDA could prioritize the gathering of food consumption patterns among children and the development of appropriate RACCs based on this information. Such information could help optimize the nutritional choices of children and their caregivers.[254] If such data have not been developed, it is not because they would not be beneficial, but because insufficient consideration has been given to the nutritional needs of children.

Mandated disclosure and child-specific DVs are only two possible approaches to improving nutritional labeling for child-oriented food products. No doubt additional approaches could be developed if the FDA were to convene a working group with a central focus on improving nutrition labeling of foods primarily consumed by or targeted to children.[255]

251. *See id.*

252. *Id.* at 167.

253. *See*, PANEL ON MACRONUTRIENTS ET AL., INST. OF MED., *supra* note 186, at 176–78 tbls.5-20, 5-21 (2005); Gidding et al., *supra* note 155, at 2063 tbl.3.

254. The IOM has developed various nutritional recommendations for various age groups, including infants and children. *See, e.g.*, PANEL ON MACRONUTRIENTS ET AL., INST. OF MED., *supra* note 186, at 30–34, 1319–1331 (2005); STANDING COMM. ON THE SCIENTIFIC EVALUATION OF DIETARY REFERENCE INTAKES ET AL., INST. OF MED., DIETARY REFERENCE INTAKES FOR THIAMIN, RIBOFLAVIN, NIACIN, VITAMIN B6, FOLATE, VITAMIN B12, PANTOTHENIC ACID, BIOTIN, & CHOLINE 566–67 (1998).

255. As explained above, the Acting Commissioner of the FDA testified that the Centers for Disease Control and Prevention's *Children's Food Marketing Project* will conduct such a study. *The Supersizing of America: The Federal Government's Role in Combating Obesity and Promoting Healthy Living*.

B. Case Study 2: The Happy Meal: Some Sad Facts

"Fast food"—restaurant food that is prepared and served quickly at low cost, often for take-out consumption[256]—constitutes a significant percentage of Americans' diets. "According to a 2004 study conducted jointly by the American Academy of Pediatrics and Children's Hospital in Boston, such consumption among U.S. children ages four to nineteen has increased approximately 500% since 1970."[257] In 1999, money spent on away-from-home foods comprised 47.5% of total food spending, and "[i]t is projected that, by 2010, 53% of the food dollar will be spent away from home."[258] Adolescents are a particular target of fast food marketing, and "[a]n estimated 75% of adolescents eat fast food [one] or more times per week."[259]

In recent years, the role of fast food in promoting obesity has emerged as a topic of great interest and debate in the medical and public health community.[260] Some studies have found correlations between increased consumption of food prepared outside the home and overweight in children.[261] For example, a study of 101 girls aged eight to twelve years at baseline and eleven to nineteen years at follow up found that consumption of two or more fast food meals per week predicted a higher BMI in adolescence.[262] Other studies have found correlations between fast food consumption and increased energy intake with decreased nutritional quality. A study of 6212

256. Wikipedia.org, Fast Food, http://en.wikipedia.org/wiki/Fast_food (last visited Nov. 10, 2005).

257. Michael A. McCann, *Economic Efficiency and Consumer Choice Theory in Nutritional Labeling*, 2004 WIS. L. REV. 1161, 1180 (citing Shanthy A. Bowman et al., *Effects of Fast-Food Consumption on Energy Intake and Diet Quality Among Children in a National Household Survey*, 113 PEDIATRICS 112, 112 (2004)).

258. SA French et al., *Fast Food Restaurant Use Among Adolescents: Associations With Nutrient Intake, Food Choices and Behavioral and Psychosocial Variables*, 25 INT'L. J. OBESITY 1823, 1823 (2001).

259. Cara B. Ebbeling et al., *Compensation for Energy Intake from Fast Food Among Overweight and Lean Adolescents*, 291 J. AM. MED. ASS'N 2828, 2828 (2004).

260. *Id.* at 2832.

261. *Id.* at 2831.

262. W. Stewart Agras & Anthony J. Mascola, *Risk Factors For Childhood Overweight*, 17 CURRENT OPINION PEDIATRICS 648, 650 (2005) (citing O.M. Thompson et al., *Food Purchased Away From Home as a Predictor Of Change in BMI Z-Score Among Girls*, 28 INT'L J. OBESITY 282, 287 (2004)).

children and adolescents aged four to nineteen years found that children who ate fast food consumed more total energy, energy per gram of food, total fat, total carbohydrates, added sugars, and more sugar-sweetened beverages while consuming less fiber, milk, and fewer fruits and nonstarchy vegetables than those who did not consume fast food.[263] In addition, on the days in which children ate fast food, they consumed more total energy and had poorer diet quality than on days in which they did not.[264] The study concluded that consumption of fast food among children in the United States "seems to have an adverse effect on dietary quality in ways that plausibly could increase risk for obesity."[265] Another study, conducted on 4746 adolescents in grades seven through twelve, found that frequency of fast food restaurant dining was associated with higher intake of energy and fat intake and lower intake of calcium, vitamin A, vitamin C and carotene.[266]

Unlike manufacturers of packaged foods, restaurants are not required under the NLEA to provide nutrition information for foods unless the restaurant makes a nutrient content or health claim about those foods.[267] If a restaurant makes such a claim, the restaurant need only provide information on the amount of the nutrient that is the basis of the claim.[268] As a result, "if a restaurant claims that a particular menu item is 'low in fat' (i.e., makes a nutrient content claim with regard to fat) then this requirement is satisfied by adding: 'low fat—provides fewer than 3 grams fat per serving' (i.e., the basis of the 'low fat' claim)."[269] Furthermore, the Act provides that a restaurant may convey information about the nutrients for which a nutrient content or health claim is made in various ways, such as in brochures.[270] Accordingly, a restaurant need not publish such

263. Bowman et al., *supra* note 257, at 114.
264. *Id.* at 114.
265. *Id.* at 112.
266. French et al., *supra* note 258, at 1827.
267. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2(a), 104 Stat. 2353, 2355 (codified as amended at 21 U.S.C. § 343(q)(5)(A)(i) (2000)); 21 C.F.R. § 101.9(j)(2) (2005).
268. 21 C.F.R. § 101.10.
269. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 6; *see* 21 C.F.R. § 101.10.
270. 21 C.F.R. § 101.10.

information on the menu or menu board.[271] In addition, making a claim about a particular nutrient "does not trigger a requirement to disclose complete nutrition information for that item or meal."[272]

Thus, although fast food is a significant source of energy for children and adolescents, and is contributing to both overweight and undernutrition in this population, purveyors of fast food are currently under no legal obligation to provide information that could help younger Americans make more informed food choices. In excluding restaurants from nutrition labeling requirements under the NLEA, Congress prevented children, and those making food-purchasing decisions for them from, obtaining information that could improve their health.

An examination of the components of a McDonald's "Happy Meal" provides a concrete example of the consequences of excluding fast food from NLEA requirements. While McDonald's is not the only purveyor of fast food, 90% of American children between the ages of three and nine consume food from McDonald's.[273] Accordingly, the restaurant chain is, in some sense, exemplary of the potential negative impact of fast food consumption on children in the absence of adequate nutritional labeling.

According to its Web site, McDonald's "offers a range of menu options to help meet your family's nutrition needs."[274] Among these choices are the "Happy Meal" and "Mighty Kids Meal" menu selections.[275] The Web site provides percent RDI information on the Happy Meal corresponding to children ages four to eight and percent RDI information for children ages nine to thirteen for its Mighty Kids Meal.[276] The distinction indicates that these groupings are the intended age groups for the product. Yet, the calorie content of the Happy Meal ranges from 360–660 calories,[277] while the calorie

271. *Id.*

272. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 6; *see* 21 C.F.R. § 101.10.

273. McCann, *supra* note 257, at 1180.

274. McDonald's, Kids Meals at McDonald's, http://www.mcdonalds.com/app_controller.nutrition.categories.kidsmeals.index.html (last visited Oct. 16, 2005) [hereinafter McDonald's, Kids Meals].

275. *Id.*

276. *Id.*

277. McDonald's, Nutrition Information for McDonald's Happy Meals, http://www.mcdonalds.com/app_controller.nutrition.categories.happymeals.ind

content for the Mighty Kids Meal ranges from 440–850 calories.[278]

The McDonald's Web site asserts that "[k]ids need a variety of vitamins and minerals every day to help them grow strong, play long, and learn better in school" and claims that "[f]oods in McDonald's Happy Meals and Mighty Kids Meals can help supply many of these important nutrients," in particular calcium, iron, zinc, vitamin A, vitamin B6, vitamin C and vitamin D.[279] Indeed, the Web site provides percent daily values of these nutrients in all of its Happy Meal and Mighty Kids Meal choices.[280] For example, a Happy Meal containing four pieces of Chicken McNuggets, a small order of french fries, and eight fluid ounces of 1% low-fat white milk provides 500 calories, 45% RDI of calcium (for children ages four to eight), 15% RDI of iron, 33% of zinc, 30% of vitamin A, 125% of vitamin B6, 25% of vitamin C, and 50% of vitamin D.[281] However, if a twelve-ounce cup of Sprite is substituted for the milk, the selection, while still totaling 500 calories, provides only 2% RDI of calcium, 4% of vitamin A, and 0% of vitamin D.[282] In other words, neither the Chicken McNuggets nor the french fries—the components of the meal actually prepared by McDonald's—contribute significantly to the calcium, vitamin A, or vitamin D content of the Happy Meal.

Notably absent from the nutritional labeling provided in the Kids Meals section of the Web site is the amount of fat, saturated fat, trans fat, carbohydrates, sodium, and fiber contained in a Happy Meal or Mighty Kids Meal.[283] To find this information, it is necessary to go to the McDonald's nutrition information sections of the Web site.[284] Interestingly, nutritional information in these sections is provided in absolute amounts—e.g., grams, milligrams—and not as a percent DV.[285] Returning to the Chicken McNuggets

ex.html (last visited Oct. 16, 2005).

278. McDonald's, Nutrition Information for McDonald's Mighty Kids Meals, http://www.mcdonalds.com/app_controller.nutrition.categories.mightykidsmeals.index.html (last visited Oct. 16, 2005).

279. McDonald's, *supra* note 274.

280. *Id.*

281. *Id.*

282. *Id.*

283. *See id.*

284. *Id.*; McDonald's, *supra* note 277.

285. McDonald's, *supra* note 274; McDonald's, *supra* note 277.

Happy Meal discussed above, the meal—with eight ounces of 1% milk—provides 23 grams of fat, 6 grams of saturated fat, 3.5 grams of trans fat, 35 milligrams of cholesterol, 720 milligrams of sodium, 3 grams of dietary fiber, and 12 grams of sugar.[286] If one were to calculate the percent DV based on a 2000 calorie diet—which, given that the meal is intended for children between four and eight would likely overestimate the consumer's caloric needs—these amounts would correspond to 35% DV of fat, 30% DV of saturated fat, about 12% DV of cholesterol, 30% DV of sodium, and 12% DV of dietary fiber.[287] In other words, the Chicken McNuggets Happy Meal contains a significant amount of fat and very little fiber. Moreover, the chicken nugget selection is moderate in fat content compared with some other possible selections. For example, a Happy Meal with cheeseburger, small fries, and milk contains 640 calories, 26 grams (40% DV) of fat, and 50 milligrams (almost 17% DV) of cholesterol, based on a 2000 calorie diet.[288]

Looking at the Mighty Kids Meals, the quantity of McDonald's-generated food—i.e., chicken nuggets, hamburger, cheeseburger, and french fries—is larger, and the percent DV of fat, cholesterol, and sugar are accordingly larger.[289] The highest calorie choice—the double cheeseburger, small fries, and 1% chocolate milk jug—contains 850 calories, 36 grams (55% DV) fat, 15 grams (75% DV) saturated fat, 90 milligrams (30% DV) of cholesterol, and 94 grams (31% DV) total carbohydrate.[290] Thus, a nine-year-old consuming the Mighty Kids double cheeseburger, fries and chocolate milk will obtain over half of his or her DV for fat—assuming the child requires a 2000 calorie diet—and almost half of his or her overall caloric needs at one sitting. If children eating such meals do not compensate

286. McDonald's, *supra* note 277.

287. These figures were obtained by dividing the given amounts by the values provided on nutrition facts panel for a 2000 calorie diet. The nutrition facts panel amounts are less than 65 grams total fat, less than 20 grams saturated fat, less than 300 milligrams cholesterol, less than 2400 milligrams sodium, 300 grams total carbohydrate, and 25 grams dietary fiber. For information on these values, see CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 240, http://www.cfsan.fda.gov/~dms/foodlab.html.

288. McDonald's, Happy Meals, *supra* note 277.

289. McDonald's, Mighty Kids Meals, *supra* note 278.

290. *Id.*

in other meals during the day, they are likely to over-consume both in terms of aggregate calories and in calories derived from fat. Yet at the same time, unless their other meals during the day are very high in those nutrients that are lacking or absent in the Mighty Kids Meal—including fiber, most B vitamins, and, if soda is substituted for milk, calcium and vitamins A and D as well—a child will receive less than the recommended daily intake of essential vitamins and minerals.

In a 2004 article, Michael McCann argues that consumer choice theory would support the mandatory disclosure of nutritional information for restaurant foods aimed at young children.[291] Consumer choice theory is "a model of individual decision-making in a free market, and it assumes that individuals are able to rank the outcomes that result from their choices"[292] by determining the "relative utility of one choice over another, balanced against abilities and budgetary constraints, which attach a relative cost to each prospective choice."[293] In the context of food selection, the article posits that a consumer would rank his or her food consumption preferences based on what food qualities are important, such as taste or nutrition, would consider the food possibilities available in light of income, price, and accessibility of desired items, and would make a selection at the intersection of food preferences and food possibilities.[294]

The article further argues that consumers significantly underestimate the nutritional content of fast food, and that their ability to make choices to satisfy their preferences is undermined by these erroneous beliefs:

> [W]hen individuals rely on false premises in purchasing fast food, they misinterpret the consequences and content of their selections, and thus fail to achieve maximum utility for their purchasing power. In other words, their supposedly rational decision to purchase fast food incorporates false premises, thus rendering their choice inherently uninformed.[295]

291. McCann, *supra* note 257, at 1243.
292. *Id.* at 1177.
293. *Id.*
294. *Id.* at 1177–78.
295. *Id.* at 1176–77.

McCann further contends that parents of young children place a particularly high premium on nutritional content and have a low tolerance for risk when selecting food items for their young children.[296] Therefore, requiring the disclosure of nutritional content would likely affect parents' calculations regarding preferences. McCann concludes by asserting:

> [I]n the consumer choice paradigm, the disclosure of such nutritional content would reconfigure the food "utility" of various options for children, since in this setting the value of "nutrition" considerably exceeds that of "taste." In short, consumer choice theory predicts that nutritional disclosure for children's fast food items would prove uncommonly meaningful.[297]

A forthcoming government study may add to the body of knowledge regarding the impact of nutritional labeling on fast food choices.[298] According to ClinicalTrials.gov, a Web site on which government-funded clinical trials must be listed, researchers at the University of Minnesota plan to enroll 600 individuals, ages sixteen and older, in a study that will examine fast food selections following educational or counseling interventions.[299]

Because Congress exempted restaurants from the NLEA, the FDA's options for improving nutritional information are admittedly limited.[300] Nevertheless, the FDA could do more with the authority it currently possesses under the NLEA to make child and adult consumers of fast food more aware of the potential health hazards of these foods.[301]

296. *Id.* at 1178.

297. *Id.* at 1243.

298. ClinicalTrials.gov, Nat'l Inst. of Diabetes & Digestive & Kidney Diseases, Effect of Nutrition Labeling on Fast Food Choices, http://www.clinicaltrials.gov/ct/gui/show/NCT00127660 (last visited Oct. 16, 2005).

299. *Id.* Only clinical trials for "serious or life-threatening diseases and conditions" must be listed on this Web site. *See* Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 113, 111 Stat. 2297, 2310–12 (codified as amended at 42 U.S.C. § 282(j) (2005)).

300. 21 U.S.C. § 343(q)(5)(A)(i) (2000).

301. For example, the FDA could clarify the percent DV relative to serving size, or have "health" symbols for restaurant menu items. *See, e.g.*, CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 26.

Even if restaurants voluntarily amend their disclosure policies and provide some nutritional information, such information will likely fail to adequately address children's nutritional needs absent new FDA labeling requirements. For example, McDonald's recently announced that it will voluntarily provide limited nutritional information on its food wrappers by the end of 2006.[302] According to the restaurant chain, the wrappers will disclose how many grams of fat, protein, carbohydrates, and sodium are in each food product and include a chart showing the percentage of the government's recommended daily intakes.[303] However, the recommended daily intake chart will be based on adult nutritional needs,[304] which, as previously discussed, differ from those of most children.[305] Thus, the nutritional label on a McDonald's Mighty Kid's Meal or Happy Meal will not be informative—and may even be misleading—to the children and their caregivers who typically consume these meals. Additionally, McDonald's will disclose the nutritional information only after a customer has purchased McDonald's food, and therefore has already made a decision—in the absence of nutrition information—to consume it.[306] As a result, McDonald's promised nutritional information will still fail to adequately inform children and their caregivers about the nutritional inadequacies of the restaurant's food.[307]

As the next Part discusses, the FDA could use its considerable influence as arguably the nation's most recognized public health agency to promote awareness about the possible health hazards associated with consumption of fast food.

302. Melanie Warner, *McDonald's to Add Facts on Nutrition to Packaging*, N.Y. TIMES, Oct. 26, 2005, at C1; Press Release, McDonald's, McDonald's Announces Industry Leading Customer Initiative (Oct. 25, 2005), http://www.mcdonalds.com/corp/news/corppr/2005/cpr_10252005.htm;.

303. Press Release, McDonald's, *supra* note 302.

304. *Id*.

305. *See* Gidding et al., *supra* note 155, at 2063.

306. *See* Warner, *supra* note 302.

307. *See generally id.* (explaining that there are still limits on the amount of information the new labels actually provide to the consumer).

VI. THE USE OF THE "BULLY PULPIT"—ANOTHER POSSIBLE VEHICLE FOR FDA ACTION

The NLEA directed the FDA to engage in consumer education regarding nutrition labeling and the importance of healthy dietary practices.[308] Along these lines, the Obesity Working Group (OWG)[309] report discussed the need for appropriate messaging around the "calories count" theme—i.e., that weight control is tied to controlling caloric intake—and even tested slogans aimed at delivering this message.[310] The OWG recommended partnering with other organizations to educate Americans about obesity and leading healthier lives through better nutrition.[311]

With respect to restaurant food labeling specifically, the FDA Commissioner directed the OWG to "develop an approach for working with the restaurant industry to create an environment conducive to better-informed consumers."[312] Consistent with this mandate, the OWG recommended that the FDA "encourage restaurants to provide more, and more readily available, nutrient content information at the point-of-sale."[313] The OWG report also recommended that the FDA "encourage consumers routinely to request nutrition information in restaurants," reasoning that "such demand may help create an impetus for more restaurants to provide such information."[314] Further, it recommended that the FDA engage in a pilot program under which participating restaurants would voluntarily provide "standardized, simple, and understandable nutriational information, including calorie information, at the point-of-sale

308. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2(c), 104 Stat. 2353, 2357.

309. *See supra* Part IV.

310. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 10, 13.

311. *Id.* at 13. For instance, the OWG recommended partnering with the Girl Scouts of the USA and state universities to educate consumers. *Id.*

312. *Id.* at 24.

313. *Id.* at 26. Consistent with this approach, the Center for Science in the Public Interest contends that posting nutritional information on the menu boards restaurants use to display the eatery's food selections would allow consumers to consider the information prior to making a purchasing decision. Warner, *supra* note 302.

314. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 26.

in a restaurant setting."[315] Lastly, the OWG proposed that the agency provide incentives for restaurant participation such as "allowing restaurants to use FDA's name to promote the pilot in advertising, on stickers, and on their menus; and/or coupling the pilot program with an overall FDA education campaign, which may include space on restaurant menus or on separate handouts for FDA messages on healthy lifestyles."[316]

While these approaches could be beneficial, the FDA could also speak more clearly and directly to the hazards of both fast food and of certain child-oriented packaged food products. Indeed, the language of the NLEA specifically directs the FDA to speak out in the interest of improving the public's dietary practices.[317] If it chose to, the FDA could therefore identify hazards in the marketplace and highlight their specific impact on children. Through the use of press releases, brochures, fact sheets, radio and television interviews by FDA officials, and the Internet, FDA officials could make consumers aware of the nutritional content of restaurant and packaged foods targeted at children, and provide guidance on types of foods of which consumers should be wary. While the agency may be limited in its ability to publicly shame particular food manufacturers, it nevertheless could expose the more egregious examples of child-oriented products in grocery aisles and fast food chains, and thereby put consumers on notice regarding perils about which they may have been unaware.[318]

315. *Id.* at 27.

316. *Id.*

317. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2(c), 104 Stat. 2352, 2357. The NLEA directs the secretary of Health and Human Services to "educate consumers about . . . the importance of . . . maintaining healthy dietary practices." *Id.*

318. Although individual food manufacturers may have a claim for defamation or libel against the FDA if the FDA speaks out against a particular manufacturer, a claim for defamation likely will not be sustained if the FDA speaks out against a class of products. *See* Ajay Nutrition Foods, Inc. v. FDA, 378 F. Supp. 210 (D.N.J. 1974), *aff'd*, 513 P.2d 625 (3rd Cir. 1975) (holding that an entire industry cannot sue for defamation after the FDA issued a press release referring to the industry as "nutrition quacks").

As the recent passage of the Food Allergen Labeling and Consumer Protection Act indicates,[319] Congress has the capacity to amend the FD&C Act and thereby expand the FDA's authority in the interest of the health and nutritional needs of particular consumer groups—in that case those with food allergies.[320] More public efforts by the FDA to inform consumers of the hidden hazards of fast food to the health of American children could similarly spur Congress to amend the FD&C Act to include restaurant food within the ambit of the NLEA.

VIII. CONCLUSION

In retrospect, the task of protecting consumers was in some respects easier when the government's mission was to remove obvious toxins such as formaldehyde from the food supply.[321] Today the dangers from the foods we eat are more subtle, and therefore more insidious, since they involve a complicated interaction between personal behavior and market behavior.

The FD&C Act was an important first step in requiring the manufacturers of packaged food to speak truthfully about the products they purveyed in the marketplace. The NLEA expanded the amount of information that must be disclosed about the nutritional content of packaged foods, and also restricted the claims that could be made for various nutrients. The NLEA has been successful in increasing adult consumers' awareness of the nutritional content of the foods they eat and in incorporating nutritional information into their consumption decisions.[322]

In implementing the NLEA, however, the FDA has failed to consider the specific nutritional needs and cognitive abilities of children, apparently viewing all children over four as "mini-adults." Yet childhood, in addition to being a time of significant physical growth and development, is also a key "teachable moment" for healthful eating behaviors that can influence lifelong health status. By failing to consider the nutritional needs and cognitive abilities of

319. Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, 118 Stat. 905 (to be codified in scattered sections of 21 U.S.C.).

320. *See id.*

321. *See* Janssen, *supra* note 16, at 32–36.

322. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 16–17; Kreuter et al., *supra* note 14, at 281–82.

children, the FDA has thus missed an opportunity—at a time when obesity among children has reached epidemic proportions—to educate both children and their caregivers about the nutritional content of the foods targeted to them, thereby improving their nutritional choices.

In its next phase of implementing the NLEA, the FDA should adopt a child-centered approach: it should focus on foods marketed primarily or exclusively to children, and consider what nutritional labeling requirements would assist children and their caregivers in adopting healthful dietary practices. Even where the FDA currently lacks authority to mandate labeling, as in the case of fast foods, the FDA should use its public health "megaphone" to inform consumers about the high calorie and fat content, and low essential nutrient content, of these food selections. Data indicate that consumers systematically underestimate the calorie content of fast foods.[323] Thus, FDA publicity would correct misperceptions among children and their caregivers, thereby facilitating more informed food choices. As a first step, the FDA's implementation of the NLEA has resulted in the availability of nutritional information helpful to adult consumers, however, it has been insufficient with respect to children. Children are a growing target of food marketing, and the FDA must reconsider its one-size fits all approach. As data on childhood obesity demonstrate all too starkly, this size is literally being outgrown.

323. *See* CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FDA, *supra* note 10, at 60.